

HOUSE OF LORDS

Select Committee on Intergovernmental Organisations

1st Report of Session 2007–08

**Diseases Know No
Frontiers: How effective
are Intergovernmental
Organisations in
controlling their
spread?**

Volume II: Evidence

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NOTE:

The Report of the Committee is published in Volume I, HL Paper 143–I.
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Minutes of Evidence

TAKEN BEFORE THE SELECT COMMITTEE ON INTERGOVERNMENTAL ORGANISATIONS

MONDAY 4 FEBRUARY 2008

Present	Avebury, L	Howarth of Newport, L
	Desai, L	Jay of Ewelme, L
	Flather, B	Soley, L, (Chairman)
	Geddes, L	Steinberg, L
	Hannay of Chiswick, L	Whitaker, B

Memorandum submitted jointly by the Department of Health, Department for International Development and Foreign & Commonwealth Office

INTRODUCTION

1. The Government welcomes the Committee's decision to select this issue as the subject of its first inquiry and looks forward to assisting the Committee's considerations. This memorandum is submitted jointly by the UK government departments responsible for the government's contributions in this area. The Memorandum outlines the Government's overall approach to working through intergovernmental organisations on health and specifically on communicable diseases. The annex responds to the questions set out in the Committee's call for evidence.
2. The Government architecture for dealing with all the aspects of these particular diseases does not fall to any single Department or Agency. The answer to question 6 in the Annex does outlines the roles of most of the key Departments.

TACKLING INFECTIOUS DISEASE

3. Throughout the world, communicable diseases are a threat to economic growth and human development. Tackling communicable diseases is crucial for the UK's security and if it is to meet many of the Government's domestic and international Public Service Agreement targets.¹
4. Over 50% of all child deaths are attributable to diarrhoea, pneumonia, malaria, measles and AIDS.² Most of these deaths are in developing countries. Without tackling them we will not meet the Millennium Development Goals (MDGs).
5. The World Health Organization (WHO) reported that in 2005 there were 8.8 million new cases of TB and 1.6 million deaths. Yet, if TB disease is detected early and fully treated, it quickly become non-infectious and is eventually cured. Early and complete treatment is also essential to ameliorate the increasing global problem of drug resistance.
6. HIV is one of the greatest threats to eradicating poverty, sustainable development and achieving the MDGs. In sub-Saharan Africa, it is the leading cause of death and the World Bank has predicted that, unless action is taken, parts of Africa will face "economic collapse".³ Treatment programmes are increasingly being rolled out, but in the developing world (at the end of 2006, most recent figures) just over two million people in low and middle income countries were receiving therapy. This represents 28% of those in need of treatment. Europe is affected by HIV too, particularly in some of the new EU member states and neighbouring countries in Eastern Europe. In Western Europe, infection rates are continuing to rise, although deaths from AIDS have fallen.

¹ http://www.hm-treasury.gov.uk/pbr_csr/psa/pbr_csr07_psaindex.cfm

² UK Chief Medical Adviser. Health is global: proposals for a UK Government-wide strategy. London: Department of Health, 2007

³ Bell C, Devarajan S and Gersbach H (2003) *The Long-run Economic Costs of AIDS: Theory and an Application to South Africa*, World Bank, www1.worldbank.org/hiv_aids/docs/BeDeGe_BP_total2.pdf

7. But communicable diseases are also a threat to the UK. A Chief Medical Officer's report, *Getting ahead of the Curve*, was published in 2002.⁴ It outlined the threat of infectious diseases to England and identified a strategy for how England would tackle communicable diseases more effectively. The report said that while major infectious diseases kill only a small number of people compared to the past, infection is still important: 40% of people consult a health professional each year because of infection.

8. Emerging diseases remain a constant threat to the UK and other countries. Since the 1970s, there have been at least 30 new or emerging infectious diseases. Most have not shown rapid global spread, but some have. Severe acute respiratory syndrome (SARS) was one example where there was rapid global spread. Between March and July 2003, there were 8,000 cases of SARS in 26 countries and 774 people died. In Canada, SARS was estimated to have cost the economy C\$1.5 billion in 2003. The global economic impact of SARS was estimated at US\$30 billion.

9. During the four years 2003–07, avian influenza (H5N1) has infected over 350 people in 14 countries and over 217 have died.⁵ This virus could mutate and cause a human pandemic. While there has not been a pandemic since 1968 another one is inevitable, whether or not it arises from H5N1. Estimates are that the next pandemic will kill between two million and 50 million people worldwide and between 50,000 and 750,000 in the UK.⁶ Socioeconomic disruption will be massive.

10. The Office of Science and Innovation (OSI) 2006 report on the Foresight Project, *Infectious Diseases: Preparing for the Future*, comprehensively outlines the threat of infectious diseases today and in the future.⁷ It considers the ways that we can respond by developing systems to detect, identify and monitor new and emerging infections.

11. Tackling communicable diseases requires a concerted effort from governments, non-governmental partners and multilateral agencies. When agencies work together they can achieve much. Immunisation programmes are a case in point. They have underpinned much of the gain made in childhood survival over the last few decades in developed and developing countries. Smallpox, which had previously affected 10 million people per year, claimed its last victim in 1978. We are now all working to ensure that polio becomes the second disease to be eradicated.

THE ROLE OF INTERGOVERNMENTAL ORGANISATIONS IN HEALTH

12. The Government attaches vital importance to the international architecture, including organisations such as the United Nations and the international financial institutions. As the Prime Minister said in his speech at the Lord Mayor's Banquet on 12 November, "To build not just security but environmental stewardship and prosperity free of global poverty, I want a G8 for the 21st century, a UN for the 21st century, and an IMF and World Bank fit for the 21st century". The Foreign Secretary has also stressed the crucial challenge of using the international system to create the necessary synergies for action. In his first speech in July he said that "The risk of financial crises, climate change, and health pandemics cannot be mitigated by individual countries; they require collective action on a global scale".

13. As the Foreign Secretary's speech indicated, there is increasing recognition that, with accelerating globalisation, health is an issue that needs to be addressed across national borders as well as across a wider range of government departments than those traditionally associated with health policy. In response to this the Government is currently developing a cross-government Global Health Strategy that identifies how the UK will engage on health internationally for the benefit of the UK population and UK health protection, and for the promotion of better health worldwide, including how the Government engages with international organisations to achieve this.⁸

14. Intergovernmental organisations, including the UN agencies, development banks, global funds and health partnerships, have a central role in health and specifically the control of the spread of communicable diseases. For example, the World Health Organisation (WHO) has a crucial role in disease surveillance and in providing high quality guidance to countries on acceptable standards of disease prevention and treatment. It also makes a major contribution through technical assistance to countries in boosting basic health services, monitoring health outcomes and accessing resources from global funds. The World Bank plays a

⁴ Chief Medical Officer for England. *Getting ahead of the curve*. London: Department of Health, 2002

⁵ http://www.who.int/csr/disease/avian_influenza/en/index.html

⁶ National Framework for responding to an influenza pandemic

⁷ Office for Science and Innovation. *Infectious Diseases: Preparing for the Future* The Foresight Project. Department of Trade and Industry. 2006

⁸ The rationale for the Global Health Strategy is outlined in a report by the Chief Medical Officer for England—*Health is Global: Proposal for a UK Government-Wide Strategy*

complementary role in assisting the development of health systems to deliver the basic health services which help control communicable diseases. The World Bank and the regional development banks can ensure that health is prioritised in national development frameworks and budgets. They will not move away from disease-specific initiatives but complement health systems strengthening through broader financing for public services and longer-term budgetary support. Global health initiatives such as the Global Fund to fight AIDS, TB and Malaria (GFATM) and the Global Alliance for Vaccines and Immunisation (GAVI) also have a key role. It is estimated that the GFATM now provides 66% of all global TB and malaria funding, and about 22% of global funding for HIV/AIDS. It is estimated that GAVI has prevented 2.3 million premature deaths, and has provided 166 million additional vaccines. UNITAID (a new partnership) provides significant funding for medicines for AIDS, TB and Malaria, and negotiates significant price reductions and invests in “niche” or neglected products (eg paediatric formulations of antiretroviral therapy).

PROMOTING A COHERENT INTERNATIONAL RESPONSE

15. The Government works in close partnership with these organisations to promote global health and the achievement of the health-related Millennium Development Goals (MDGs) generally and specifically to combat communicable diseases. A key part of this is promoting effective operation and working together. There is considerable scope to improve the effectiveness and coherence of these and other intergovernmental organisations working on health and communicable diseases by strengthening the performance and accountability of individual institutions and encouraging more effective co-operation between agencies, and between the agencies and governments. The International Health Partnership launched in September 2007⁹ is combining health system strengthening with improved alignment by donors and international health agencies including those with a disease-specific mandate.

16. The UK is committed to promoting a more coherent international response to health, based upon a sensible division of labour and joint accountability in supporting country plans and priorities. The current architecture is crowded and poorly coordinated. Within the diverse group of organisations there is no agreed vision or clarity over roles. This is particularly the case for WHO (WHO is either engaged in, or hosts, multiple partnerships) and the World Bank over assisting countries to develop national health systems. The International Health Partnership represents a UK response, which helps encourage a common framework for action on global health and a balance between disease specific (vertical) and health systems (horizontal) investment.

17. The Government considers that global health initiatives will also continue to play an important role but the transaction costs they impose on governments must fall and they must collaborate better with national processes in implementing countries. They should also support strengthening of health systems that deliver health services more broadly—for example, ensuring better integration of common interests, such as reproductive health and HIV and AIDS services. The GFATM is well placed to do this, and to support comprehensive approaches to AIDS, TB and malaria and underlying health services. GAVI, with long term and predictable financing provided through IFFIm—the International Finance Facility for Immunisation—can play a key role in helping countries put in place stronger systems for vaccine delivery as part of the overall effort to improve health services.

18. In the medium term, the Government believes the large number of existing initiatives should be rationalised through mergers. In the shorter term, the global funds, regional and international finance institutions and UN systems need to demonstrate much closer collaborative support of country health plans.

UN REFORM

19. The UK strongly supports the UN reform agenda for achieving greater coherence, effectiveness and efficiency of UN to deliver progress against the MDGs. DFID spends approximately \$1 billion a year through the UN. It is important that these funds are given in a way that advances the UN reform agenda across the totality of the UN system.

20. This means making hard choices about funding the parts of the UN system that are reforming and performing well. While overall the UN makes a significant contribution to health, duplication, overlap and competition between agencies (WHO, UNICEF, UNFPA and UNAIDS) and numerous global health partnerships leads to inefficiencies.

21. At the global level, health funding to UN agencies is often fragmented and insufficient for the implementation of strategic plans. DFID seeks to provide, and encourage others to provide, central institutional support through core funding to UN institutions which demonstrate results, not earmarked

⁹ <http://www.dfid.gov.uk/news/files/pressreleases/ihp.asp>

funding to fight specific diseases. At a country level the UK supports the creation of “One UN teams” that will respond coherently to countries’ developmental priorities. DFID favours funding joint programmes under unified UN country plans rather than standalone health initiatives of individual agencies.

January 2008

Annex A

1. *A recent report on Communicable Diseases by the UK Department of Health stated that “post-war optimism that their conquest was near has proved dramatically unfounded”. What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis?*

Some of the diverse range of micro-organisms which cause infectious diseases have proved extraordinarily resilient to our attempts to conquer them. The discovery and development of effective antibiotics, and increasing success with vaccination probably contributed to much of the early optimism in the post-WWII era. However, new challenges have arisen, including the difficulty in developing effective vaccines against some agents, the emergence and spread of drug-resistance, and the emergence of new diseases. These factors, combined with others such as increasing travel and migration, and the increasing vulnerability to infection of some population groups, demonstrate that efforts to control infectious disease increasingly require co-ordinated global action. The ability of national and intergovernmental organisations to work together effectively and respond rapidly to the threats presented by infectious diseases will become increasingly important. The global situation is not necessarily deteriorating, but it is changing.

2. *What reliable data exist regarding the numbers of people infected globally with the four diseases on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?*

For AIDS, TB, and Malaria it is difficult to obtain reliable data. In most low income countries, there is no vital statistics system. There are no data for registering deaths, particularly cause of death, and where they exist the data are incomplete. As a result, the most reliable data on health come from large household surveys, in particular, the Demographic and Health Survey (DHS) (funded by USAID), which has long-term data on fertility, and infant, child, and maternal mortality. More recently, the DHS has expanded into HIV/AIDS.

For TB, it is uncommon enough that household surveys are not appropriate for measuring TB. Instead, countries are dependent on administrative data from national TB programmes. These data are better for cure rates, but incidence data are problematic because they will depend on whether people seek treatment. Since many people do not access care, estimates for the disease will be under-estimated. As a result, the TB programmes use modelling to predict the rate of tuberculosis complemented by administrative data.

For malaria, the data on incidence are problematic since it is difficult to know who exactly has malaria. Malaria is often over-diagnosed and many people with fever think that they have malaria, but they do not. There are need developments in malaria surveillance such as disease specific surveys and greater use of rapid diagnostic tests.

For HIV/AIDS, there are great difficulties in measuring the disease at the population level. Particularly when the disease is concentrated in marginalized populations such as drug users, it is notoriously difficult to measure. Often, HIV/AIDS is measured using women attending ante-natal clinics. This often is not representative and therefore cannot be extrapolated. There is a need for sentinel surveillance sites.

There is a real need to improve data in developing countries including vital statistics, but also sentinel surveillance for communicable diseases such as HIV/AIDS.

Because of lack of information, WHO uses modelling to predict HIV/AIDS, TB, and malaria. All of these models depend on good data to drive the models, but for many countries this does not exist. The World Health Report, first published in 1995, is WHO’s leading publication. Each year the report combines an expert assessment of global health including the amount of disease, disability and death in the world today that can be attributed to a selected number of the most important risks to human health.

TB is of concern in the UK as an ongoing public health problem. Surveillance of TB is undertaken by the HPA, the National Public Health Service in Wales, the Communicable Disease Surveillance Centre (Northern Ireland) and Health Protection Scotland. The Health Protection Agency (HPA) contributes to international surveillance in collaboration with EuroTB (WHO Collaborating Centre), European Centre for Disease Control (ECDC) and WHO.

Malaria is not transmitted in the UK but around 1,500 to 2,000 cases are reported each year in travellers returning from endemic areas.¹⁰ Data on malaria are reported by the HPA's Malaria Reference Laboratory¹¹ which is based at the London School of Hygiene & Tropical Medicine. This laboratory provides diagnostic and reference services for imported malaria reported in the UK.

In their latest Annual Report¹² on HIV and sexually transmitted infections (November 2007) the HPA estimated that at the end of 2006, 73,000 people (of all ages) were living with diagnosed or undiagnosed HIV in the UK. Approximately 31% were estimated to be undiagnosed. The number of new HIV diagnoses in 2006 was estimated to be 7,800. The major factor contributing to the rapid rise in the number of new HIV diagnoses since 1999 has been increased diagnosis of infections acquired through heterosexual contact in high prevalence areas, mainly Africa. The estimate for new diagnoses for 2006 was similar to estimates for 2004 and 2005 indicating that the annual number of new diagnoses is stabilising. Men who have sex with men (MSM) remain the group at highest risk of acquiring HIV in the UK and there were an estimated 2,700 diagnoses in MSM in 2006.

The number of people infected globally with H5N1 can be obtained through either the European Centre for Disease Prevention and Control (ECDC) or the WHO; however, the system is only as good as input from the member countries.

The International Health Regulations (2007) place an obligation on signatories to notify the WHO of any event—irrespective of its cause—which occurs within its territory, which may constitute a public health emergency of international concern. Annex 2 has a list of factors to consider in deciding whether an event should be notified to the WHO. It also states that any case of “human influenza caused by a new subtype” must be notified.

As at 17 January 2008, there have been 350 confirmed cases of H5N1 infections since 2003, and 217 of these have been fatal, demonstrating the high fatality rate of 62%. The majority of human cases have been as a result of direct close contact with sick or dying infected poultry; unfortunately, the nature of back yard flocks living in close juxtaposition with people means that further spread and human cases are likely to continue to occur. To date avian flu viruses, including the H5N1 strain, do not pass the species barrier easily, and where person to person spread has been reported in relation to H5N1, it has been very limited and unsustainable.

3. *What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? And what improvements might be made?*

International disease surveillance takes place at both the global and the European level. The UK also conducts its own surveillance as a contribution to the international system. International surveillance is a complex and evolving architecture and the UK is keen to see it operated in a coherent way.

At the global level, WHO has a new system to monitor outbreaks of disease, drawing on the pioneering work of the Canadian Public Health laboratory that used web-search methods to monitor epidemics. This surveillance is now enshrined in international law through the International Health Regulations (IHR).

WHO's Epidemic and Pandemic Alert and Response (EPR) programme has six core functions:

- To support Member States for the implementation of national capacities for epidemic preparedness and response in the context of the IHR(2005).
- To support training programmes for epidemic preparedness and response.
- To coordinate and support Member States for pandemic and seasonal influenza preparedness and response.
- To develop standardized approaches for readiness and response to major epidemic-prone diseases (eg meningitis, yellow fever, plague).
- To strengthen biosafety, biosecurity and readiness for outbreaks of dangerous and emerging pathogens outbreaks (eg SARS, viral haemorrhagic fevers).
- To maintain and further develop a global operational platform to support outbreak response and support regional offices in implementation.

This programme includes a Global Outbreak Alert & Response Network (GOARN)—a technical collaboration of existing institutions and networks who pool human and technical resources for the rapid identification, confirmation and response to outbreaks of international importance. Notification of avian influenza in animals takes places through the World Organisation for Animal Health (OIE).

¹⁰ <http://www.hpa.org.uk/publications/PublicationDisplay.asp?PublicationID=101>

¹¹ <http://www.malaria-reference.co.uk/>

¹² http://www.hpa.org.uk/infections/topics_az/hiv_and_sti/publications/AnnualReport/2007/default.htm

Within the EU, the Network for the Surveillance and Control of Communicable Diseases seeks to promote cooperation and coordination between the Member States, with the European Commission, with a view to improving the prevention and control of communicable diseases. The Network includes an Early Warning and Response System (EWRS). The European Centre for Disease prevention and Control (ECDC) will assist the Commission in operating the EWRS. The ECDC also produces a communicable disease threat report (CDTR), which is intended as a tool for European epidemiologists in charge of epidemic intelligence activities in their national surveillance centre. The European Commission also has a role in the notification of avian influenza in animals. The National Microbiology Focal Points have also been established and will collaborate with ECDC to improve the comparability of data across member States and to agree the criteria for diagnostic testing as necessary.

At a national level, Defra's International Disease Surveillance team monitors occurrence of major animal disease outbreaks (including avian influenza) worldwide as an early warning to assess the risk these events may pose to the UK. One of the most important outcomes of this surveillance work are Qualitative Risk Assessments which are designed to give a balanced account of the threat to the UK of the disease incidence. Two of Defra's qualitative risk assessments have significantly contributed to development of the World Organisation for Animal Health international standards on notifiable avian influenza.

All these systems are only as accurate as the information that is input. In many developing countries surveillance of infectious disease is not routine, nor can there be complete reliance upon the diagnoses given nor the cause of death. In developing countries, epidemiological studies are not routinely conducted thoroughly in connection with outbreak to identify the source. Improvements in capacity and capability within countries is still the pre-requisite for good diagnostics and surveillance and consistency of data.

4. Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years?

The eight UN Millennium Development Goals¹³ (MDGs) range from halving extreme poverty to halting the spread of HIV/AIDS and providing universal primary education, all by the target date of 2015 and form a blueprint agreed to by all the world's countries and all the world's leading development agencies. Goal 6 is to halt and begin to reverse the spread of HIV/AIDS, and the incidence of malaria and other major diseases. DFID leads for the UK on the MDGs but the Health Protection Agency/NHS contribution is technical support and expertise in the control and treatment of HIV/AIDS, malaria and TB.

The Global TB programme is well organised and poised for making great progress. The Global Plan to Stop TB 2006–15¹⁴ is a comprehensive assessment of the action and resources needed to make an impact on the global TB burden.

There is renewed interest in malaria and especially in expanding access to existing effective interventions particularly insecticide-treated bednets, indoor residual spraying of insecticides, and treatment with Artemisinin Combination Therapy (ACT). This would significantly decrease mortality from malaria, but is not sufficient to eradicate it in sub-Saharan Africa.

Despite significant inter-governmental efforts, H5N1 avian flu in birds is endemic in several countries and continued transmission from poultry to people is likely as local farming practices are too embedded to expect changes in the next few years. Spread from wild birds into poultry is also likely to continue. Several other strains of avian flu are endemic in wild bird populations, with wild water fowl playing a major part in providing a reservoir of infection for the circulation of avian flu viruses globally via migratory birds. Any one of these virus strains could be the origin of a pandemic flu virus in the next 10 years and wild bird surveillance is important in monitoring the pattern of virus circulation.

5. What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?

Weak and underfunded developing country health systems lie at the heart of the problem. Global prevention and control is hindered by poor surveillance infrastructure, laboratory capacity, and containment mechanisms, uneven access to affordable medicines and vaccines, by a lack of transparency over competition and pricing down the medicines supply chain. In addition there is a lack of clarity around the use of intellectual property, unsystematic research and development priority-setting including innovatory approaches.

¹³ <http://www.un.org/millenniumgoals/>

¹⁴ <http://www.stoptb.org/globalplan/>

Progress against AI, specifically, is hampered by difficulty in changing local farming practices in poor countries, wide prevalence of viruses in wild birds, the economic importance of poultry, leading to vaccination options over culling, the difficulty in management of animal hygiene in live bird markets and in control of cross-border informal trade in some world regions.

Also, not all countries have the resources or capacities to put in place a seasonal influenza vaccination policy and, in the event of an influenza pandemic, it is also recognised that current stock will not meet world-wide demand.¹⁵ There needs to be an improvement to rapid response strategies in poorer, more vulnerable, countries.

These blockages might be removed by:

- Increased commitments by developing countries to prioritise their own health financing at national level and strengthen systems. Intergovernmental organisations can help by reinforcing this message to health, planning and finance ministries. The International Health Partnership (IHP) is developing a model for health systems strengthening support.
- Better priority setting for R&D backed by predictable funding, including firm commitments to existing mechanisms and to develop innovative financing mechanisms to promote the development of, and access to, new health technologies.
- Global commitment to improving pricing policies, for example through the Medicines Transparency Alliance being launched in a number of countries with WHO and the World Bank.
- Intergovernmental organisations that are best placed to utilise the intellectual property system to promote both innovation and access and monitor the impact of intellectual property provisions on both.
- Further implementation of the WHO's Global pandemic influenza Action Plan to increase vaccine supply, which aims to substantially increase vaccine supply capacity. The UK Government donated £2 million to the development of the Plan in November 2007.
- Further deployment of the €2.7b pledged by the international community to fight avian and pandemic influenza.

6. *What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?*

The Department of Health is the lead policy department on combatting these diseases in England. (This role is carried out by the Scottish Executive Health Department, the Welsh Assembly Government and the Northern Ireland Department of Health, Social Services and Public Safety in Scotland, Wales and Northern Ireland respectively). In addition the Department of Health works closely with and through the Health Protection Agency (HPA) and intergovernmental organisations, in particular the WHO, to promote an effective international response to these diseases.

The HPA's role as a non-departmental public body is to provide an integrated approach to protecting UK public health, with communicable disease as a key part of its remit. (The HPA will be responding separately to this call for evidence.)

DFID works closely with a range of intergovernmental organisations who take action in response to some or all of these four diseases including the World Bank and UN agencies (WHO, UNAIDS, UNFPA, UNDP and UNICEF), and non UN agencies, such as the Global Fund (GFATM), GAVI Alliance (on vaccines) and UNITAID (medicines). DFID increasingly works closely with the agencies to improve their effectiveness in delivery of their objectives.

Defra monitors the spread of animal diseases globally and carries out risk assessments and puts in place measures to minimise the risks of the spread of exotic disease to the UK. Defra also provides technical support to other government departments (principally DfID) to assist in their programmes with the intergovernmental organisations.

FCO supports the work of other government departments overseas and helps in the delivery of health policy through its network of posts eg. lobbying and advocacy at country level on HIV/AIDS issues.

While the Government believes that the UN and the various global partnerships make a significant contribution to health and HIV/AIDS, there is duplication, overlap and competition between agencies which leads to inefficiencies. In health the UN is particularly fragmented. The former UN Secretary General's High

¹⁵ http://www.who.int/csr/resources/publications/influenza/CDS_EPR_GIP_2006_1.pdf

Level Panel on System Wide Coherence, of which the Prime Minister was a member, recommended the UN should be reorganised to achieve better results. The resulting “One UN” model is now being piloted in eight countries.

7. What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient “joined-up” thinking in approaching the problem?

This is a huge subject: many factors influence the spread of disease. We would single out three for specific attention here: social inequality, poor infrastructure and climate change.

- The reasons why poor people in low income countries suffer from high rates of illness, particularly infectious disease and malnutrition are fairly clear: little food, unclean water, low levels of sanitation and shelter, failure to deal with the environments that lead to high exposure to infectious agents, and lack of appropriate medical care.
- Inadequate health systems and general infrastructure, and poor farming practices, contribute to the cause and spread of disease. Poor border controls over the movement of birds, for example, facilitate spread amongst poultry flocks.
- Exposure to projected climate change is likely to affect the health status of millions of people worldwide, through increases in malnutrition, in death, disease and injury due to extreme weather events, in the burden of diarrhoeal disease, in the frequency of cardio-respiratory diseases, and through altered distribution of some infectious disease vectors.

The UK firmly believes that multisectoral action is needed to tackle these multisectoral issues. Our forthcoming Global Health Strategy will look at action across Government to promote good global health. We are tabling a resolution on the health impacts of climate change at this year’s WHO Executive Board. We await with interest the report of the WHO Commission on the Social Determinants of Health which will report later in the year.

8. Cases of Tuberculosis fell progressively in the UK until the mid-1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of Tuberculosis infections in Britain? And how could intergovernmental action help to reverse the trend?

The HPA has provided detailed figures on TB in the UK in 2006.¹⁶ 8,497 TB cases were reported in 2006 in the UK, a rate of 14.0 per 100,000 population. TB in England was at its lowest level in 1987 (5,087 cases in England), and since early 1990s, there has been an upwards trend. However, both the number of cases and the rate in 2006 were very similar to those for 2005. Further years of data are nevertheless required to assess whether these results indicate a slowing in the overall trend of increasing numbers of cases. The London region accounted for the largest proportion of cases (40%) and had the highest rate (44.8 per 100,000). 72% of cases were non-UK born. The proportion of drug resistant cases of TB has stayed relatively stable with multi-drug resistance remaining at about 1%.

UK Visas works with the International Organization for Migration to screen migrants for infectious TB in certain high-risk countries. Residents of 16 countries must undergo this pre-screening test if they are applying for a visa to visit the UK for six months or more. This scheme, which is still in its early stages, is designed to test the effectiveness of methods for detecting infectious TB in people wishing to travel to the UK. It should also enable a more effective international response to the spread of TB, and encourage individuals to seek early treatment. Passengers from other countries which are high risk for TB are subject to screening on-entry. Asylum seekers accommodated by the Home Office are offered a health check, including TB screening, as part of their induction process, which almost all accept.

Whilst the overall rate in the UK is low, TB is still a public health problem and rates are high in certain inner city areas and in people born abroad. Incidence is also high in certain other hard-to-reach, or hard-to-treat groups.

¹⁶ <http://www.hpa.org.uk/publications/PublicationDisplay.asp?PublicationID=110>

We look to the Global Plan to Stop TB to contribute to global reductions in TB, from which we expect resultant benefits in the UK.

9. *Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions—eg HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?*

There are a number of barriers in tackling TB that include the following:

- Treatment requires long-term, regular antibiotic use for it to be effective.
- Long incubation periods of TB mean that patients may carry latent infection for years before they develop active disease.
- The emergence of drug resistance and co-infection with HIV poses special challenges.
- Health systems must be able to cope with demand.
- Health care workers must be properly educated in TB prevention and control.

It is estimated that one third of the world's population are infected with the TB bacillus. However, only 5–10% of these will go on to develop disease, although rates are much higher for people co-infected with HIV. People living with HIV are more susceptible to developing TB disease and TB is the leading infectious killer of people with HIV/AIDS globally.

First-line TB treatment requires the use of four drugs over a period of six to nine months. This places a significant burden on patients and on health infrastructure and resources in many countries. Failure to complete a course of treatment can result in poor health outcomes and the development of drug resistant TB. HIV treatments interact poorly with a key first-line TB drug (Rifampin), complicating the treatment of people co-infected with HIV and TB.

TB management requires effective case identification and access to treatment programmes. Directly Observed Therapy (DOTS) provides an internationally recognised detection, treatment and management strategy for TB. Over 89% of the world's population live in countries that have adopted the DOTS approach. The UK uses DOTS in specific cases following a risk assessment for drug adherence of patients.

Treatment of drug resistant TB is more complex, requires longer treatment courses and is many more times more expensive than treatment with first-line drugs. The development of new drugs that are easier to take, over a shorter course of treatment, could make a significant contribution to reducing the cost and complexity of TB programmes and increase their reach and impact.

The Global Plan to Stop TB 2006–2015¹⁷ sets out an ambitious and comprehensive programme to achieve the MDG 6 goal of “halting and beginning to reverse the incidence of TB” by 2015. It includes actions to support equitable access to TB drugs and diagnostics for all and for development and introduction of new drugs (by 2010), field diagnostics (by 2010) and vaccines (by 2015). If fully implemented, it is estimated that 14 million lives will be saved between 2006–15.

10. *To what extent do you believe that the 2004 Stockholm Convention limiting the use of DDT against Malaria-carrying mosquitoes has been a factor of increases in the spread of the disease? Has any risk analysis been carried out comparing the relative dangers to human health posed by DDT and Malaria?*

The Stockholm Convention does not prevent the use of DDT for malaria vector control and does not limit the use of DDT against malaria-carrying mosquitoes. Therefore it cannot be considered a contributing factor to the increase in the spread of the disease.

There is no risk analysis comparing the relative dangers to human health of DDT and malaria. It would be impossible to carry out such an analysis in a meaningful way. Malaria is one of the leading causes of death in Sub-Saharan Africa and targets young children. The effects are acute. DDT is considered an endocrine disrupter and studies point to reproductive disorders in men from exposure to DDT. It does persist in the environment for many decades, has been found in human tissues such as breast milk and it may be transported around the globe ending up in environments where it has never been used such as the Arctic. The toxic effects of DDT are chronic and, given the persistence of the chemical in the environment, it could take years and even generations for the resulting effects to materialize.

¹⁷ <http://www.stoptb.org/globalplan/>

While the Stockholm Convention does not prevent the use of DDT for malaria control, it does encourage the development and implementation of alternative products, methods and strategies. A number of partnership initiatives have been established to promote such alternatives, including collaboration with the World Health Organisation.

11. *What intergovernmental action is planned or in hand for early detection of the transmission of Avian Flu from birds to humans and of human-to-human transmission in potential source countries? Is this proving sufficiently effective to prevent an Influenza pandemic? What more could be done?*

Within Europe, EC Directive 2005/94/EC for the control of avian influenza in birds applies. Internationally, the multi-lateral agencies including the WHO share information on animal zoonotic diseases under the Global Early Warning and Response System (GLEWS).

In relation to suspected avian influenza in humans, confidence in national surveillance and detection varies according to country. Inter-governmentally, under the International Health Regulations, governments are required to notify WHO of any event that they assess (using the algorithm set out in the IHR) as a potential public health emergency of international concern (PHEIC). Human Influenza caused by a new subtype has to be notified under the IHR as a potential PHEIC. WHO, working with the European Centre for Disease Prevention and Control and other specialised agencies, under the Global Outbreak Alert and Response Network (GOARN) system mobilises experts from around the world to support countries in investigating and controlling significant outbreaks of any infectious disease including avian influenza in humans; this could be with surveillance, detection, rapid response, and treatment. In addition, avian influenza viruses appearing in humans that have spread to humans should be shared with the WHO Global Influenza Surveillance Network (GISN) for surveillance, risk assessment, and preparation for vaccine seed. WHO reports confirmed cases of avian influenza in humans on their website, and has produced and updated guidance on rapid response and containment which applies in any country, including Europe.

These systems have worked reasonably well to date in avian influenza human outbreaks. However, we rely on the quality of surveillance, investigation and reporting in countries such as China, Indonesia and others. Improvements need to be made in surveillance, detection, laboratory capacity, and containment strategies, as well as general infrastructure. Communication and responses need to be regularly tested, WHO run regional exercises to test various aspects of detection and response. Of course, not only will the quality of detection and containment mechanisms play a vital role in the early stages of preventing/containing a pandemic, the nature of the virus and location of the virus will also play its part.

One particular serious issue since the beginning of 2007 relates to the very limited sharing by Indonesia of its avian influenza viruses found in humans with the GISN. Indonesia is seeking rights to control who should have the virus taken from individuals in Indonesia, as well as the purpose of its use. WHO and its member countries are currently addressing this, including providing more equitable access to vaccines and other benefits for the more vulnerable countries.

More clearly needs to be done to improve detection, surveillance, and general response capacity building. The UK gave £2 million in November last year to further develop the WHO Global pandemic influenza Action Plan to increase vaccine supply. This plan strives to increase capacity building in the more vulnerable countries. Also, there have been various international conferences to mobilise pledges of financial support to tackle avian and human influenza, notably in Beijing in January 2006, in Bamako in December 2006 and in Delhi in December 2007. In all, some \$2.7 billion has been pledged, with the UK pledging £35 million (in addition to substantial contributions via the European Commission)—the largest pledge by an EU Member State. Some of this money is administered by the World Bank by means of a trust fund; some is administered bilaterally whilst some is channelled through multi-lateral organisations. The United Nations System Influenza Co-ordinator and the World Bank have produced a forward look of gaps to direct future spend, as well as progress reports addressing where the money has been spent.

At the Delhi Conference, the UK was instrumental in calling for proposals for a 3–5 year International Forward Strategic Plan to build on and strengthen efforts to date and to drive inter-governmental action, both for the control of avian influenza and to ensure a better readiness for a possible pandemic. This will be presented to the next major international conference, scheduled for October 2008 in Cairo.

Although WHO prepare regional Exercises, and the EU has run a pandemic preparedness Exercise too, an international Exercise centrally co-ordinated by WHO, with all WHO regions, the EU, and selected countries would be an excellent way of testing how a global response would work, and would no doubt highlight many lessons to be learned.

12. To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?

In general, resistance to antibiotics is not currently a primary driver of transmission for the four diseases. However, resistance is already a major problem causing increased morbidity and mortality and raising the complexity and costs of disease management for AIDS, TB and malaria.

Concerted action is needed to support the proper selection, management and use of drugs and other health commodities to prevent, diagnose and treat the four diseases by health professionals. Increased efforts are needed to improve health system capacity and availability of predictable financing to ensure the reliability, coverage and consistency of drug and commodity supplies and to deliver training on best practice to health professionals and education on treatment and prevention to communities. Surveillance systems to monitor the spread of drug resistance must be improved. Initiatives are needed to make second-line treatments for HIV, TB and malaria more affordable and available when required. Investment in R&D for new treatment and prevention options is essential for sustainable responses to communicable diseases.

WHO plays central role in providing accurate information and technical support on the emergence of, and response to, drug resistance for the four diseases.

DFID is a major contributor to the Global Fund for AIDS, TB and Malaria (GFATM) (£360 million to the GFATM (2008–10) as part of a long-term commitment of £1 billion through to 2015) and UNITAID (a 20 year commitment of up to £760 million, subject to performance review) that provide considerable funding to support reliable access to quality medicines and health commodities.

DFID is leading the development of the Medicines Transparency Alliance (MeTA), which will work with partners internationally to strengthen pharmaceutical systems and reliable access to quality and affordable medicines. MeTA will be launched in 2008.

Also, DFID invests just under £25 million each year in product development partnerships to develop new drugs for malaria, TB and other tropical diseases and for the development of vaccines and microbicides to prevent HIV transmission.

Malaria

In highly endemic countries, treatment of malaria does not play a significant role in limiting transmission but is central to reducing illness and mortality. There are considerable global levels of resistance to traditional treatments, such drugs are cheap, but ineffective in many parts of the world, resulting in wasted resources and poor health outcomes. Artemisinin Combination Therapies (ACTs) are effective but currently more expensive than established drugs and coverage, particularly in sub-Saharan Africa is low. DFID supports a number of initiatives to accelerate the uptake of ACTs and to help ensure their proper use, thereby delaying the emergence of resistance. WHO has issued guidance to countries recommending that ACTs are adopted as first treatment for malaria. The GFATM, UNITAID and the US President's Malaria Initiative are providing resources to support ACT adoption. Intensified pressure on the malaria parasite will increase the potential for resistance to existing drugs and insecticides. It is essential that sustainable malaria efforts include investment in the development of new drugs, insecticides and, ultimately, a vaccine. DFID has provided matched funding of £10 million with the Wellcome Trust over five years to the Medicines for Malaria Venture and is considering options to support incentives to encourage industry development of malaria vaccines.

Antimalarial drug resistance hinders malaria control and is therefore a major public health problem. The WHO publication *Drug Resistance in Malaria*¹⁸ describes the state of knowledge about this problem and outlines the current thinking regarding strategies to limit the advent, spread and intensification of drug-resistant malaria. There is also further information on drug resistance on the WHO website¹⁹ and the Secretariat of the Roll Back Malaria Partnership facilitates access to quality affordable antimalarial medicines including combination therapies and other essential supplies through the commodity services unit²⁰.

¹⁸ http://www.who.int/malaria/cmc_upload/0/000/015/040/bloland.html

¹⁹ <http://www.who.int/drugresistance/malaria/en/index.html>

²⁰ <http://www.rollbackmalaria.org/aboutus.html>

TB

The UK has committed to provide £360 million to the GFATM (2008–10) as part of a long-term commitment of £1 billion through to 2015. 17% of GFATM expenditures are on TB. DFID has committed nearly £9 million to the funding of the Stop TB Partnership from 2002–08. DFID is providing £6.5 million (2005–08) to the Global Alliance for TB Drug Development to accelerate the research and development for new TB drugs that will reduce treatment complexity and duration.

The HPA National Mycobacterium Reference Unit (MRU) and regional reference laboratories in England, Wales and Northern Ireland provide drug susceptibility data on TB. The MRU is a WHO SupraNational Reference Laboratory and European Co-ordinating Center within the Global Programme on Drug Resistance and operates an External Quality Assurance programme for drug resistance on behalf of the WHO.

HIV

Successful treatment of HIV requires 95% adherence to treatment regimes. Over time, most patients will develop resistance to anti-HIV drugs requiring access to second and third line therapies, which are routinely available in developed countries like the UK. While the cost of first line HIV therapies available in least developed countries has fallen as low as \$100 in recent years, second line treatment regimes may cost between four and more than 10 times this. The onset of resistance can be delayed by ensuring that patients have reliable access to affordable treatment services that are suitable to their circumstances. WHO has developed and updates guidelines for the treatment of HIV, including strategies to change drug regimes when resistance emerges.

The transmission of drug resistant HIV (primary drug resistance) is recognised as a problem in developed countries. There is limited evidence of levels of primary resistance in developing countries. There is no evidence that drug resistance is itself driving transmission, although it is true that the risk of HIV transmission increases if individual viral loads are high, for example, if treatment is not available or failing. Primary resistance limits the treatment options available to those infected, potentially increasing complexity, costs and treatment outcomes.

In 2005, the international community committed to achieving universal access to HIV and AIDS prevention, treatment and care by 2010. UNAIDS and WHO provide technical assistance and monitor progress in achieving this goal. In addition to country and bilateral expenditures, the GFATM, UNITAID and World Bank MAP programme provide substantial multilateral funding for international HIV and AIDS efforts.

As part of its Taking Action strategy on HIV and AIDS, the UK committed to spending £1.5 billion on HIV related programmes between 2005–08.

Avian Flu

In advance of a pandemic it is difficult to predict the potential role of antiviral resistance. There is some limited evidence to show the potential of the H5N1 virus to develop resistance to antivirals, which may limit its effectiveness in mitigating the consequences of infection during a pandemic. Generally, antibiotics would only be used to treat any complications arising from influenza.

13. In a number of countries, including the UK, there is a problem with hospital-acquired infections. What intergovernmental sharing of knowledge is taking place to help bring this problem under control?

There is little formal exchange of information but there are plans for an EU recommendation on hospital-acquired infections (HCAIs)—we expect something this year but have no firm timetable. There are some EU projects covering HCAIs and ECDC has an interest in surveillance but generally most international collaboration is through professionals in the field.

The WHO World Alliance on Patient Safety, chaired by Sir Liam Donaldson, has a key role in international action on hospital-acquired infections.

WHO are working with the Commonwealth Fund on an initiative to develop five safety solutions to be implemented by the participating countries. Referred to as the “High 5s” the aim of the initiative is to introduce five patient safety solutions in 10 hospitals within seven participating countries and to evaluate the effectiveness of these solutions.

England and Wales will be taking part in this initiative and the National Patient Safety Agency (NPSA) has been nominated as our lead technical agency. The NPSA has led the development of the solution on the prevention of high concentration drug errors. The four other solutions concern the prevention of hand-over errors; the prevention of continuity of medication errors; the promotion of effective hand hygiene practices; and the prevention of wrong site/wrong procedure/wrong person surgical errors.

DH holds the co-chair of the group designing the economic evaluation of the “High 5s”, pre- and post-implementation.

There has also been a separate strand of work led by the WHO collaborating centre for patient safety solutions to develop and agree generic standardised solutions to nine known areas of risk, including hand hygiene / infection control. These were distributed to all WHO countries in May 2007, to take and build in specifics depending upon their national health systems. The overall purpose is to guide the re-design of care processes to prevent human errors from reaching patients.

14. *Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?*

By conferring a temporary exclusivity, patents provide an important incentive for the development of new healthcare products where there is an assured demand for the products of research and development, as is the case in developed countries. However, in the absence of such a demand, which is the case for many products which are predominantly required in developing countries, the incentive offered by intellectual property rights is limited. That is why governments, including the UK government, have invested significantly in research and development on products needed to fight major diseases in developing countries such as HIV/AIDS, TB and malaria.

Because they allow firms to price their products above cost in order to recoup the cost of their research and development programmes, patents can also be one of several contributory factors in determining the price of medicines and other healthcare products in developing countries. In recent years the international community has taken a number of steps to address this issue. These include the World Trade Organization Declaration on the TRIPS Agreement²¹ and Public Health agreed in Doha in 2001 which stated that the TRIPS Agreement “does not and should not prevent Members from taking measures to protect public health . . . and, in particular, to promote access to medicines for all”. The Declaration highlighted the flexibilities that exist in TRIPS to facilitate access to medicines. As a result of the Declaration, WTO members are now in the process of ratifying an amendment to the TRIPS Agreement which allows countries without manufacturing capacity to import generic medicines from other countries under a compulsory licence. It also allowed least developed countries not to enforce patent protection for pharmaceuticals until at least 2016.

The Government supports the right of developing countries to use compulsory licensing provisions in order to facilitate access to medicines. The Government considers that a principal purpose of compulsory licensing provisions is to bolster the ability of countries to negotiate effectively with providers of patented medicines, and the actual use of compulsory licensing provisions should be judicious.

Apart from these actions, many pharmaceutical companies have instituted differential pricing policies for selected products and countries under which they charge lower prices in least developed and low income countries in particular for drugs targeted at HIV/AIDS, TB and malaria.

Although a considerable amount has been achieved, further intergovernmental action is underway. In 2006, WHO established the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property to draw up a global strategy and plan of action aimed at securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries. This is due to report to the World Health Assembly in May 2008.

In respect of avian flu, WHO has held a series of meetings to consider the issues associated with the sharing of influenza viruses and access to vaccines and other benefits, in particular the impact of intellectual property rights on access to vaccines. Further work in this area is planned.

²¹ The Agreement on Trade-Related Intellectual Property Rights

15. *What interchange exists between States in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?*

The main interchanges with other countries in which the UK is currently involved relate to preparation for pandemic influenza. The exchanges of information and learning that take place can then be shared more widely through intergovernmental mechanisms such as the WHO.

The European Union, through the Health Security Committee and the EU Presidency, WHO and the Global Health Security Action Group²² (GHSAG) and the International Partnership on Avian & Pandemic Influenza (IPAPI, a group set up by the USA) are the key vehicles through which information and best practice is shared and compared, and a global response for dealing with outbreaks, affecting human health, is coordinated.

WHO actively trains clinical people in the regions by sending in response teams when a cluster of human avian flu cases are found; the European Centre for Disease Prevention & Control (ECDC) is also involved in the field, in facilitating the exchange and assessment of good practice, and in providing technical input. The WHO have also produced treatment and diagnosis guidelines and recommendations for human cases of H5N1.

Defra funded Veterinary Laboratories Agency (VLA), Weybridge, is recognised by the World Organisation for Animal Health as the World Reference Laboratory for avian influenza. VLA is a leading research and laboratory organisation in avian influenza and supplies diagnostic reagents to many laboratories worldwide.

The GHSAG was set up following the attacks on the World Trade Centre on 11 September 2001, to develop proposals and actions to improve global health security²³. The network has been designed to respond swiftly in the event of a crisis; it has a Pandemic Influenza Working Group which meets to share information via regular international conferences, meetings, and on-going exchanges of information about pandemic planning.

16. *The International Health Regulations 2005 are intended to provide a global framework for the rapid identification and containment of public health emergencies. How effective do you consider this response system to be? Do improvements need to be made?*

The new IHR were adopted by the World Health Assembly in 2005, but came into global effect in June 2007. Prior to formal commencement, member states had agreed that they would endeavour, within their existing legislative frameworks, to implement key aspects of the IHR that would be helpful in the event of a pandemic flu outbreak. The UK was already well-advanced in its flu planning, but instituted forthwith the UK's "IHR National Focal Point" (IHRNFP—a key formal function defined in Article 4 of the IHR 2005) by administratively designating the Health Protection Agency as holding this function. This designation was later formalised in The Health Protection Agency (Amendment) Regulations 2007 (SI 2007 No. 1624), which came into force in July 2007. The Government has also brought forward the Health and Social Care Bill which updates the existing Public Health (Control of Disease) Act 1984 in several respects, including enabling the Government to take (if it considers it appropriate to do so) actions that might be recommended by WHO.

As at December 2007, the new IHR have thus been in full effect for only six months. They have not been put to a serious test in that time, so it may be premature to reach conclusions on their effectiveness. However the Government strongly supports the IHR 2005, and is satisfied with the functioning of the UK's IHRNFP, which has exercised the procedures laid down in the IHR on a number of occasions.

Recent global initiatives on avian influenza have contributed to on-going improvements in timely notifications of outbreaks in animals to the World Organisation for Animal Health.

17. *What intergovernmental planning has been undertaken to cope with the impact of an outbreak of infectious disease caused by deliberate release of micro-organisms into the environment? Is there adequate liaison between the various agencies involved, including intelligence, law enforcement and health care professionals? How could action by intergovernmental bodies help further?*

Regular and on-going risk assessment is undertaken across all government departments—coordinated by the Cabinet Office—to prepare for, and plan against, the effects of a deliberate release of micro-organisms into the environment. The Home Office leads particularly on CBRN (chemical, biological, radiological and nuclear) issues.

²² It is made up of the G7 countries plus Mexico.

²³ http://ec.europa.eu/health/ph_threats/com/preparedness/docs/ev_GHSAG_2006.pdf

There is considerable cross-government cooperation to ensure that workable plans are put in place, and tested on a regular basis. The Security Services report across Government on the identified risk/threats. The Joint Terrorist Advisory Committee and other agencies liaise on the intelligence available, to determine the type and extent of preparations necessary to mitigate any deliberate releases into the atmosphere.

While overall strategic planning is undertaken at the inter-governmental level, planning for the actual response to an attack is undertaken at local multiagency level—with the benefit of centrally produced guidance such as the Mass prophylaxis and Smallpox plans.

Intergovernmental bodies such as the National Security, International Relations and Development (NSID) [Prepare] and [Protect] Committees meet regularly to plan for the protection of UK citizens.

UK membership of international bodies like the European Union Health Security Committee and the Global Health Security Action Group (GHSAG) ensures cooperation with international colleagues results in a coordinated approach to meeting any terrorist threat. The UK also works on a bilateral basis with international colleagues as required.

18. *Though our remit is focused specifically on known infectious diseases, we would be interested to know how you view the global threat from new or previously unrecognised ones and from the transmission of infections from animals to humans*

The global public health threat from new and emerging infections is considered to be greatest from zoonotic infections—those that are naturally transmissible from animals to man. Since the 1970s, over 30 previously unknown infectious diseases have emerged and most of these have been zoonotic. Some of these, such as H5N1 avian influenza, do not readily pass the species barrier and are not easily spread from person to person, whereas SARS CoV spread easily in the right environment. In addition to new infections emerging, there is also the issue of known infections arising in places where they have been previously unknown. The arrival of West Nile Virus in the United States and its rapid spread across nearly all states is a good example of a vector borne zoonoses taking a country by surprise. The opportunities for new and emerging infections to be introduced by an influx of migrant workers from areas where they might have been exposed to new or emerging infections is highlighted in a recent report on migrant health.²⁴ Similarly, close connections between countries due to families connecting with relatives provide opportunities for rapid transfer of infection globally. However, it is changes in demography, cultural habits and tourism, with new opportunities for close contact between the animal habitats and man, that remain the main influences on the emergence and spread of new infections.

It is estimated that over 75% of new and re-emerging human diseases are zoonoses and their emergence is often linked to environmental changes brought about by human activity.

What SARS and H5N1 avian influenza have reminded us is that the emergence of infection in one continent can rapidly become a global public health threat. It is inevitable that such new and zoonotic threats will continue to occur, and what is needed to combat the threat is sound animal and human health surveillance systems, rapid reporting mechanisms and embedded diagnostic capability and capacity, particularly in those areas where it is most likely that a new zoonotic infection will occur (Asian, African and Indian continents). The importance of global collaboration on health has been recognised for a long time, but the threat of a pandemic of influenza has served to sharpen our focus on early detection and containment measures and recognition of the unimportance of national and geographical boundaries in containing the spread of disease.

The surveillance and data collection systems and international collaborations on zoonoses in particular set out above (see Q2 response) provide a firm foundation for this global approach.

For the UK, staying ahead of this potential threat relies on training clinicians to be alert to the potential for new or emerging infections and to the possibility that migrants and returning tourists might have an exotic infection. Maintaining excellent diagnostic facilities capable of detecting infections that are not native to the UK is essential, as is sound horizon scanning, such as is undertaken by the Chief Medical Officer's National Expert Panel on New and Emerging Infections (NEPNEI).

²⁴ http://www.hpa.org.uk/publications/2006/migrant_health/migrant_health.pdf

19. *What resources (subscriptions, staff, training, medicines etc) does the UK Government commit to intergovernmental bodies to help in the fight against the four diseases listed?*

The UK provides resources to intergovernmental bodies working on these diseases through funding (both core unearmarked contributions and specific contributions to programmes and initiatives), in-kind contributions (for example, expert input to committees, working and expert groups) and staff secondments. The Government's support for research into these diseases is also an important underpinning contribution to the work of intergovernmental bodies.

The table below lists recent relevant financial contributions to intergovernmental bodies by the UK government.

<i>Intergovernmental body</i>	<i>£m</i>
<i>Annual core unearmarked resources (a proportion of which will be allocated to agency programmes to fight the 4 diseases):</i>	
WHO:	
DH (2007)	13.6
DFID (2007)	18
UNICEF: DFID (2007)	21
UNDP: DFID (2007)	55
UNAIDS: DFID (2007)	10
UNFPA: DFID (2007)	20
<i>Other resources:</i>	
UNFPA Global Programme to Enhance Reproductive Health Commodity Security (which will have an impact in the UN's response to HIV/AIDS): DFID (2007–12)	100
UNFPA RHCS in fragile states DFID (2007)	5
UNICEF children with HIV/AIDS programmes: DFID (2004)	44
GFATM: DFID	
2008–10	330–360
2011–15	up to 640
Roll Back Malaria Partnership: DFID (1998–2007)	49
Stop TB Partnership: DFID (2002–08)	9
UNITAID international drug purchase facility (HIV, TB, malaria): DFID (over 20 years)	up to 760
Medicines for Malaria Venture: DFID (over 5 years 2005–10)	10
Drugs for Neglected Diseases Initiative: DFID (2005–08)	6.5
Global Alliance for TB drug development : DFID (2005–08)	6.5
Tropical Disease Research: DFID (2005–08) this is a special research programme of WHO	4.5
WHO pandemic flu surveillance: DH (2005)	0.5
WHO Global Pandemic Influenza Action Plan to increase vaccine supply: DH (2007)	2
WHO Total UK Government pledge to fight avian and pandemic influenza	35
Secondments from UK Government to intergovernmental organisations—avian and pandemic influenza related	0.5

Annex B

WORLD HEALTH ORGANISATION DEVELOPMENT EFFECTIVENESS SUMMARY*

CONTEXT

Mandate

The World Health Organisation is the United Nations specialised agency responsible for matters relating to health. Its objective is the attainment by all peoples of the highest possible level of health. Normative work: promoting research, generating new knowledge and formulating of policies, strategies, guidelines and standards, is WHO's core work. WHO has a key development role and is committed to attaining the health targets identified in the MDGs. WHO currently pursues 35 areas of work under five basic headings: Improving

Health Outcomes; Responding to Outbreaks and Emergencies; Tackling Health Determinants; Strengthening Health Systems; Focusing on Results Based Management (RBM). From 2008, WHO's work will be organised around 13 Strategic Objectives.

Size

With headquarters in Geneva, WHO have 145 country and 6 regional offices. Expenditure in the biennium 2004–05 was US\$ 2,944.4 million with 37.5% spent at HQ level, 27.0% at regional level and 35.5% at country level.

Key Issues

Interpreting WHO's role, as a specialised agency, within the wider UN reform agenda will be a challenge for the organisation—this includes clarifying WHO's respective roles and functions of Headquarters, Regional and Country Offices. This will be informed and modified by how they participate in the One UN country pilots. Improving Financial Resources management is a priority area. There is an unhelpful resource ratio of 26%:74% between assessed contributions and voluntary contributions—funding which is largely earmarked for specific activities—which severely hampers WHO's ability to carry out its core work. WHO intend to redress the imbalance of earmarked funding, and the restrictions this places on activities by 2013.¹⁰ However the latest proposed programme budget for biennium 2008–09 shows even greater imbalance of 22.7%:77.3%.¹⁰ In terms of the key issue of health systems strengthening, WHO needs to define and play its role vis-a-vis the roles of other agencies such as the World Bank. With the effects of climate change becoming more apparent WHO will have a key role to play in the response to global health security resulting from it. WHO has appointed a new Director General, Margaret Chan. She has confirmed her commitment to ensuring participation in the UN reform process. We hope to see a positive response at regional and country level. WHO needs to continue to demonstrate leadership in helping to simplify the current complex health architecture and proliferation of global health partnerships. WHO has seen many successes at the global level and some success at the regional and country levels, however lack of information makes it difficult to counter the perception of variable country level performance.

IS WHO BUILDING FOR THE FUTURE?

Summary

WHO have made significant strides over the last few years in institutional reform. Some areas such as the Results Based Management Framework have been significantly improved. There are other areas, such as staff development, which will take longer to see significant changes. WHO has taken an active part in the UN reform process as a member of the UN Development Group (UNDG). Papers to the January and May 2007 Executive Boards outlines WHO's Views on UN reform, and their engagement, including in the pilots, to date. These demonstrate movement and a change of position over the previous months. The new Director General, Margaret Chan, has confirmed her commitment to UN Reform and we expect to see more focus on contributing to the One UN Pilots. However it is early days and we need to wait to see what the strongly independent regional offices will do to support the DO. The country support network have agreed a strategy for building capacity of country teams and addressing the harmonisation and alignment agenda. One important challenge is posed by the interdependence between some of the reform elements across the organisation resulting in delay in fully implementing reform policy.

COMMITMENT TO CONTINUAL IMPROVEMENT

To what degree is WHO committed to UN reform?

⇒ WHO share the views of the international development community of the need to improve effectiveness and impact, and the need for the UN system to demonstrate more effective actions relevant to the needs of the 21st century. WHO is committed to investing in collective UN action and reform. WHO believe that diversity of the UN system is a source of strength, and that the outcome of the current UN reform debate should be a better articulated division of labour.⁹

Does the Board require management to act on performance results?

⇒ Results are measured against indicators set in the programme budget. But reports are not published before the next budget is published. Performance Assessment Reports include lessons learnt against each area of work along with details of how they will be applied in the next biennium. The new Medium Term Strategic Plan¹⁰ sets out a clear framework for results based management providing indicators, targets and resources required for their achievement. The importance attributed to RBM is reflected in the location of the Evaluation Unit within the DG's office.²

BUILDING KNOWLEDGE AND LESSON LEARNING

Does WHO have adequate mechanisms for learning and spreading lesson learning?

✓ WHO is a knowledge-based organisation. The exchange and dissemination of information about health conditions and the Maintenance of health has been a central activity of the Organisation since its founding.¹³ Internet and published materials are widely disseminated. WHO have made some progress in sharing knowledge and good practice with member states through its Knowledge management and information cluster. A new partnership is hosted by WHO—The Health Metrics Network. It seeks to increase the availability and use of timely, reliable health information by catalysing the funding and development of core health information systems in developing countries.² National offices in priority countries need to improve their communication strategy and proactively disseminate regular updates that inform key stakeholders in simple terms of the interpretation of the WHO mandate in emergencies in the local context.

RESULTS BASED MANAGEMENT

✓ WHO is committed to results based management and has a well defined framework starting with the General Programme of Work providing the long term strategic direction to set priorities that will be outlined in the Medium Term Strategic Plan. Performance is assessed biennially with additional thematic, programmatic and country evaluations to critically assess outcomes.²

STAFF DEVELOPMENT

What is the level of staff satisfaction? Not reported in the public domain

Not reported in the public domain.

HOW WELL IS WHO MANAGING ITS RESOURCES?

Summary

WHO's ability to prioritise and fund its work is significantly restricted by the high level of earmarking by donors against voluntary contributions. These contributions account for 74% of funding to WHO in comparison to 26% assessed contributions. This results in an imbalance of attention and resources going to issues important to member states while other pertinent areas are neglected. WHO recognises that it needs to improve the predictability of its financing if it is to more effectively manage its resources as set out in the MTSP.¹⁰ The role of WHO as a normative and standards setting agency points to less not more decentralisation. However WHO is moving towards greater decentralisation at regional and country levels. The regional layer has an important technical support and performance monitoring role but in the case of WHO, the regions have a unique semi-autonomous status, making any reform-minded changes to the regional level very difficult. WHO take the opposite view to this.

CORPORATE GOVERNANCE AND STRATEGY

Is WHO's corporate strategy based on a clear definition of mandate and comparative advantage?

✓ WHO has identified its strengths as its neutral status and nearly universal membership, its impartiality and its strong convening power. WHO has a large repertoire of global normative work and many countries rely on WHO standards and assurances in medicine. Based on evidence of where WHO could make the biggest difference to health outcomes, 35 areas of work were identified within four strategic priorities directly linked to the mandate. From 2008–13, WHO's work is clearly described through 13 Strategic Objectives of the Medium Term Strategic Plan.

RESOURCE MANAGEMENT

What proportion of the budget is spent against the period to which it was allocated?

✓ The latest financial report states that there was an average under-spend of 3.6% across work areas; therefore 96.4% was spent.⁶

What percentage of total expenditure is spent on administration?

x This is not clear from financial report, but appears to be 18.2% calculated from figures in the 2004–05 Financial Performance report. Direct Costs are recovered directly from the projects, Programme Support Costs are set at 13% and are recovered from extra budgetary projects and finally Fixed Indirect Costs are financed from regular/core income.⁶

Is the agency committed to robust efficiency targets?

x WHO have not published any efficiency targets but have identified areas where savings could be achieved through implementation of the Global Management System beginning 2008 and through the natural decline of some programmes eg Polio.¹⁰

How well is WHO's resource allocation criteria aligned with its corporate strategy and comparative advantage?

✓ The latest report shows a much tighter distribution of budget variance illustrated by the small under-spend. More areas of work were closer to their budget targets.⁴

STAFF MANAGEMENT

To what extent is staff recruitment, postings and promotions meritocratic and transparent?

x WHO have started to implement contract reform to provide an easier, transparent recruitment and postings process. They have implemented a global competency framework which has been integrated into major human resource functions.²

Is there an agreed human resources strategy in support of WHO's strategic plan?

⇒ WHO recognize that good planning of human resources based on actual and projected needs is essential to effective programme implementation at country level and have improved staff mobility and rotation to address this issue.² Inductions and ongoing training for WHO staff in interpreting and delivering the HAC (Health Action in Crisis) emergency mandate need to be enhanced and delivered at the national level whenever possible and additional focus and resources need to be identified to support these activities. Training packages for staff at national level need to be further developed and delivered to improve capacity to create quality proposals to donors.¹¹

OPERATIONAL MANAGEMENT

Is WHO sufficiently decentralised to enable it to respond flexibly to country demand?

⇒ WHO is already significantly decentralised with six regional and 147 country offices. Emergency response activities require standard operating procedures to be finalised that are tailored to maximising speed and efficiency of internal resource flow and minimise bureaucracy and unnecessary delay. Training programmes in the understanding of standard operating procedures should be further developed and finalised and implemented as widely as possible at National, Regional and HQ levels of WHO. A system for monitoring the implementation of and compliance with standard operating procedures needs to be put in place at all levels of the organisation.¹¹

Does WHO's Management Information System provide accurate, useful and timely information for programmatic decision-making?

⇒ WHO have developed a draft information and communication technology strategy. 85 locations have access to WHO intranet but the use of IT across country offices is patchy.² WHO plan to update their MIS system to an Oracle based system in mid 2007, which will link resources more closely to programme outcomes.

How clear and effective are WHO's financial management procedures?

⇒ The Programme, Budget and Administration Committee (PBAC) are responsible for monitoring WHO's financial management procedures. They are in the process of implementing new policies on a range of financial management issues to clarify and improve procedures.¹⁴

HOW WELL IS WHO MANAGING ITS PARTNERSHIPS?

Summary

There is a perception that WHO is being stretched in too many directions by the growing number of Global Health Partnerships (GHPs). A positive development is a report on Partnerships to be presented to the January 2008 executive board, which will look at this whole area. With the introduction of a Health Systems Cluster and greater clarity on strategies of GHPs we should encourage WHO towards greater harmonisation. Although the Country Cooperation Strategy (CCS) encourages dialogue beyond the Ministries of Health there is sometimes a tendency to restrict partnerships, to health ministries and exclude wider constituencies at country level. This close relationship with health ministries can, on occasion make WHO representatives reluctant to challenge government policy on difficult issues. The MOPAN survey will review donor perceptions of WHO in 2007. Country governments turn to WHO for assistance in preparing proposals and monitoring reports and WHO cooperate well in this. However lack of resources and lack of the right people on the ground mean that they are not always able to respond in a timely manner.

VOICE

What mechanisms exist for developing countries to influence the strategy of WHO?

✓ WHO has global membership: developing countries are on the Executive Board and they participate in the World Health Assembly.⁵

How actively is WHO promoting the participation of civil society?

✓ WHO operate a Civil Society initiative which enables informal and official relations with NGOs at the HQ level. There is no evidence that WHO is unresponsive and it seeks to engage with civil society where possible particularly at global level and within key partnerships such as stop TB or Roll Back Malaria.¹ NGOs in official relations can attend governance body meetings and make statements although they cannot participate in debates.⁵

PARTNERSHIP BEHAVIOUR

What mechanisms are in place to seek feedback from partners and what do the results show?

⇒ No global partners survey. Outside of World Health Assembly, not known if any formal and regularised mechanisms exist and are active.

How willing is WHO to challenge and assist governments on difficult/controversial issues?

⇒ WHO engage with governments on difficult and controversial issues that have a high profile at the regional and global level. Recent examples include implementing travel restrictions during the SARS outbreak and introduction of the new International Health Regulations. There is less evidence of challenging at the country level.

ALIGNMENT

To what extent does this organisation foster government ownership through the project/programme cycle?

✓ The WHO Country Cooperation Strategy represents a balance between country priorities and WHO priorities. It is a vehicle for WHO alignment with national health and development plans and strategies such as PRSPs and SWAPs.⁴

What % aid flows to government sector is reported on national partner budgets?

Information not available in the public domain.

What % of TC flows are provided through coordinated programmes consistent with partners' national strategies?

Information not available in the public domain.

Does WHO use countries' own public financial management and procurement systems?

x No. WHO has set up its own electronic procurement system, operating on the basis of reducing costs by bulk buying, etc.³

Is the number of Project Implementation Units decreasing or non-existent?

Information not available in the public domain.

In what ways has WHO been aligning its strategy/programme/projects with national strategies?

✓ WHO has a Country Cooperation Strategy framework which clearly identifies consultation with all stakeholders as being essential to developing country plans.⁴ 90% of country offices use these to deliver WHO core functions.

HARMONISATION

To what extent does WHO participate in local donor coordination activities such as sector working groups/thematic groups?

✓ WHO participates extensively in sector working and thematic groups although the quality of participation can be personality dependant and relies on the relative strengths of both the WHO representative and the UN Resident Coordinator.¹ WHO will build more effective alliances within the UN and broader development community, to harmonise the health architecture at country level, and engage in reform process towards an effective country team under a common UN lead.⁵

To what extent does WHO share information with other donors?

✓ WHO publishes and disseminates information widely and readily answers queries.⁵

What evidence is there of harmonising procurement and consulting services procedures, disbursement policies and evaluation practices?

No evidence available in public domain

WHAT DO WE KNOW ABOUT WHO'S COUNTRY/GLOBAL RESULTS?

Summary

As a global norms and standard setting agency, WHO have played a key role in significant achievements in health outcomes such as tobacco control, eradication of infectious diseases (such as Smallpox), and preparations for global health security issues such as Avian Flu, and SARS. WHO now has a stronger planning and results focus at the country level, though it is difficult to assess how effective WHO are at this level based on publicly available information. WHO need to demonstrate their effectiveness at the country level through greater transparency and reporting of country level performance. WHO still work in vertical health initiatives and until recently have not sufficiently contributed to building countries' sustainable health systems. WHO need to build on the leadership they are now demonstrating at the global level on strengthening health systems, by leading and coordinating at the country level with the World Bank, GFATM and other UN agencies. As a norms and standard setting agency their role at the country level should be more about providing strategic health policy advice to governments, than project implementation.

COUNTRY/GLOBAL RESULTS

What information is available on the WHO's performance at country level?

⇒ No country-level performance information in public domain. Regional offices publish information on WHO performance based on results based management.² WHO aggregate initially at the regional level and then again at the global level to provide aggregate performance against global targets.

What evidence is there of the independence, credibility and utility of WHO's own evaluations?

⇒ External evaluators are part of the team which carried out pilot, country evaluations to assess the development of country specific cooperation strategies.¹²

What result is WHO having at country level?

⇒ WHO's performance assessment is focused on thematic areas rather than countries, for example, in their "making pregnancy safer" area of work, 29 more countries received technical and policy support for maternal and newborn health, 37 more countries received support to adapt and introduce standards, guidelines and tools recommended by WHO.²

What results is WHO having at the global level?

✓ There have been significant successes, for example: small pox has been eradicated; polio has almost been fully eradicated; and the "three by five Initiative" has helped 1.3 million HIV positive people to access anti-retroviral medicines. WHO also helped to monitor and contain a global epidemic of SARS and contributed significantly to the eradication of Small pox.²

PORTFOLIO QUALITY

What is the % of projects/programmes which met their targets?

⇒ No aggregated assessment of portfolio performance in public domain. Performance Assessment Report outlines progress on myriad of individual targets.²

How does this vary across sectors, regions and countries?

⇒ Because there is no aggregated assessment of portfolio performance it is difficult to make comparisons across sectors, regions and countries. This is a presentational issue rather than data not being available.

REFERENCES

- ¹ DFID's 2004 Multilateral Effectiveness Framework (MEFF) report
- ² Programme budget 2004–05 Performance Assessment Report
- ³ Programme budget 2006–07
- ⁴ 11th General Programme of Work
- ⁵ WHO website.
- ⁶ Financial Performance 2004–05.
- ⁷ Human Resources Annual Report.
- ⁸ Ownership, Alignment, Harmonisation and Results—Building partnerships with WHO donors towards an improved and simplified management of voluntary contributions.
- ⁹ “WHO and UN reform”—consultation document.
- ¹⁰ Medium Term Strategy Plan (MTSP).
- ¹¹ Health Action in Crisis: mid term evaluation of the three year programme to improve the performance of WHO in crises.
- ¹² Report of Office of Internal Oversight EBPBACI_3.
- ¹³ WHO Knowledge management strategy.
- ¹⁴ Financial Report 1 January 2004 to 31 December 2005.
- ¹⁵ WHO Country offices and country focus report 21 April 2005.

BACKGROUND

This fact sheet is designed to summarise information available on the effectiveness of WHO. It collates the latest published information in four key areas from a variety of sources including the Multilateral Effectiveness Framework (MEFF)¹ as well as a range of WHO's own Annual Reporting^{2–10} and assesses areas of strength (✓) and weaknesses (x) and where progress is mixed (⇒).

* DISCLAIMER

The Effectiveness Summary is a tool designed to simply present the latest available information on WHO's effectiveness. It is prepared by DFID covering a range of multilaterals. The summaries will inform policy but are only one of a range of criteria and sources of evidence considered in recommending future DFID funding allocations. The balanced scorecard format organises what we believe to be the objective sources of information available on four aspects of each organisation's internal effectiveness. It does not measure actual development results on the ground or the merits of the organisation's development objectives. The text within each summary box provides a short analysis of what we believe this information tells us. Any unreferenced text is DFID analysis not in the public domain. It should be noted that the amount of information available and the quality and reliability of information varies considerably across organisations, so there is a limit to which the summaries will be used for comparative purposes.

Examination of Witnesses

Witnesses: PROFESSOR DAVID HARPER CBE, Director General Health Improvement and Protection, Department of Health, DR STEWART TYSON, Head of Profession for Health, Department for International Development, and DR CAROLE PRESERN, Counsellor to the UK Mission in Geneva, examined.

Q1 Chairman: Welcome and thank you for your time and expertise. You will have an opportunity to see the evidence that is given in transcript form so that you can correct any matters of fact or clarify anything that is in need of that. I particularly want you to feel free on future occasions to submit further evidence if that is the result of this process this

afternoon. If you want to send us in anything else, that would be very welcome. In the questioning that takes place now, although the questions may be directed to one of the three of you, if one other wants to respond as well, please indicate and you can certainly do so. In other words, I want full participation. If I may, I will start. One of the things

I have been aware of for a while and have been focusing on, I suppose, myself particularly, and it comes out in your evidence, is this need for clarity over role and vision or, if you like, the architecture which I think you refer to of these governmental organisations. I was struck by one of your comments in Paragraph 16 of your wording where you said that “the current architecture is crowded and poorly coordinated. Within the diverse group of organisations there is no agreed vision or clarity over roles.” I wonder if you could expand a little on that and also say what you think needs to be done. I would also like, as a follow-up on this, an idea of how much that is a problem, particularly for the World Health Organization and the way we use the World Health Organization.

Professor Harper: I will turn to my colleague in a moment. First of all, may I say how pleased we are to have the opportunity to be here this afternoon to follow up our written evidence with a discussion on this really important issue of the global control of infectious diseases and diseases such as tuberculosis, malaria, HIV/AIDS and avian influenza with the prospect of it becoming at some point a human pandemic. These are truly global challenges and they require global solutions of course. It is very important that we have a coherent and robust approach to the international institutions. I am also very pleased that I am joined this afternoon by my colleagues Carole Presern from the Foreign and Commonwealth Office and Stewart Tyson from DFID, because I think these huge challenges cannot be tackled by one Department of State or Agency. We are looking forward to our discussions. On your first question, Chairman, may I turn to Stewart Tyson?

Dr Tyson: I do not know what the procedure is, but can I submit three pieces of paper to circulate that will give you a picture of the problem in health. There are more than a hundred of these specific disease-focused initiatives, set up for good reason because of perhaps perceived failures to address Leprosy or Micro-nutrients or TB or Malaria. Each of them has their own structure, their own process, their own interaction with countries, and it causes large problems, not least of which is transaction costs for government. One example is Vietnam, which in 2005 had almost 800 donor missions in one year. The combined administrative burden on countries of all of these well-meaning partnerships is very significant. The second slide is about how donors fund drugs as one example. This was in Kenya in 2005. Instead of working to an integrated national plan and to trying and strengthen the procurement and logistic system—this would be typical of many countries—lots of donors are funding specific drugs through parallel channels that bypass the national system and really leave little behind. We know that when the project finishes, the money goes elsewhere and the national system has not been strengthened. The third

one was an attempt in Tanzania to try and work out the architecture around AIDS. If we look at a typical, highly donor dependent country, we might see 20 UN agencies, 35 bilateral agencies, 20 global, regional banks or financial institutions and 90 global health initiatives. Trying to get all of these to work collectively together has, I think, been one of the great challenges. If I can pass that round, it will give you at least a picture of the starting point.

Q2 Chairman: Are you going to send us copies?

Dr Tyson: I can send email copies later. That really was the basis of the International Health Partnership that the Prime Minister launched towards the end of the summer last year. It is an accelerated effort in eight countries to try and apply the principles of aid effectiveness as signed up to in Paris in 2005 and to apply that to the health sector. There was a great deal of enthusiasm on the part of governments to try and hold donors and other partners to account, to get us all behind a nationally-owned plan, to align our support to national planning processes and, where possible, to channel more resources through the government system and, perhaps most importantly, to commit us to a joint process of mutual accountability. We will help strengthen the plan; we will provide resources to help deliver it; and there are obligations on the part of both governments and donors and non-government organisations to try and get us working together. I would suppose the second big area where attempts have been made to rationalise this architecture has been the process of the last UN Secretary-General, Kofi Annan, who set up a High Level Panel on which the Prime Minister of Norway and Gordon Brown, when he was the Chancellor, both sat. That is trying to make sense of the UN process at country level and trying to move the UN from being lots of different agencies working on well-meaning agendas but not collaborating very well, to working to a coherent, single country plan for the United Nations. That process again is being rolled out, I think, in about ten countries with the plan to take it through to a higher scale. You asked a question specifically about the World Health Organization. I would say that from our perspective at DFID we are extremely positive about the leadership of the World Health Organization at the moment in Margaret Chan, who shares many of our concerns on the architecture, the complexity, the fragmentation and the overlap. She is working very effectively with her counterparts in the World Bank. I think, for the first time in many years, we see WHO and the Bank working very well together to try and progress these agendas, but it is a big challenge and one that is going to be with us for some time.

Q3 Chairman: If neither of you want to come in on that, can I ask about the One-Country plan, then? Do you see this as one way in which you can try and bring the fragmentation together, if I can put it that way?

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Dr Tyson: I think it would help, but there are also other interventions that we can support. I will give you another example. It would not be atypical, in an African country where there is a high prevalence of HIV, for UNICEF to come along to a DFID office or to another donor with a proposal to do more on orphans and vulnerable children. Then UNFPA may come along with a proposal to do more on condom distribution. Then UNAIDS may come along to do more on rights and stigma. The response of many of the country advisers that have found themselves in this position has basically been to send them away and to try and get them to work together, to put together a more coherent and collaborative plan, where each of them will work to their own strength but they will be working to one plan that will be embedded in the country plan.

Q4 Chairman: I am interested in what you are saying about the World Health Organization making some improvements. One of the things I picked up in your note is that, when you are talking about the diverse group of organisations, you say: "This is particularly the case for WHO (WHO is either engaged in, or hosts, multiple partnerships)." I read that not so much as a criticism as that this is where the problem is. Was I reading that right? That was in Paragraph 16 of the evidence.

Dr Tyson: I would say that is a problem. It has happened by default really. Many of these global health initiatives, as I said, were set up because of a perceived failure of the international community adequately to reflect a particular issue. Roll Back Malaria I think was one of the first; it was established in 1999. Because of the scale, I think, we were seeing many deaths of children; we had seen malaria fall off the priority list as AIDS and other health agendas have come up. At the time that these initiatives were set up, there was a desire to see them embedded or hosted by part of the multilateral system. Typically, that was either WHO, which hosts many of them, or UNICEF as the two big health agencies. So GAVI (Global Vaccines Alliance) is closely allied to, and administratively hosted by UNICEF. Most of them are in WHO. The scale of expansion of these partnerships has required a re-think of that. It may be that a partnership was set up to progress an agenda, to raise the profile, to strengthen advocacy, to generate more resources to get to countries to deal with a particular issue. At some point, we have to re-think: is there still a role for the partnership or could it be absorbed back into WHO? The last point is that many of these were set up because of the then perceived nature of WHO, which as an inter-government organisation, was good at dealing with governments but really was not very good at engaging with civil society, academia and other international stakeholders on these issues.

Q5 Chairman: Are the other organisations of a similar view to you? Do you think some of the organisations you are talking about would agree with you that this is a problem and that this is one that needs to be addressed?

Dr Tyson: I think most organisations would see that it needs to be addressed but it sometimes comes into conflict with different models of aid delivery; for example, many of the European donors would favour supporting a national plan through programmatic instruments, pooling resources, providing sector budget support or general budget support. Japan and the US traditionally have been much more focused on very specific projects with tight control over inputs and a focus on delivering outputs in the short term. The classic example is PEPFAR, the huge US investment in AIDS. It is there; it is providing very substantial resources. We try to work with the group to find where we overlap and where we can complement each other's activities. Most donors would recognise the need, including WHO, to re-think the architecture, to look where there are possibilities to either merge some of these single issue partnerships or, in some cases, to reabsorb them into the World Health Organization or another parent body or, in the most extreme cases, perhaps to disband them, but that would probably be some time in the future. So far we have seen one merger. We had one group, the Safe Motherhood Initiative that had been around for 20 years, working on trying to improve health outcomes of mothers in pregnancy. We had a second group called the Healthy Newborn Partnership looking at just the problems of neonates, children in the first month of life. Then we had a very strong Child Survival Initiative supported by UNICEF that was looking at childhood beyond the pregnancy period. We successfully argued that it was ridiculous to have each of these knocking on the door of donors or the door of the Minister of Health or Finance in a developing country and that there was a great deal to be gained from them working collectively together. That has emerged as an international agreement really to work around a continuum of care. You cannot further reduce child mortality unless you deal with newborn mortality, and you cannot effectively deal with newborn mortality unless you have a healthy mother who survives pregnancy. These individual partnerships have all merged into one. So far, that is the only example where we have taken a step to rationalise the architecture.

Q6 Lord Hannay of Chiswick: Could I carry on a bit from there but moving away from architecture to substantive responses to communicable diseases? Have you identified yourselves, the British Government, areas where intergovernmental and international co-operation in this field is lacking and

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where there needs to be such co-operation or more of such co-operation than there is at the moment? As the opposite side to that coin, have you identified areas where not just there is confusion through the multiplicity of instruments but where too much is being done or things are being done which are not very effectively done intergovernmentally?

Dr Tyson: I would argue that there is a case for more international co-operation to make sure that we are all on the same page, that we are supporting a coherent, comprehensive national plan. AIDS again would probably be a good example. We have seen investment in health aid increase from \$6 billion to \$14 billion over the period 2000 to 2005. A great deal of that money has gone into AIDS, TB, malaria and childhood vaccination, but very little money has gone into nutrition, which is associated with 50 per cent of child deaths; there is very little progress in improving the half million women who die in labour every year. The only way that we can get a better balance of those investments and to make sure that the money that we spend builds a health system for the long term is through intergovernmental processes. I would argue very strongly that the International Health Partnership gives us that model that we can build on. That is moving forward. As for the balance, is there too much aid going into some areas? I do not argue that there is too much money going into AIDS. I would say that there is an imbalance with what is going into broader health services and, within the AIDS opus, there is an imbalance between money going into prevention, treatment, care and palliative care at the end of the day, because really only about one-third of those people who need treatment for what is a deadly disease and can turn into a chronic disease are getting treatment.

Q7 Lord Howarth of Newport: I am sure that almost everybody concerned wrings their hands. I imagine a great many people involved in different organisations with different kinds of activity within the international health scene wring their hands about the incoherence, overlap and rather chaotic aspect that it sometimes assumes. I was in Northern Uganda a couple of years ago and saw this very vividly and talked to UN organisations there, voluntary sector organisations, representatives of the Ugandan Government and to DFID; they were all very unhappy about the ineffectuality, the poor value for money and the disappointing effectiveness of all the goodwill and all the effort that goes in. We all know that it is very difficult to corral the big bureaucracies, or indeed the smaller voluntary organisations, because they have their own accountabilities and their own *raison d'être*. It would seem that very energetic and active diplomacy is going to be needed to make an impact on this problem and that targets, timetables or milestones would need to be set. Can

you talk a little more about what determination there is internationally actually to try and make an impact on this problem rather than just note that it is there and set up another committee to try and deal with it?

Dr Tyson: We are making an impact. Take AIDS again; there are two million people on antiretroviral treatment now. That figure was 100,000 not too long ago. The number of women who are getting preventive treatment in pregnancy is increasing. Prevention is a difficult area because what works in one place may not work in another.

Q8 Lord Howarth of Newport: Is it almost despite the system that this good progress is being made? It could have been even better and more coherent across the system.

Dr Tyson: I would say that over the years, and Uganda is a good example, we have seen a switch in our donors' new business to what they saw as a more effective way of doing business. Getting behind a nationally owned plan is critical, trying to put more of the resources through government systems to strengthen them. Today we need a health system that can deliver against AIDS, TB and malaria, the big major problems, but, in ten years' time, heart disease, diabetes, cancer, cardiovascular diseases generally will dwarf the current figures on AIDS. At the moment we have very large amounts of resources for the major communicable diseases. Our challenge is to use them in ways that build a system for the future: adequate numbers of a trained health workforce where they are needed; information systems that can track changes, one way or another, in health services; basic infrastructure and basic outreach. They are as applicable to the three diseases that you are focusing on now as they are to future challenges. Again, returning to Uganda and going back five or six years, Uganda had persuaded donors to support the national plan and had made a shift away from the situation where two-thirds of all external resources had nothing to do with the national plan; they were not funding the priorities that the Government of Uganda had set out. Over five years that turned two-thirds to one-third. Putting money into strengthening the financial systems meant that the Minister of Health could go along to the Minister of Finance at the appropriate time and say, "This is the budget you gave us last year. It has all been used and it has all been accounted for. As a result of this, we have trained 5,000 more health workers. We have renovated 200 health facilities. Our immunisation data have gone up from 60 per cent to 80 per cent. We are making headway in the following areas." Those are the sorts of processes that we want to be supporting in many countries. It has been confused by the rapid expansion in project-tied assistance, I think, which is looking at one aspect of health. It is looking through a TB lens or an AIDS lens or a

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malaria or a nutrition lens without seeing the bigger picture and seeing the need to invest in those systems.

Q9 Lord Howarth of Newport: I think to a certain extent, diplomacy goes with this?

Dr Presern: You were asking whether there was recognition of the chaos. I think there has been fairly clear recognition that the situation could not go on. A number of Member States pushed that WHO had a discussion on Partnerships, which went to the Executive Board in January. That will result in a World Health Assembly paper which is going to look, I think, a lot more at the sorts of criteria that WHO accepts for partnerships at a global level. How this plays out in the country, though, is what Stewart has been alluding to. Quite some years ago a number of countries—France, the US and several others—got together to create a global task team on AIDS because there was a recognition, particularly in the AIDS sphere, that there was again chaos at country level. That played out into one-country teams, the stopping of people banging on different donor doors, a clearer division of labour amongst the UN agencies involved in AIDS, and recognition from us centrally that we should not be funding agencies that were contributing to the chaos; we should reward those that were actually helping the governments do their job better. Finally, perhaps on the Global Fund, which has sometimes been accused of adding to the chaos by putting other layers of co-ordination at country level, there is a very clear recognition and demand, both globally and from country partners, that the structures that were set up around the Global Fund have probably got to cease to exist. The country co-ordinating mechanism should be merged with national AIDS councils, with the Departments of Health and so on. I think there is a clear recognition and some proaction; there could probably be more but it is definitely on everyone's radar at country and global level.

Q10 Lord Geddes: I have three quick questions. The first I suppose is a NONIE question. You dealt almost exclusively with the global situation. Given your representation as witnesses, are each of the three of you entirely confident that there is no fragmentation within the United Kingdom?

Professor Harper: I think to say “entirely confident” is perhaps difficult. We have improved enormously in recent years in terms of engagement at the various levels. I was going to give, in the context of a recent question, examples of good practice. As well as looking at the operational level and what is happening on the ground, and of course that is vital, I have seen change in some areas where there is a clear engagement between the different players at the political level. We have been focused very much on the African situation and some of the other

developing countries. However, the UK plays an important part in other areas, other regions. The European region is broader than the European Union, and the UK plays an important part in the WHO Euro region. For example, just recently there was an inter-ministerial conference on TB which specifically set out to attract Health Ministers and Finance Ministers, so that there could be that dialogue between the different key groups. Nationally I think the dialogue at a political level has really improved a great deal, but that goes through the various levels and across the agencies. It is hard to be absolutely confident that all of the links that are necessary are made because it might imply, apart from anything else, complacency, and we are absolutely not complacent. Politically in the areas that we are considering this afternoon, and a lot of others, there is real engagement across the different agencies.

Q11 Lord Geddes: Going to the other end of the spectrum, if you like, on the global scene, do you think there is ever going to be the possibility where you could get one international organisation to lead globally on health matters? In other words, if I might be over-simplistic, to solve the fragmentation problem? That is half the last question. The second part of it is: is it only by achieving that single entity to sort out the fragmentation that the UK taxpayer can get value for his money?

Professor Harper: Perhaps I could answer first, and then turn to Carole Presern. I think it is reasonable to work towards having a single agency or a smaller number of agencies. From the UK perspective, we would see the World Health Organization as being that agency for a variety of different reasons. It is a challenge, and I think there will be interfaces of one type or another because of the multitude of players that have a legitimate role in this. I think we recognise that in order to make improvements in the health area, whether nationally or internationally, very often the key players are outside the health sector. So it is very important to have those necessary levers and the ability actually to deliver in a broad constituency.

Dr Presern: I think WHO is that agency but we have to recognise that the landscape has changed and, with players like Gates and so on coming along, this has changed much of the way that international aid is financed. Something that has been started is an informal meeting of the eight heads of the health agencies. It is a very embryonic group but it was encouraged by the UK that these people should get together—Gates, UNICEF, WHO and several others—and see whether there could be a very real dialogue and discussion about who should be taking this leadership role. Things have fragmented and it has really become quite out of control. WHO under Margaret Chan, I think, is well poised to step

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forward and accept the challenge. Other people respect her greatly and I think will defer to her leadership.

Professor Harper: If I may add one other comment, if we come on to talk about avian influenza and pandemic influenza situation a little later, I think that is a good example where the majority of countries, if not all countries, that are playing a key role in that area specifically look to the World Health Organization for their leadership. I can say a little more later but, looking at it nationally, one of the reasons for really beginning to develop our ideas on a Global Health Strategy with Department of Health leadership but recognising that this is very much an cross-Whitehall, a cross-Agency strategy, was to try to brigade the interests so that we have a more efficient system. I am happy to expand on that a little later.

Q12 Lord Avebury: Briefly, could I bring together two of the answers that you have given so far? First, on the International Health Partnership, you said that this was the means by which we hope to obtain a more co-ordinated approach through governments at the recipient level. Then you also said that there was an imbalance between prevention and treatment and palliative care. I think that was particularly in relation to HIV/AIDS. Are there not going to be different attitudes to this split within the recipient countries that would make it more difficult to obtain a shift in resources such as you were aiming for? If it is correct to say that this imbalance has existed and you need to move resources away from treatment towards prevention, then the ownership of the process by the recipient governments would mean that you have a persuasion job to do, which may not be equally successful in all the countries. It might be possible for you to illustrate your answer to this by reference to the eight countries in which the International Health Partnership is already working.

Dr Tyson: It is early days for the International Health Partnership but the high level compact that was signed in Downing Street in September committed donors to a direction of behaviour, governments to a direction of behaviour, and civil society also to try and get them, again working to a single plan and working in a coherent way. I will be going to this meeting where the government spends £3.50 per head per year roughly, \$7, and the figure of \$10 public spend would not be atypical for most of the countries we work in in Africa. Very little of that money is provided as flexible, on-budget resources that enables governments to move money in different directions. A great deal of it is provided as tightly-focused project support, which can only be used for specific interventions, not just AIDS interventions but only for treatment or only for prevention or only working in sectors. So it is a terrible juggling act if you are one

of these governments where there are many donors and there are many development banks and whatever in trying to make sure all the pieces of the jigsaw in the national plan are filled. The challenges for donors are to put more money through government systems to give governments that flexibility. The challenges for governments are to embrace the fact that 70 per cent of health services are being delivered by either the private sector or civil society, and many countries do not quite accept that yet. There is still a strong culture of public provision and public delivery rather than perhaps public provision and pluralistic delivery. There were also obligations on the part of civil society to work more collaboratively with government. I have just come back from Nepal. There are somewhere between 20,000 and 30,000 non-government organisations working in Nepal, a country emerging from conflict with very weak institutional capacity to manage them. If not anarchy of delivery of services, it probably is not too far away from that. The International Health Partnership, we should not forget, builds on 15 years of experience in trying to get all partners, donors, civil society and the private sector working behind the national plan. It has not come out of the blue. We do have quite a lot of positive experience to build on. I think in all of those countries the principles have been wholeheartedly taken on by governments for one very clear reason—that they feel that the heads of these agencies, the eight major UN and Global Partnership agencies, and many of the bilaterals and a number of private partners like the Gates Foundation, all signed up to the principles. They really have something to hold in the face of the German Government if they are doing strange things at the country level, or WHO if they are going on a different track. There is great enthusiasm there. At the moment, those high level compacts are now being translated into country level agreements and memoranda of understanding to take country programmes to the next level. We are supporting countries with catalytic funding to help them go down that route. In some cases it might be that the national plan is a little bit divorced from meaningful resources; the plan could be strengthened. Some countries have highlighted the health workforce crisis as an issue that needs to be urgently addressed and they are looking to work with others within that mix of eight countries to look at current best practice: what can Ethiopia learn from Zambia or Mozambique from Kenya.

Q13 Lord Jay of Ewelme: I should declare an interest, first of all, as Chairman of the medical charity Merlin, which operates in many of the countries we have been talking about and indeed receives support from a number of agencies we are talking about. I wanted to ask a slightly more

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detailed question about WHO, if I may, picking up something which I think a number of you have said. I think it must be right that, in so far as there is to be a lead agency, it should be WHO, and I was interested and glad to hear what you were saying about the increasing effectiveness of WHO under Margaret Chan and also the willingness, as I understood it, from the donor community to see that more needed to be done in the direction of greater coherence. What I sometimes hear said is that that is all fine in Geneva but that WHO at regional level is less effective and the rather more political structure of the WHO's regional offices means that there is a bit of a conflict sometimes between Geneva and the regions and this can affect at times the effectiveness of the country offices in the delivery of WHO and other programmes. I just ask for your comments on that and whether you think, if WHO were to have more of a role in pulling the architecture together, it itself will need to reform.

Professor Harper: Perhaps I could start with that question. I will come back again to one particular region, WHO Euro, which is a region that perhaps people do not automatically think of in the context of the diseases that we are talking about this afternoon. But, of course, particularly with some of the more easterly countries, the issues around HIV/AIDS and TB in particular are very similar to the sorts of situations that exist in sub-Saharan Africa and some of the countries that we have been touching on. I have heard the criticism, of course, that WHO has in the past been seen as working as different organisations. I can say that I have seen some evidence of that in times gone by at first hand. I am currently the Executive President of the Regional Committee in WHO Euro, and I would say without a doubt that the situation has transformed under Margaret Chan in the way that she personally relates to the regional offices. I am told through the Regional Director in WHO Euro that she has frequent teleconferences and frequent meetings; she goes to the regional committees. She has brought the organisation together as one organisation in the last 12 months I think in a very encouraging way indeed.

Dr Presern: There has been a lot of internal reform in WHO in terms of recruitment of staff. You will always have the situation, when you have Regional Directors elected, that you have to be extremely careful how you then appoint people. There has been a lot of HR reform and most of the jobs now are openly advertised and selected on merit. I think they have a way to go still but there is definitely willingness there.

Q14 Lord Jay of Ewelme: Could I ask a follow-up on that and then one question picking up something that Professor Harper said? Would you, perhaps from a DFID and a Geneva perspective, recognise the improvement in the regional offices that Professor

Harper has described as happening in Europe? Perhaps Professor Harper could comment on the relationship between WHO Europe and the ECDC, which has been set up in Stockholm, and how they relate to each other?

Professor Harper: The relationship between ECDC and Stockholm and Copenhagen, I think, is settling down. It is fair to say that, when an organisation is new and looking to establish itself, it can take some time for the relative roles and the complementary roles, and particularly working towards some sort of synergy, to develop. There are some very good examples, not least in the area of pandemic influenza, where teams of scientists from ECDC and from the European Commission separately and from WHO Euro have been visiting countries to assess their state of preparedness. That is a very good example of where it can work, but I am bound to say that it will take some time before we realise the full potential of the various organisations.

Q15 Baroness Flather: There is not a straight answer to my question. I am very interested in the smaller organisations which work in that. You have mentioned that Nepal has 20,000 to 30,000 and most countries have lots of small NGOs. Some are, in fact, funded by the governments of the countries and by other countries and so on. I have always felt that they are very jealous of their own little domains, so to speak, and they are very frightened of co-operating with other people because they feel they are going to be submerged and their funding will disappear as a separate organisation. I suppose a number of people who work in the field also feel threatened by that and there is a sort of silly competitiveness about a lot of the organisations. I wanted you to comment on that and see whether there is anything in the future that you think might be able to persuade them to work together.

Dr Tyson: I think that is a fair description of many of the challenges. Many European NGOs in particular have a very strong focus on service delivery, and that may be appropriate in a setting like Nepal where there has been conflict for ten years and services have all but disappeared in many parts of the country. Nepalese, European or American NGOs can deliver very basic services, bring services to people and start to set up the building blocks for the future system. In other countries where government capacity to deliver is much stronger, they do need to re-think their timeframe of getting out of direct service delivery and perhaps to focus more from my perspective, and most of my experience is in Africa, on demand and accountability, advocating for governments to do more on health and to make it a greater priority and holding governments to account for what they do deliver. I have this view that people in Africa have many challenges and many problems and they do not

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ask a great deal of their political leadership; too often that political leadership does not prioritise health. There are many challenges: growth, education, the environment, whatever, and health often comes rather low down that list. I think NGOs also have to look not just at how they engage or impact on the development effort at country level but what the consolidated impact of 20,000 or 30,000 is and how they can work together, how they can be speaking the same language as government and working to support national priorities. I give you a very simple example. A couple of years ago in Malawi, at an annual review of the national health plan, there was a small NGO called the Child Health Lung Project, which was trying to do something about pneumonia in young children but which was essentially establishing a completely vertical structure. It had European staff; it had an office; it bought drugs—not through the government system, it delivered the drugs down to the country level; it trained staff just in improved treatment for kids with pneumonia; and it reported back. It is good work; it could demonstrate in a small pilot project that, if you give kids an effective drug and you train the staff well, you can reduce deaths from pneumonia. But in the grand scheme of things, after three years, when the money ran out and they had gone somewhere else, it left little behind. I think that issue also has to be at the back of any NGO. Think sustainable.

Q16 Baroness Flather: I have known many projects that train workers to teach ordinary people about the effect of HIV and then the money goes and those people who are being trained have nothing and they cannot keep working for nothing. You have done the work and wasted the money. I also wanted to ask about accountability, which you mentioned. That is a big problem in a lot of the African countries. How can these organisations hold governments to account? What do they do to make sure that the money that will go to the government will be used for health?

Dr Tyson: I think money going to the government and being used effectively is not a great problem. In many, if not most, of DFID's African partners we have moved a large part of our resources into budget support. We have confidence that the policy environment is good, the practice is good, and the audits tell the same story. I think NGOs have got to get into a relationship where they are seen as a supportive part of a government and they have to use appropriate channels to lobby government. Nothing is worse than seeing a European or an American NGO haranguing a Ministry of Health in an annual review. That voice needs to come from well-respected national civil groups who are focusing on their particular area of added value. On the Tanzanian review not so long ago there was a very interesting

advocacy group of Tanzanians who were really just focused on accountability. They produced the audit report from the year before and they asked the government what it had done about these anomalies and what action it had taken. Undoubtedly, next year the pressure will rise and rise and governments will respond accordingly, but it is a difficult balance.

Q17 Lord Geddes: This follows that to an extent and I will be brief. The Health Protection Agency in their written evidence to us was more than somewhat damning about the UK influence on WHO relative to the amount of money put in by the UK. It said, and I quote: "The UK has relatively little influence on the direction of WHO activity compared to other countries who frequently contribute less but take an active role in influencing global policy." That is a Government agency. Can you give your views on that?

Professor Harper: Yes. It surprises me to hear that. I think that at least part of the comment, as I understand it, related specifically to Phase 1, 2 and 3 clinical trials. If it is a broader comment than that, it does surprise me, as I say. I think the UK has reasonable influence, some might say even substantial influence, within the WHO environment; not least, we are currently members of the Executive Board, which is the governing body for the World Health Assembly. At an operational level we also have very strong links scientifically; we have the operational links but we also work at a strategic level. For example, at the recent Executive Board meeting just a couple of weeks ago, the UK presented a draft resolution on the health impact of climate change. This is something that we had been considering for some time. We have discussed it internationally with a number of countries and it received, I think, if not unprecedented support, very substantial support from of the order of 40 countries. This is, I hope, an example of a specific area where the UK feels strongly we should be playing a global part in tackling that particular global challenge. This is now an area that will form, I would expect, a big part of WHO's future work: the health impacts of climate change.

Dr Presern: I think there are several examples where the UK has exerted influence, but I think the power of influence is not always to do it yourself or to be seen to be doing it yourself but to work with others, as we often do in the European Union. When we were co-ordinating positions in the World Health Assembly or with other Member States, particularly on UN reform for example, we felt it was more effective to work through Asian and African countries that have more to benefit, and the UK taxpayer obviously, through efficiencies gained. We can point to several examples on: sexual reproductive health, specific thematic issues and the medium-term strategic plan, which sets the direction for the

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organisation. The UK had a key role, I think, in trying to shape the objectives, particularly trying to streamline some of them on health systems. I could point to several other examples.

Q18 Lord Geddes: In a nutshell, you would refute that HPA evidence, is that right?

Dr Tyson: It would be interesting to find out what was behind it. I also think that we do have huge strategic engagement with WHO but we are working at a fairly high level to try and provide our resources in a way that enables WHO to deliver more with its resources. Remember that WHO is a little bit of a hostage to fortune in the same way that we could do a similar diagram of the bilateral agreements with WHO. The last time I looked they had 4,600 bilateral agreements with donors. A great deal of the money that comes in to WHO is just for this issue and you cannot use it for anything else; you cannot use it to strengthen your staffing in neglected areas; you cannot move it across to another area. We are at the moment coming to the end point of a joint strategy with WHO between the Foreign Office, DFID and the Department of Health. Our intent, and WHO's intent, is that more UK resources are provided as flexible, long-term funding. We will put in place a number of fairly robust indicators of progress to take us in that direction.

Q19 Chairman: When you became aware of this statement by the Health Protection Agency, did you think: we had better have a word with them about this?

Professor Harper: To the best of my knowledge, the comment was made in relation to operational issues and particularly in relation to TB and clinical trials, but I will follow that up and perhaps we could clarify the situation before the HPA. The HPA will be able to clarify the situation for the committee.

Q20 Chairman: I think it does need clarifying, does it not. If they are saying that and it was in the evidence to us, it is a rather different picture in a sense than you are presenting today.

Professor Harper: We will certainly have a discussion with our colleagues at the Health Protection Agency and ask them to clarify the situation for the committee.

Q21 Baroness Whitaker: You have told us some very positive things about what the Government is doing to promote the harmonisation of health programmes with all the countries and also quite a lot about getting other governments, IGOs and NGOs to share our view of the need for some rebalancing between health systems and specific projects. This is obviously of crucial importance to our inquiry, so I think we should check: have you told us all that you are doing in this area? And what more do you think could and

should be done on rebalancing and creating a general international consensus?

Dr Tyson: I think it is a critical issue whose time has come, this focus on building health systems for the longer term or focusing on short-term deliverables against specific diseases. If we look at the major bilateral programme on AIDS, the US President's Emergency Plan for AIDS Relief (PEPFAR), PEPFAR has spent \$19 billion in its first five years. The indications we have from discussions with the Congressional Committee are that, whichever administration gets in in the US election, PEPFAR's budget is anticipated to be between \$30 billion and \$50 billion over the next five years. This brings massive responsibilities to use that money in ways that build the long-term health system. For example, in Zambia PEPFAR works through contracting NGOs, gives them short-term targets and very rounded targets. They have to get so many people on treatment by the end of Year Two, Year Three, Year Four. How do they do it? They put an advert in the paper in Lusaka and they hire 400 health workers. Where do they take them from? They move them from one part of the health system, where they are delivering children and providing general health services looking after kids, to work just on AIDS. This is a no-win/situation; it is robbing Peter to pay Paul. PEPFAR and many other big agencies that work in this targeted approach have recognised that they cannot go any further unless they deal with many of the systematic barriers, particularly getting adequate numbers of trained health workers where they are needed at the right time, and we are working very closely with them on that. There is a lot of talk about whether we need vertical approaches or whether we need horizontal approaches. We need both. We need to be building the long-term system to deliver, as I said, against the future challenges as well as the current ones, and we need the benefits of short-term targeted investment. I think it gets confusing. For example, I have seen people talk about the diagonal, and the Japanese are currently talking about weaving the vertical and the horizontal. The Japanese Minister of Health, I thought, had the best slogan, which was, "Campaign vertically. (Get the money where the money is) and spend it horizontally". Spend it in ways that both deliver AIDS outputs—that is what the focus of the resources is for—but also deliver for the longer term. Finally, the Japanese also have taken up this issue and it will be the core of the preparatory meetings in a couple of weeks' time in Japan for the G8 meeting later in the year. They, more than any, have been very influential in channelling much more resources into AIDS, TB and malaria and were very influential in setting up what became the Global Fund, but they have recognised the need to balance and the need to do much more on MDGs 4 and 5, child health and

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maternal health, where there has been limited, if any, progress to date.

Q22 Baroness Whitaker: That will be interesting to watch. What about rebalancing beyond health? I think you mentioned nutrition. There is also piped water; there is also education in washing your hands after defecation, which I think UNICEF did—and I should declare an interest as a Trustee of UNICEF UK. Those are things which are not exactly the province of health professionals or of health ministries in funding.

Dr Tyson: I think increasingly they are. The health strategy that DFID launched six or nine months ago was one of the streams of work, working with education, with social protection, with water and sanitation, these areas that do impact on health. But we cannot pretend that all the health problems are going to be realised through actions in the health services area. Again, on the Japanese agenda, that is one of the critical issues, to look at the broader contribution beyond the health sector.

Q23 Baroness Whitaker: I recognise that DFID does that. In fact, I have seen it do it in action. But what about the international organisations? Would you say they are equally seized of ancillary-to-health issues?

Dr Tyson: I think groups like UNICEF are, yes. WHO, being a largely technical and normative agency, is perhaps less so, but then their programmes at the country level are often more modest than those of UNICEF. UNICEF has a very substantial investment in all of these areas.

Q24 Baroness Whitaker: In your document if I can call it your document, Professor Harper, “Health is Global”, the Chief Medical Adviser talks about a Government-wide Steering Group in the first part of last year, which will lead the process. I wondered what the impact was so far of the Government-wide Steering Group.

Professor Harper: There is a Ministerial Group that is chaired by the Minister of State for Public Health, Dawn Primarolo. She chairs a Top-Level Group of Ministers from various Departments, including of course DFID, the FCO, Treasury, Ministry of Defence, Defra, what is now DBERR and others—the Devolved Administrations, for example. That is the Group that has oversight of the development of the Global Health Strategy itself. There is a shadow group of officials who are working to pull together the strategy, which is due shortly to go to Ministers for their consideration.

Q25 Baroness Whitaker: So you are not at liberty to say what the results are so far?

Professor Harper: Not of the strategy at the moment.

Q26 Baroness Whitaker: When is this likely to be available?

Professor Harper: In the next few months.

Q27 Lord Hannay of Chiswick: You say that accountability is not a problem if you are dealing with your preferred programme—rather—than—project approach. But surely it must be a problem in quite a number of countries where there is serious maladministration and corruption, although there may not be in the one example you gave of Tanzania. To what extent do you think that, in fact, these issues of corruption and maladministration are going to be a seriously inhibiting factor against your desire to see more and more done through sustainable programmes and less through projects. And, secondly, to what extent is, say, the American approach, where I would imagine this is very clearly identifiable, of a preference for projects over programmes driven by domestic political and social preferences, their determination not to help family planning programmes, et cetera? And is that remediable?

Dr Tyson: With regard to the first one, we would use the aid instrument applicable to the country situation. So in Nigeria or the Democratic Republic of Congo, or in a country that is emerging from conflict where we have grave concerns about governance and accountability, we would use project approaches. We would work through NGOs, we would work through the UN, and that is very much how we do work in these settings. As things developed, we would try to put in place a mixture of approaches. Nepal might be an example where it is emerging from a long period of conflict. We pool the resources with other donors to support key elements of the national plan but we also have a substantial programme working on efforts to reduce maternal mortality in a big part of the country. If things deteriorated, we would go in and out of those instruments as we have done in Ethiopia. On the second one, the changes will come with the change of Administration. Do not forget that the US was (and probably still is) the largest supporter of contraceptives and family planning programmes in the nineties. It has changed fairly radically with this Administration but, if the Democrats get in, we have heard from colleagues in the USA that they would expect investment in family planning broadly to double or even treble.

Q28 Lord Howarth of Newport: Given the recognition that Dr Tyson has described of the imperative of building healthcare systems in developing countries, can we have an assurance from Professor Harper that our own NHS has now

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foresworn recruiting qualified medical staff from those countries?

Professor Harper: As you will probably be aware, we have a code of practice for an ethical approach to recruitment, one of the first countries in the world to do that. It is something that our ministers feel very strongly about.

Q29 Baroness Flather: I was going to bring up population and I was very glad that Lord Hannay did bring it up. How is it going with DFID itself, because the Millennium Development Goals will not be met without focusing on population? That is one thing. The second thing I want is how does Gates spend his money? You have told us how PEPFAR works. It is becoming huge now. It really is almost like a government now.

Dr Tyson: Yes, I think Gates dwarfs many of the UN programmes. We had a list of what we were putting into other agencies, but I was looking today, in anticipation of this, to see what Gates is spending, and it is probably around \$3 billion a year. We work very well with Gates. I suppose in their first phase, their first five or so years, they have been looking at the magic bullets—what needs to be researched, where are the quick wins. But I think, as their resources have increased and as they have covered many of the investment needs and some of the focal areas, they have recognised that they have to address this issue of health systems. We had a meeting with them a week or so ago. They are doing two pieces of work at the moment. One is developing a maternal/child health strategy, and they got together with experts from the London School of Hygiene and the Institute of Child Health to look at what they are doing and where there are opportunities to support it. Again, at a meeting of IPPF last week the Gates Adviser who was there was saying that they are developing a reproductive health strategy, and that will be on broad-based family planning. It will exclude abortion, but I think all the other areas will be appropriate. It will be interesting to see the nature of these and how they have made that switch from low-hanging fruit, as it were, to getting involved in some of the difficult areas.

Q30 Baroness Flather: The low-hanging fruit are hydrolysides(?) which are not going to come, are they?

Dr Tyson: Something will come in the next two to three years. It will not be perfect.

Q31 Baroness Flather: It has been going for a while.

Dr Tyson: The AIDS vaccine as well, we think, will be there for another 10 or 20 years.

Q32 Baroness Flather: The AIDS vaccine is further away.

Dr Tyson: Well, we could have one tomorrow. That is the challenge.

Q33 Lord Jay of Ewelme: Could I go back to one question which I did ask but which did not in the end get answered earlier on, and that is whether you think that the regional offices for WHO, other than in Europe, are going to make the same positive efforts as the Europeans?

Dr Tyson: The big worry is, say, AFRO. I think that Gro Harlem Brundtland, when she was the Director General of WHO, started to make positive outreaches to the regional directors and tried to bring them more into the fold, and I think Margaret Chan is taking that up. We have always seen it. If you asked any DFID adviser in Africa, they would say the weakest link of WHO is the regional office, but I think there are signs that they are talking of decentralising their staff to put them in country offices to support governments in developing their national plans. There is also, I think, strong pressure from the African Union on WHO to do more, and they have developed a very sound and what I would say is a very sensible health strategy for Africa that WHO/AFRO has clearly contributed to. I could answer this question better in about a week because the meeting in Ethiopia I am going to is a meeting of all the health advisers in Africa and AFRO will be a big issue. So, if it is acceptable, I will say no more now.

Q34 Lord Jay of Ewelme: It would be very helpful to have a note after the meeting

Dr Tyson: I will send a short note on what their collective view is.

Q35 Chairman: That would be very helpful. Does Dr Presern want to come in on this?

Dr Presern: We are members of PaRRO and RIPRO. I think there have been improvements in those areas. I suppose the area we know least is EMRO, the Eastern Mediterranean, because if we are not members of the regional committee we can only go as observers, so again I would not be able to comment on improvements in EMRO. I do not know if Professor Harper can.

Professor Harper: No, I cannot. In a sense to reiterate a little of what I said earlier, the regional director of Europe does meet with his regional director colleagues from the other regions and, at least as far as hearsay is concerned, he tells me that the relationship between the regional offices more broadly and the centre, the headquarters in Geneva, has improved quite substantially over the last 12 months.

Dr Tyson: There is a unique situation at WHO. WHO is the body that governments trust. They see that it is their organisation, it is the first place they will go to

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for a source of technical advice and they are in a very privileged position, and so I think it is up to us really to find effective ways to support them. That does not mean pouring money into Brazzaville or elsewhere but finding ways to work more effectively and strengthening the reforming part of the organisations as best we can.

Q36 Lord Avebury: Can I ask you about co-ordination of activities on TB and HIV? I am sure you have seen RESULTS UK's criticism of our efforts, which is based on research they carried out in what they call 18 high-burden countries where DFID has a bilateral presence. They say that only two country offices reported that they were providing any direct support for TB and HIV collaborative activities, and five others that they were indirectly supporting those activities through acts of assistance to national TB and/or HIV programmes. Why have we not gone further down this line? And have DFID got plans for remedying this situation?

Dr Tyson: I think I would probably accept the criticism in the same way that I would accept the criticism that we have not been as proactive as we could have been in making sure that investments in AIDS are benefiting wider reproductive health. Many advocates would say that as we have seen AIDS resources increase, we have seen a corresponding drop in investment in broader family planning, abortion, whatever—the broader opus of reproductive health. I was looking today at a response to a Parliamentary Question or some briefing that was done for a Minister on this, and I did not find the answer very credible really, and I think we do need to go back and look again. I would say that part of it is that in many countries, such as Tanzania, Uganda, Malawi, we are providing substantial resources into the budget or health budget of the country to enable the government to deliver on its priorities as reflected in the national plan. In essence we are putting money into the government's systems so how governments spend that is of great interest to us, but we cannot then say, "We want you to carve out ten per cent of it to strengthen your work on HIV/TB". But I think the comments and results are completely rational. This is a focus of the work of one of the research consortia that we fund as well, looking at models where we can work together and learn from emerging good practice.

Q37 Lord Avebury: I think Tanzania and Uganda are two of the countries where RESULTS UK gave really good marks, but that does not alter the fact that for the majority of these 18 high profile countries

we did not have adequate programmes for collaborative efforts with TB/HIV, and it would be good to see some sign of that. Can you tell us of any further plans that DFID has for rectifying the balance?

Dr Tyson: Perhaps I could submit on that again after the meeting in Africa. It should not be too difficult. There are so many areas of overlap, not just in the people who are coming with TB or HIV but in the approaches that are needed to deal with chronic care, to provide treatment, often through or supported by community networks, making sure that patients comply with medicine, decent information systems. I think, if I were an adviser working in a country again, I would turn away people who are coming with single-issue projects and say, "Go and talk to your counterparts in TB or in AIDS and come back with a consolidated approach". I suspect that Malawi will tell us a very strong story but I could not get any data before leaving the office tonight.

Q38 Chairman: Before I move on to the Medicines Transparency Alliance can you clarify for me this problem with avian influenza viruses and the problem with Indonesia in sharing information about that? I am not sure I understand what is happening there.

Professor Harper: The Government in Indonesia some while ago now, the best part of 12 months, took a decision for a variety of reasons to stop sharing the virus that was circulating and causing human cases and deaths in Indonesia. The significance of that for the global community is that very early access to the virus itself is essential in terms of determining whether the virus is changing genetically where it could become closer to or even change into a virus that is readily transmissible from human to human. So there is a global security issue. But also, of course, for vaccine manufacture, if that were to be necessary, the earlier the access to the virus itself the sooner the process can be conducted to end up with a vaccine. So the manufacturers are very keen, through the collaborating centres and the Global Influenza Surveillance Network, to access that virus. It is a very complex area that has been discussed a great deal internationally with the Government of Indonesia and many countries, most recently at the Executive Board, a couple of weeks ago, of the World Health Assembly, but also in November at an intergovernmental meeting. The essence of it seems to be the lack of transparency that Indonesia feels exists in terms of where the virus goes and what is going to be done with it, whether it is going to be used for research or for the development of medical counter-measures such as vaccines. In a sense they are prepared to hold onto this as a bargaining chip.

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That is the view from the rest of the global community.

Q39 Chairman: It is not predominantly an embarrassment that that is a problem there, as it was with China and SARS originally?

Professor Harper: It is very important in the context of the International Health Regulations because, as you will be aware, the International Health Regulations came into force in June of last year and this is the first test case, if you like, for an incident of public health significance between different countries. So, for global surveillance, this is a test of the International Health Regulations and that is a big concern to the global community because we worked long and hard to develop the International Health Regulations. This is one of the examples where we would like to see them fully in effect.

The Committee suspended from 5.30 pm to 5.43 pm for a division in the House

Q40 Lord Avebury: My next question follows quite neatly on from the previous one and is about the Medicines Transparency Alliance, which you referred to in answer to a previous question and which sounds like a very important initiative. I am wondering if you could tell us a little bit more about what is planned and how it is going to help resolve the problem.

Dr Tyson: I cannot really. I would say it is work under development and it is building on the perceived success of the Extractive Industries Transparency Initiative. It has identified a number of separate entries and it will be trying to build again on work that, for example, the Global Fund is doing, which is setting out clear data on pricing. The transparency side in the fund of highlighting how much countries are paying for the same product is the starting point, and it might be that one country is paying seven times the price for antiretrovirals than another one and that is the first stage of trying to get a more rational approach. I was asking those who work on the initiative what the incentives will be for countries to engage in this process and for international pharmaceutical companies to engage in it, and it seems that there is a lot of enthusiasm on the part of the big international pharmaceutical companies but how that translates down to their local affiliates in countries is another issue.

Lord Avebury: You would think that all the countries would be keen on it because they would see it as a means of bargaining down the price. But I cannot see what is in it for pharmaceuticals, because if this comparison is going to be done on that sort of basis then surely everybody is going to demand that those prices are available?

Q41 Chairman: Has anybody got a view on that? This seems to me to be an important area but it is a fairly new and emerging area, is that right, in terms of getting agreement on it?

Dr Tyson: It is an emerging area.

Q42 Chairman: There must be a struggle going on between money for research, which will be the companies' argument, and the countries' pricing mechanisms or whatever?

Dr Tyson: It is an emerging area and it is one where the preparatory work is being done. Another initiative which has some overlap is efforts to try and establish a global subsidy for artemether combination treatment—you know, the new drugs for malaria—that unfortunately cost about \$10 or \$12 for a course rather than ten cents for chloroquine. There are similar efforts there to deal with many of the issues around transparency of pricing, making sure that there is competition, that we do not create a monopoly, putting in place clear and effective systems to monitor prices and price changes. It is an area where there is enthusiasm but I think we recognise that it is very difficult when dealing with the pharmaceutical industry to take at face value what they say is their cost price.

Q43 Chairman: Their argument is about research, is it not?

Dr Tyson: Their argument is about research and that is one side of it. There are also other arguments in countries where they may not want transparency in the prices that they are paying for drugs, frankly because of corruption, and historically we have seen corruption on both sides. It is an issue that we are going to try and drive forward in these first seven countries which have indicated enthusiasm for going down this route in the same way that with the International Health Partnership there are eight countries there which have taken to this and want to make it work, and it will be a learning experience for us all.

Q44 Lord Hannay of Chiswick: We have just begun to talk a little bit about research and we have talked up to now about programmes and budgets and so on. To what extent is there international co-operation or discussion or dialogue about where the main research effort is going? I can see that this is not terribly easy when you are talking about big pharmaceutical companies, who indeed may get into antitrust problems if they did. But to what extent is there a back-up effort so that the huge resources that are going into research from people like Wellcome and others are being directed in a consistent way? Secondly, I saw in the papers a suggestion that, in the

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event of a pandemic, there could be consideration given to compulsory licensing of drugs and vaccines. That sounds a very exciting idea indeed but one which, I imagine, bristles with innumerable legal problems. Could you just explain a little bit how you could overcome problems both at the national level and more widely? What would be the legal powers? Who would have legal powers to make compulsory licensing of drugs and vaccines in the event of a pandemic?

Dr Presern: The TRIPS flexibilities allow for this compulsory licensing in the case of a public health emergency. As for how it actually operates, I think it has barely been used by any countries. Thailand has done it and possibly Brazil has threatened to do so. From our side it seems a sort of last resort option—and, I think, by most countries—because they also recognise that you have to be able to give some incentives to stimulate research and development. It has certainly been used in AIDS programmes around the world when antiretroviral drugs prices were very high, and it did help in some cases to bring down prices.

Q45 Lord Hannay of Chiswick: So you are talking about it being done by the individual nation state under its own legislation within its own jurisdiction?

Dr Presern: Yes, but it has international cover.

Q46 Lord Hannay of Chiswick: But presumably you are talking about a global pandemic. That would be completely insufficient. That would not actually address the problem at all if Thailand went for compulsory and nobody else did. It would not help very much, would it?

Professor Harper: If I could add to that, it is not entirely clear to me how it is relevant at the moment to the pandemic influenza situation, not least because, as you indicate, there is limited global capacity. So the approach at the moment is to encourage the World Health Organisation to play its lead role in this. You will be aware that for the likes of Tamiflu, one of the key anti-virals, we would hope, in a pandemic, WHO have established a stockpile for use in those countries that do not have their own materials. When it comes to a vaccine, we touched earlier on the issue around Indonesia and virus sharing and, of course, the manufacturers need to have rapid access to the virus. That is where a lot of the international energy is focused at the moment. I think we are some way from a situation where I could see compulsory licensing playing a role for the sort of reason you allude to.

Q47 Lord Hannay of Chiswick: Could I have an answer on the other question about co-ordination of research—to what extent there is intergovernmental effort to ensure that the main thrust of research goes

in the directions that the international community thinks are the most necessary?

Professor Harper: There is a variety of different groups that are active, not least within the World Health Organisation itself. For example, the Department of Health's Director General for Research and Development is playing one of the key roles in an area of R&D for the World Health Organisation, but it is hard to generalise across the breadth of research and development in some of the areas even that we have been talking about today. There are some specific areas of good practice. I cannot really comment on a generalised statement for co-ordination and collaboration. There are lots of mechanisms through learned societies, through other government agencies, through the research councils in the context of the UK, and they are very well linked internationally, but I am not really in a strong position to comment on the breadth of co-ordination.

Dr Presern: There were efforts in WHO to get more of a research strategy in place and there are organisations like the Global Research Forum which tries to highlight that 90 per cent of the world's research spending is spent on ten per cent of the world's diseases and is trying to get some international agreement on redressing the balance.

Dr Tyson: I think DFID's approach has been to support ongoing connections with a range of partners. Much of the research effort into new products has been driven by the Gates Foundation in trying to get the public and private sectors to work together to develop new generations of health commodities, whether it is drugs, vaccines, an AIDS vaccine through IAVI, Medicines for Malaria, and TB drugs through Aeras, and we will continue to do that as the DFID research budget is about to double. Our strength is not generally in basic science research. There are others out there with far greater budgets and far greater capacity, but where we feel we do have an advantage and a model that has been built up over many years is in supporting operational research, getting products into health systems and delivered to the population. We fund ten or 11 research consortia, bringing together the best of northern institutions with southern counterparts, often even working across a number of countries, and their focus is on the major health challenges of the day. We have such consortia working on AIDS/TB/malaria but also on mental health. I think in the next round of proposals we will probably have cause to establish consortia on nutrition and non-communicable diseases. That is the sort of role split. We also fund pieces of more basic research with the MRC and others such as Wellcome. We are working to our particular strengths. In developing one drug we could spend the entire DFID budget probably in a year.

Chairman: Do not do that!

Q48 Lord Jay of Ewelme: My question is related to the access to and distribution of drugs. It is very striking, travelling even in the most backward parts of Africa, how much more effective the distribution systems are for soft drinks and basic commodities than they are for even the most basic drugs and medicines. I just wondered if you thought there were lessons to be learned from, or indeed help to be given by, the private sector in improving the distribution of medicines to rural areas.

Dr Tyson: I do, very much, and everywhere where you can buy Coke, if you look behind the Coke you will probably find chloroquine and aspirin or paracetamol. It gets there. The Prime Minister is trying to get a revitalised effort around the Millennium Goals with seven years to 2015 and there is a process of reaching out to the private sector to get them engaged in development efforts. It is not just around delivery mechanisms, if you can get Pepsi or Coke on board with their logistic systems, but we have seen a major effort in News Corporation to get engaged in scaling up the effort on insecticide-treated bed nets, so there is a big effort to reaching out with the private sector and I am sure there are many opportunities in the future.

Chairman: Finally, I want to turn to the International Health Regulations.

Q49 Baroness Whitaker: What difference are they going to make, would you say?

Professor Harper: That is a very good question. As I said earlier in the context, of the Indonesian virus sharing issue, the International Health Regs came into effect fully in June of last year. These regulations have taken a great deal of time and energy to develop and they replace the old International Health Regulations which went back, as far as the sixties. They were a very passive set of regulations and they covered a very limited number of diseases, four of them to be specific—cholera, plague, yellow fever and smallpox. The new regulations cover all public health hazards in the sense of infectious diseases, toxicological hazards and radiation hazards, and they are far more active. They put the responsibility on a country that becomes aware of a public health emergency of international concern to report that to the World Health Organisation. If there is a weakness at the moment—and it is very early days, we are only six or seven months into the implementation—it is that there is no provision for enforcement. The very example that we have been touching on this afternoon around virus sharing by Indonesia might be a very significant one. There are a number of people, colleagues of mine in other countries, who are concerned about that issue particularly from that perspective: there is no provision for enforcement.

Whether that proves to be a weakness or not we do not know yet.

Q50 Baroness Whitaker: As I understand it, it is an opt-out joining system, so presumably the United Nations members have not opted out.

Professor Harper: That is right.

Q51 Baroness Whitaker: I think Article 59(3) says that every member's administrative arrangements were to be fully adjusted by June of last year unless they made a declaration, in which case they have until June this year. I do not know if it is known how many member states have made such a declaration.

Professor Harper: I do not know, is the answer.

Q52 Baroness Whitaker: How many members are capable of implementing them? What about their surveillance capacity? What about harmonisation of disease reporting and things like that? What is your assessment of how well they can comply, let alone whether they want to or not?

Professor Harper: It is very variable. I think it is linked inextricably with the sort of discussion we have had this afternoon on health systems in the broader sense. So many of the countries most affected, for example, by avian influenza, are those we are looking to to have improved surveillance systems in place, so that there is the prospect at least of picking up human cases and even human-to-human transmission in that specific disease area. That is a weakness. I do not know numerically how many countries would have difficulty in fully implementing the International Health Regulations but it is clearly down to the global community, not least because, as we say in our Global health Strategy, global security is one of the key drivers. It is in the interests of the UK, of course, to do whatever it can to help health systems and surveillance and other features of public health systems in those countries that do not currently have them or where they are not of a standard that we might like to see for the likes of pandemic influenza. I cannot say what the number might be. Countries are working hard to do this, and in fact looked at early implementation of the International Health Regulations specifically in the context of pandemic influenza.

Q53 Baroness Whitaker: So is the UK gearing up its support for countries' health monitoring systems in order to help them comply?

Professor Harper: We have been trying to play a part for years in trying to make more robust the systems that exist. We work, as we were saying earlier, at an operational level with expert advice and with our scientists and public health experts playing a role either through WHO or bilaterally with other countries to try and help them, and it is very much

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part of the development agenda with pandemic influenza and avian influenza. There has been a very large international drive to increase the amount of resources in terms of pledges from a whole variety of countries over the last two to three years to try to get money into those countries that really need it to improve facilities and infrastructure.

Dr Tyson: The money going into partnerships like Roll Back Malaria, Stop TB, UNAIDS, will all contribute to that sort of work. In addition, we fund the Health Metrics Network, which is a global initiative set up to try and revitalise and strengthen the broad health information system, not disease specific but including vital registration and strengthening census systems, looking across the board.

Professor Harper: I should just clarify that that is not driven by the International Health Regulations alone. However, it would help in terms of the implementation of the International Health Regulations.

Q54 Lord Hannay of Chiswick: I noticed somewhere in the papers a suggestion that it would be highly desirable for the WHO to hold a global exercise to test people's readiness to deal with a flu pandemic. Could you say something about where that is getting to and would that in itself be one means of showing up whether people were applying the regulations or not? Would it be another instrument to bring them up against the need to strengthen their implementation of that?

Professor Harper: I think it might well be. The World Health Organisation are looking at that very actively at the moment and have been for some time. As you will be aware, we have had exercises nationally. Last year we had a very large exercise, Winter Willow, which included something like 5,000 people, players right from front-line operational workers through to Ministers in the COBRA system. It is the way to test plans and it is the way to test preparedness. It is absolutely essential. It is no good having the plan alone without knowing that it will work. They are designed to demonstrate where the gaps are. A successful exercise is one that comes out with the lessons learned. I do not know exactly where the World Health Organisation are but I understand that the European Commission and the World Health Organisation are close to advertising if they have not already done so, for organisations such as the Health Protection Agency in this country to run an exercise on their behalf.

Q55 Chairman: Is there anything that any of the three of you would like to say to us about the adequacy of intergovernmental organisations or our interaction with them and about either these four diseases or any others? Or have we covered all the areas that in your view needed to be covered?

Professor Harper: I think you have covered the majority of areas. If there is anything else that we think might be material to your investigation, then of course, as we have already identified this afternoon a small number of items, we will try and submit that evidence to you.

Chairman: Very well. Thank you very much for your time.

MONDAY 18 FEBRUARY 2008

Present	Avebury, L Desai, L Eccles of Moulton, B Howarth of Newport, L	Jay of Ewelme, L Soley, L (Chairman) Whitaker, B
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Letter from Liverpool School of Tropical Medicine

Thank you for the opportunity to provide a response. This response is sent on behalf of the Liverpool School of Tropical Medicine. We provide brief responses to many of the questions below. We would also like this opportunity to factually correct one of the statements in your introduction in Paragraph 6. There is no evidence that Anopheles mosquitoes are spreading—the potential link between climate change and increased malaria transmission is that the increased temperature will allow the parasites to develop at a more optimum rate for transmission within the mosquitoes. The Anopheles mosquitoes already cover most of the world and probably did so prior to human habitation.

Responses below are brief due to time constraints but can be expanded in the verbal submission we have been invited to make.

1. *A recent report on Communicable Diseases by the UK Department of Health stated that “post-war optimism that their conquest was near has proved dramatically unfounded”. What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis?*

1. A number of infectious diseases are clearly increasing. TB specifically is increasing again in many countries. HIV, Malaria and TB all remain major problems in the heartlands of their transmission in the tropics. Other diseases specifically those spread by highly mobile bird or mosquito vectors are by their very nature difficult to contain and always have been. We do not however believe that this should be viewed as a crisis.

2. *What reliable data exist regarding the numbers of people infected globally with the four diseases¹ on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?*

2. Malaria—NOBODY accurately knows the numbers of people infected or actually dying of this disease. There have been recent re-estimates of transmission intensity which suggests levels are much higher than previously thought. TB and HIV global estimates are probably more realistic. Poverty is the route issue for much of the world’s malaria transmission, both TB and malaria infection rates have increased due to HIV. HIV has also changed the demographic patterns of malaria infection.

3. *What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? And what improvements might be made?*

3. Surveillance is very poor for many viral diseases where early warning of outbreaks is the key to successful control. Better diagnostics, improved communications and sentinel site monitoring could all be improved.

4. *Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years?*

4. Large scale programmes should give us a much better handle on this over the next few years.

¹ HIV/AIDS, Tuberculosis, Malaria and Avian Influenza.

5. *What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?*

5. Blockages to progress include; poor co-ordination of fragmented competing initiatives in many areas, lack of human capacity in many countries where transmission is endemic or likely to originate, poor use of available technology to accurately collect, assess and disseminate data. Leadership in Global health is a tricky issue at present. The mandate for this should reside with the World Health Organisation but this organisation has had obvious major failings for many years. Organisations such as the Bill and Melinda Gates Foundation are increasingly driving policy and practise through the force of funding without necessarily having an internationally agreed mandate to do so.

6. *What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?*

6. The Liverpool School of Tropical Medicine has major programmes in malaria from genomics through drug discovery, better treatment, improved policy and practise to technical assistance at country level. For HIV and TB we are active mainly in the policy and practise and better clinical treatment arenas although currently moving into the TB drug area. We do not deal with Avian Flu, other than through helping internationally to pull together the evidence on best practise to guide policy making. We have major programmes in the Neglected Tropical Infectious Diseases outside this and feel strongly that these should not be ignored. Indeed integrated control activities that target multiple diseases are likely to be as if not more successful than disease specific vertical programmes.

7. *What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient “joined-up” thinking in approaching the problem?*

7. Poverty, urbanisation, travel, agricultural practices in that order of priority.

8. *Cases of Tuberculosis fell progressively in the UK until the mid-1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of Tuberculosis infections in Britain? And how could intergovernmental action help to reverse the trend?*

8. HIV, TB multi-drug resistance and migration.

9. *Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions—eg HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?*

9. The long term treatment regimen, the time lag between presentation and diagnosis, the link with HIV and drug resistance are all major and growing issues in TB treatment.

10. *To what extent do you believe that the 2004 Stockholm Convention limiting the use of DDT against Malaria-carrying mosquitoes has been a factor of increases in the spread of the disease? Has any risk analysis been carried out comparing the relative dangers to human health posed by DDT and Malaria?*

10. DDT is not an issue as stated as its use is allowed for malaria control and its use is actually increasing. The loss of effective public health insecticides per se is an issue against the trend for increasing indoor residual spraying in many countries. All risk analysis to date show malaria a far greater human risk factor than DDT.

11. *What intergovernmental action is planned or in hand for early detection of the transmission of Avian Flu from birds to humans and of human-to-human transmission in potential source countries? Is this proving sufficiently effective to prevent an Influenza pandemic? What more could be done?*

11. No response.

12. *To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?*

12. Resistance is a factor with malaria, TB and will increasingly become a factor with HIV.

13. *In a number of countries, including the UK, there is a problem with hospital-acquired infections. What intergovernmental sharing of knowledge is taking place to help bring this problem under control?*

13. There will undoubtedly be further animal to human transmission, it is however difficult to predict when this will occur and the severity of the resultant disease.

24 January 2008

Memorandum by the London School of Hygiene & Tropical Medicine (LSHTM)

Comments concerning malaria are addressed in the memorandum from the Malaria Centre, LSHTM

1. *A recent report on Communicable Diseases by the UK Department of Health stated that “post-war optimism that their conquest was near has proved dramatically unfounded”. What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis?*

1. The assessment of the DoH is relevant and the world remains a long way from conquering infectious diseases although significant progress has been made in a number of areas. Through antibiotics, antimalarials and vaccines, the spread of CD has been curbed, notably in the developed world. However the optimism that heralded the use of effective medical interventions has dwindled with the emergence of widespread and increasing resistance to many treatments and the emergence of new diseases such as HIV/AIDS. The burden of infectious diseases remains high, especially in developing countries and particularly high for children. Increasing travel, the proximity of individuals to each other, urbanisation, changes in land use and economic pressures including in the production of food all impact on the emergence of new diseases and the re-emergence of ancient diseases like TB. These factors and others are changing the global pattern of infectious diseases, notably zoonoses and infectious diseases spread between humans—micro-organisms can spread more rapidly and become global in a matter of weeks. Threats now are greater than ever. The impact of global poverty, climate change, population growth, population movements, the globalisation of trade and changes in land use to name a few are impacting on the emergence and spread of many diseases. Globalization and forces of global change have intensified cross border activity to such an extent that it undermines the capacity to control them. In many ways national borders have become irrelevant. And whilst responses to infectious diseases are principally grounded in notions of sovereignty, the international nature of many infectious diseases challenges state-framed responses.

2. *What reliable data exist regarding the numbers of people infected globally with the four diseases² on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?*

2. Data exist although much of the data are estimates because surveillance systems are inadequate or very limited in capacity, notably in the developing world. Information gathering remains a challenge, for technical but also political reasons. This was illustrated recently by the change in total estimate of people living with HIV/AIDS (PLWHA) by UNAIDS which reduced its total estimate from 40 million people to 33 million people. In addition to global surveillance frailties, technological challenges mean that estimates may be somewhat uncertain. For example, the estimate of 8 million annual cases of active tuberculosis is largely drawn from technologies used for more than 100 years of microscopy (rather than more sophisticated and more accurate novel technologies); the estimate of one third of the world's population being infected with the organism that causes TB is, likewise, based on old techniques that lack sensitivity and specificity.

² HIV/AIDS, Tuberculosis, Malaria and Avian Influenza.

Changes in trends depend on a large number of factors, from upstream causes such as poverty and the complex drivers of poverty (for example for TB and HIV) or poultry trade (for avian influenza) to more downstream causes such as misuse of antimicrobials and failing health services in the increasing generation of drug resistant organisms, for example multidrug resistant TB. A more positive example, is the effectiveness of antiretroviral treatment for people infected with HIV. However, the emergence of drug resistant HIV is a particularly worrying scenario. By reducing mortality, prevalence of HIV has increased. This has happened even where incidence has remained stable.

Tuberculosis rates are declining (too slowly) all over the world although some find this hard to believe for the African continent, where rates have risen hugely with HIV over the past decade. The centre of the HIV pandemic has drifted south into Southern Africa. It remains a huge challenge in most sub-saharan African countries. Elsewhere, HIV is a major public health threat but is largely confined to particular sections of the population and in only a few places have generalised epidemics developed.

3. What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? And what improvements might be made?

3. WHO is running the GOARN (Global outbreak alert and response network) which is relying on government declaration but also on media report and uses the web to identify early signs of outbreaks. With the introduction of the International Health Regulations, countries are now obliged to report on serious public health threats with potential to spread beyond a country's borders. WHO is also working at the strengthening of national surveillance capacity, for specific diseases, sometimes using other disease surveillance system as the backbone for country surveillance. However countries with poor surveillance systems pose a threat to the effectiveness of global surveillance. Europe also has an early warning and response system. The experience of SARS and improvements in surveillance such that informal reports of potential problems are highlighted suggests global surveillance has improved markedly in the past decade. But weak surveillance capacity and a lack of integration between animal and human health surveillance systems remains a challenge.

For HIV and tuberculosis outbreak management plays little current role in disease control. Although there is little doubt that there are many outbreaks of TB ongoing particularly in health care settings, the background rates of transmission in the community have meant that these are not the priority in high burden countries. The arrival of multi- and extensively resistant tuberculosis have alerted disease controllers to the need for interventions to reduce the risk of transmission in congregate settings. This is an area where much more work is needed, even drug sensitive TB is probably transmitted commonly, particularly in places where HIV and TB are co-epidemic.

4. Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years?

4. In the area of infectious diseases, it is challenging to make predictions and many scientists have been proved wrong in the past doing just this. The early predictions based on transmission dynamics modelling of the unfolding HIV epidemic bear witness to this, predictions which were much more grave than reality has shown in the developed world and other areas beyond sub-Saharan Africa. The challenge stems from our lack of understanding of the complex interplay between man, organism and environment including socio-economic development, human behaviours and medical interventions. Some interventions can be very effective, such as vaccinations and for instance an HIV or a malaria vaccine would change dramatically the patterns of the diseases. Other interventions are more problematic to evaluate such as prevention interventions. The persistence of underlying factors for the spread of the main diseases and the acceleration of some of these such as intensification of global human movements means that spread could potentially accelerate in the coming years. For HIV, a vaccine remains at least a decade off. Treatment, where available, is keeping many people alive and productive. But many people remain unaware of their HIV status, and this has consequences both for their individual health and public health. The reasons why people do not seek testing are unclear. For pandemic influenza, a pandemic will occur but when remains uncertain. Other unforeseen infectious diseases will also emerge just as SARS and HIV did.

HIV—incidence has probably peaked some years ago, but the long period between infection and disease means that HIV-related illness will be a major part of the health care burden for many years to come. The more successful we are at scaling up anti-retroviral therapy, the greater that burden will be—there are still thought to be at least 4 new infections with HIV for each person starting on ARVs, so systems will become increasingly stretched to scale-up and deliver chronic care.

Effective TB control with sufficient investment should be able to reduce the burden everywhere except Africa. There may be some areas, where MDR TB leads to more severe problems, but these remain the minority of cases. In Africa it will take much longer and more innovative control approaches to make a real impact on the burden of disease. If MDR becomes common it will be even more challenging.

5. What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?

5. Blockages are many. They involve money, politics, morality, science/tools, inter-government relations, education, economic development. Some are upstream issues such as economic development and poverty alleviation—seemingly almost intractable problems. Others are downstream and include investment in effective drugs for infectious diseases that principally affect marginalised poor populations.

Briefly, a few examples include:

HIV—adherence, lifestyle issues, cost, stigma, drug resistance, health services delivery (especially in Africa).

Flu—animal husbandry, global trade imperatives, speed and ease of spread; access and cost to vaccines and drugs, surveillance is stronger globally but response capacity weak esp. in developing nations.

TB—stigma, HIV, poverty, adherence, resistance, nosocomial transmission, migration, criminal justice system links, frail health systems.

The role of inter-governmental organizations is critical in advancing and advocating evidence-based policies, in channelling funds to effective interventions, in coordinating responses to diseases, in supporting the strengthening of health systems as well as promoting economic and social development and in evaluating interventions.

Specific information concerning HIV and Herpes simplex virus type 2 (HSV-2) is included at the end of the document.

6. What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?

6. Principally research (both fundamental and applied), training, consultancies and citizenship. LSHTM has a global network of collaborators and extensive experience in all four diseases ranging from bio-medical laboratory-based research to policy analysis and intervention support.

Our resources are largely dependent on funding for research and students. We receive very little for work with WHO and Global Fund and this limits our ability to support them.

7. What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient “joined-up” thinking in approaching the problem?

7. The main non-health causes for the spread of the four main diseases are related and include poverty, fuelled by population growth and urbanization, environmental changes impacting land use and access to water, international travel and migration, global trade, human behaviour and lifestyles (sexual behaviours, drug use . . .). Many international organizations address these factors which are cross cutting across many areas of interventions.

Specific wide ranging international organizations are addressing a number of these issues and these include the World Bank and UNDP as well as bilateral agencies (DFID, AUSAID, USAID). Other organizations are more focused at a more specific range of issues such as health related issues for the WHO. The difficulty is that more and more organizations involved in health try to develop multi-sectoral approaches to both health and development, which lead to a multiplication of cross sectoral interventions by actors often in an ill-coordinated fashion. Whilst many organisations posit the need for coordination what this means in reality is sometimes unclear. Coordination for what, of whom, for what purpose? Because donors and agencies wish to

see value for money the issue of attribution is raised. Yet attributing benefit to specific interventions is problematic, particularly when several interventions are being implemented (funded by different agencies). The need for attribution also results in a multiplicity of monitoring and evaluation systems, the development of vertical implementation initiatives, and parallel administrative structures to services agencies. To define clear targets, the UN-MDG (Millennium Development Goals) were established, many of them cross sectoral. A number of initiatives have been taken to try to resolve this, notably with the Paris declaration signed in 2005, that promotes harmonization of approaches or the setting up of global agencies to channel funds for specific diseases such as the Global Fund to fight against AIDS, Tuberculosis and malaria (GFATM), or the increase of the amount of funds channelled through recipient countries budget support. However on the ground coordination and harmonisation of action remain extremely difficult to implement, notably because poor coordination between donors.

The UK government has highlighted the threats that climate change poses to health, including through infectious disease [Stern Review, etc] The Fourth Assessment Report of the Intergovernmental Panel on Climate Change (2007) reviewed the evidence for early effects of climate change on biological systems, including arthropod species, in terms of changes in distribution and seasonal activity. School staff have played an important role in the IPCC. Although evidence on movement of disease vectors is currently limited (due to lack of long term surveillance data) the IPCC concluded that the northern limit of many tick species may have moved due to climate warming in Europe and Canada. Although it is not possible to attribute single outbreaks to long term changes like climate change (eg chikungunya), there is good evidence the shifts in the current distribution of the animal disease bluetongue in Europe has been facilitated by climate warming. [ref Purse B V, Mellor P S, Rogers D J, Samuel A R, Mertens P P, Baylis M. Climate change and the recent emergence of bluetongue in Europe. *Nat Rev Microbiol* 2005 Feb; 3(2):171–81. Erratum in: *Nat Rev Microbiol* 2006 Feb; 4(2):160].

Several reports by WHO and other agencies have stressed the importance of strengthening systems for infectious disease surveillance and responses a key intervention for health protection from climate change. WHO has consistently argued that such strengthening should, as far as is possible, build on existing surveillance systems and regulations (such as the new International Health Regulations), rather than replicating existing functions. WHO has highlighted the need for systematic reviews of the suitability of existing surveillance and response systems, at national, regional and global levels, to meet the additional challenges of climate change.

8. *Cases of Tuberculosis fell progressively in the UK until the mid-1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of Tuberculosis infections in Britain? And how could intergovernmental action help to reverse the trend?*

8. A total of 8,497 tuberculosis cases were reported in 2006 in the UK, a rate of 14.0 per 100,000 population. Both the number of cases and the rate in 2006 were very similar to those for 2005. The London region accounted for the largest proportion of cases (40%) and had the highest rate (44.8 per 100,000). The majority of cases occurred in young adults aged 15–44 years (61%). TB is more prevalent in migrant populations, with 72% of cases non-UK born in 2006.

In 2006, 7.7% of tuberculosis cases were resistant to at least one first line drug, 6.9% were isoniazid resistant and 1.1% of cases were multi-drug resistant. The greatest number and proportion of drug resistant cases were among those reported in London. Non-UK born cases had greater overall levels of resistance than UK born cases, although this varied by region of reporting and age of cases. In London, isoniazid resistance was highest among UK born cases (13.7%) (HPA).

Main factors of the revival of TB in the UK are increased migration from high prevalence areas (South Asia, Africa) and increased travelling between regions and the increase in cases of HIV/AIDS, also found in people born outside the UK.

UK TB reflects global epidemiology. Initiatives such as screening at ports of departure are unlikely to impact to any significant degree on TB control in the UK. Control in countries from which migrants originate is needed—TB control demands a global response. This noted, drug resistance represents a health system failure. The UK should not be producing drug resistant disease.

The challenge is twofold—one: provide more accessible health services for immigrant communities—many are scared to register with GP, can't explain their symptoms in English etc etc. Two: improve tuberculosis control worldwide by joining enthusiastically and with real resources the Global Stop TB efforts—Gordon Brown launched it, but the funding gap is still huge. A recent paper in the *New England Journal of Medicine* (Menzies

et al) showed that for the US, it saved money to invest in tuberculosis control in Mexico. The same principle applies in the UK, although our more efficient health care system may mean that it is not actually cost-saving only cost-efficient.

9. *Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions—eg HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?*

9. Non-adherence to tuberculosis (TB) treatment is an important barrier for TB control programs because incomplete treatment may result in prolonged infectiousness, drug resistance, relapse, and death. Other barriers include social stigma, costs of treatment, lack of access to health services, poverty and lack of social support, notably in developing countries. Prevalence of HIV is also driving TB incidence up, with TB being the first cause of death among people living with HIV/AIDS. Other barriers include lack of diagnosis and poor detection. Another factor for spreading of TB is institutional spreading (prisons, health care sector).

Intergovernmental organizations play a major role in providing diagnosis and treatment protocols to health care professionals. With the issuance of the DOTS strategy in 1993, WHO has for instance supported the standardization of approach with a view to provide evidence based diagnosis, treatment, reporting and drug management protocols and to promote a reduction in non-compliance and development of drug resistance. Institutions like the GFATM provide hundreds of million of \$ to fund TB programmes in many developing countries. International organizations have also addressed the co-infection HIV/TB and encouraged national programmes that target both diseases. Finally IO have also supported reduction in drug pricing for TB (and HIV) and enabled poorer countries to better access expensive drugs such as second line TB treatment. Challenges include the integration of vertical TB control programmes into health care systems, and the sustainability of externally funded programmes if funding ceases. In addition, without HIV control TB control is likely to remain a mirage. Moreover, a partially functioning TB control programme, from a public health perspective, is worse than no programme—the development of resistance is almost guaranteed—witness former Soviet Union.

11. *What intergovernmental action is planned or in hand for early detection of the transmission of Avian Flu from birds to humans and of human-to-human transmission in potential source countries? Is this proving sufficiently effective to prevent an Influenza pandemic? What more could be done?*

11. Under the auspices of UNSIC, the UN system, the OIE, the World Bank, regional institutions (including ECDC and AU-IBAR) and national technical institutions work on the implementation of UN strategy on avian influenza. A consolidated Action Plan for Avian and Human Influenza (AHI) was drawn up. Emphasis was put on strengthening surveillance and improving laboratory capacities, health infrastructures, humanitarian response capacity, public understanding and bio-safety will impact positively on the level of preparedness for, and response to, any kind of zoonotic diseases. UN systems agencies are pursuing seven objectives as they contribute to effective national, regional and global responses to HPAI and the influenza pandemic threat (UNSIC).

However the main issue is, for many high risk countries, the lack of surveillance capacity, the integration of veterinary and human surveillance, and human pandemic response strategy development and operational capacity. These weaknesses are particularly prominent in parts of South East Asia and Africa where the emphasis has been on avian influenza control rather than pandemic human influenza control.

There are also issues around the possible duplication of actions by a myriad of actors who work on this topic.

12. *To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?*

12. Microbial resistance is increasing for the three main diseases. Levels of resistance vary according to the disease and with the geographical location. Drug resistance rates are higher for TB in Eastern Europe, and for HIV in the developed world, where a higher proportion of patients are on second or more line of treatment (though this may be partly artefactual since resistance testing of HIV is only widely available in the West). Resistance to first line of treatment for malaria is widespread and the recommendation by WHO is now to use

Artemisin in most places. Drug resistance represents health system failures—it is a man-made phenomenon. In the former Soviet Union TB drug resistance has arisen because of very poorly functioning fractured systems of care, erratic availability of drugs, bad prescribing by doctors, and patient's struggling to adhere to treatment. Spread has occurred because of transmission in overcrowded prisons and pre-detention trial centres and health care settings. The HIV epidemic in the FSU will promote further spread with likely disastrous implications for control of both diseases. Drug resistant HIV is a huge potential problem, particularly in developing countries where access to resistance testing, second line drugs, and support systems for adherence is poor. The development of resistance threatens future effective responses.

The most critical issue is the necessary monitoring of drug resistance that is not always implemented, notably in developing countries where laboratory facilities are lacking and resources are limited. This is particularly an issue with the current scale up of ARV treatment for HIV, and millions of patients now accessing ARV without a clear understanding of the magnitude of emergent drug resistance. There is a clear need for WHO to take the lead and to monitor drug resistance, notably for ARV. The issue is that many countries will not have the resources to provide second line treatment of their citizens, which means that many questions go unanswered and that IO do lack longer term perspective on that matter.

This is certainly a challenge for all these diseases and requires ongoing investment in basic biomedical science to continually seek alternative approaches to treatment.

15. *What interchange exists between States in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?*

15. States exchange experience and knowledge often under the auspices of intergovernmental organizations such as WHO, or within regional structures (EU, PAHO, CIS . . .). Sometimes regional structures collaborate with WHO in joint workshop (EU/WHO workshop on influenza pandemic for European countries). Regional collaboration bodies associated with intergovernmental organizations are a good framework for states to strengthen their knowledge and expertise for controlling infectious diseases.

16. *The International Health Regulations 2005 are intended to provide a global framework for the rapid identification and containment of public health emergencies. How effective do you consider this response system to be? Do improvements need to be made?*

16. The new IHR have just come into effect. They represent a significant improvement over the previous version of 1969 because they focus on any health threat of major significance rather than on a set number of diseases. They also rely not only on countries declaration of outbreak but on external sources for information (media report, NGO...) which is more effective.

The limitations are more in the implementation of the IHR because many countries are poorly resourced and do not have the capacity to operate an effective surveillance system. Whilst the IHR have considerably strengthened global surveillance, it could be argued that response has been less well addressed. The case of Indonesia and its reluctance to share H5N1 virus with the international community is a case in point. The IHR have not offered a way through this. Some countries may be reluctant to fully collaborate internationally if they perceive that they are unlikely to benefit equitably in resources (for example vaccines) that originate from their soil.

18. *Though our remit is focused specifically on known infectious diseases, we would be interested to know how you view the global threat from new or previously unrecognised ones and from the transmission of infections from animals to humans.*

18. In the last 25 years WHO identified at least 25 new diseases. Some always existed but they have been newly recognized as such (HPV and its role in cervical cancer), others are truly new diseases such as AIDS and SARS. Microbial resistance also drives the emergence of novel strains of old diseases, for example XDR-TB. Environmental changes associated with increase in travel will also change the geographical distribution of diseases, leading to developing countries to face diseases that they have not historically faced (Chikungunya,

West Nile virus). Novel diseases are likely to continue to emerge as they always have, exploiting changing relationships between man, animals, his environment and microbe. The transmission of these emerging infectious diseases is more likely now to become global in nature more rapidly than ever before in human history.

22 January 2008

Annex A

Additional information relating to Q5

The Global Fund has revolutionized access to treatment for those with HIV/AIDS, but there has not been a concomitant increase in prevention efforts. There is already a large investment in HIV vaccine development, but increasing pessimism about the likelihood of an effective vaccine.¹ Greater emphasis should therefore be put on other forms of **prevention of HIV infection**.

There is convincing evidence that other sexually transmitted infections (STIs) enhance the transmission of HIV during sexual intercourse by enhancing both the vulnerability of HIV uninfected persons and the infectiousness of HIV infected persons. The most common STI in sub-Saharan Africa is *Herpes simplex virus type 2 (HSV-2)* infection. HSV-2 prevalence rises steeply with age, reaching rates of more than 70% in women and 60% in men in some populations.² People infected with HSV-2 have a three-fold higher risk of acquiring HIV. This effect is highest following recent HSV-2 infection and is therefore most important in young people, the group with the highest incidence of HIV. It has been estimated that **20–50% of HIV infections may be attributable to HSV-2**,² depending on the prevalence of HSV-2 infection. An intervention that could reverse this would have a significant impact.

Treatment of herpes with antiviral drugs shows potential in reducing the infectiousness of HIV (as well as HSV-2),³ but long-term suppressive therapy is not possible at a population level. For a feasible and effective population approach, a **vaccine against HSV-2** is needed.

No vaccine is yet available, for both technical and commercial reasons. Bringing prophylactic vaccines to the market is a long and costly exercise with uncertain returns. None of the major global vaccine players (Merck, GSK, Wyeth, Sanofi-Aventis, Chiron and Baxter) is currently focusing significant vaccine development efforts on HSV. GSK is collaborating with the NIH/NIAID on a recombinant gD protein vaccine that has shown some efficacy, but only in women and only in those who are not infected with HSV-1:⁴ infection with HSV-1 is almost universal in Africa.

The most promising vaccine candidate has been developed by a British biotechnology company. This is highly effective in pre-clinical studies and safe in early clinical studies, but due to change of ownership of the company has been stuck at this stage of development. **Targeted action is needed to further the development of products such as this that are potentially of major public health importance but are languishing because of the investment needed and the uncertainty of commercial returns.**

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Examination of Witnesses

Witnesses: PROFESSOR GILL WALT, Professor of International Health Policy, DR RICHARD COKER, Reader in Public Health, London School of Hygiene and Tropical Medicine and PROFESSOR JANET HEMINGWAY, Director of the Liverpool School of Tropical Medicine, examined.

Q56 Chairman: Good afternoon. Welcome to the Intergovernmental Organisations Select Committee. You will know, I am sure, that our primary interest is the effectiveness of British government policy working through intergovernmental organisations and their organisational strengths and weaknesses. This session is being held in public. You will have the opportunity to correct any factual matters in the transcript, which will be sent to you. It is also being sound recorded. At any stage after you have finished at this meeting, if you want to send in additional information to clarify or add to anything you have said, please feel free to do so. Finally, although we will put the questions to all three of you, any of you can respond. I recognise there are two separate schools here and you might well want to give your evidence separately. Professor Walt, I understand you are from the London School of Hygiene and Tropical Medicine; Dr Coker is also from the London School; Professor Hemingway is from the Liverpool School of Tropical Medicine. One of the things that I have been interested in, which the Committee has been picking up and which is referred to in your evidence, is this issue of global surveillance capacity. The London School says it has improved in the past decade but also that there is a weak surveillance capacity and, of particular interest to me, a lack of integration between animal and human health. I wonder if you could tell us a little bit more about that, expand on what those improvements are and also what the weaknesses are.

Dr Coker: I think the SARS crisis forced a re-think globally on global surveillance and was really, in a sense, a dry run for pandemic flu. What became clear through that was that surveillance around the world needed to be better collated, faster and different sources used, so not only full national surveillance programmes but also more informal systems of surveillance needed to be drawn upon. The reason we mentioned in our submission the lack of capacity and integration between health surveillance systems was when we were reflecting on pandemic flu preparedness, where there is a clear link between animal surveillance and human surveillance systems. If we look, for example, at Africa, where there has been a considerable amount of investment in the last couple of years in animal surveillance and poultry surveillance, surveillance for pandemic flu has not been strengthened to the same degree. That said, there are initiatives in Africa to try to bring together these different surveillance systems, but I think as an illustration of the parallel streams of surveillance that is not a bad example. I think that is replicated elsewhere in the developed world as well. If we want

to have an early warning system that tells us about the potential for human pandemic, then we need to have a good animal surveillance system which is linked to human surveillance systems.

Q57 Chairman: Is your main point that the key weakness is between animal and human health surveillance? Is that right?

Dr Coker: It is the linkage between the two and the development of the two to different degrees.

Q58 Chairman: To different degrees in what sense?

Dr Coker: For example, the emphasis at the moment in Africa in poultry surveillance because of anxieties around avian flu but there is a lack of capacity development for human pandemic flu in Africa.

Q59 Chairman: Where do you think the weakness of that part of the surveillance could be improved? Which organisation would be most well-placed to look at improving that surveillance?

Dr Coker: In a sense it falls between two international agencies, WHO and FAO, and that may be the reason why there has been this somewhat parallel system developed.

Q60 Chairman: When you say the WHO, is that the regional structure of it? Or is it the international structure? There is some suggestion that maybe the regional structure is not as effective as the international structure. I do not know whether you would agree with that, but do you think that is a factor?

Professor Hemingway: I came back last week from a meeting of AFRO, where they are at the moment looking at how they set up a global surveillance system for pesticide resistance in malaria. It is clear that there is a complete lack of understanding within AFRO as to the level of complexity of what they need to put together if they are going to properly integrate information. They were talking about working at the level of Excel spreadsheets and Access databases in the current climate, where we have really good GIS systems that properly integrate with databases.

Q61 Chairman: Sorry, what are GIS systems?

Professor Hemingway: Geographical Information Systems where you can display your information properly, you can integrate that information and you can query that information. The fact that an organisation like AFRO does not understand what needs to be done—and, even worse in some ways, does not understand that it does not understand what needs to be done—I think causes us to step back and

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think that we have a serious problem here. I think we have moved hugely down the path of being able to understand how we should integrate this kind of information both with the animal systems and with the genomic systems, where we have got used to dealing with huge amounts of information on a global system that we need to share. That has not been translated into infectious diseases for the developing world and that needs to be done. I do not see that happening and the leadership for that actually coming from the WHO at the moment.

Q62 Chairman: Who should it come from?

Professor Hemingway: I think that is the obvious place where it should be coming from and getting the right people within the communities who do understand how these systems ought to be operating, but it just is not happening at the level that it should be at the moment.

Q63 Chairman: You talked about “us” having a good understanding, by which I presume you mean “we, the medical profession”. But you then talked about the way the structure does not understand it sometimes not understanding that they do not understand. I am not quite sure which ones you are identifying as having that weakness.

Professor Hemingway: I think there are a large number now of very efficient and very effective global databases that have been designed for sharing large amounts of information and those are now integrating together in a way that actually allows the international community to query those databases. Genomics is an obvious example of that and is the one I am most familiar with, but others are hot on the heels of that. We should not need to re-invent the wheel and invent that all over again and learn the lessons all over again for the health systems. If we know how to put those very large information systems together and we know how to integrate them with geographical systems, with health systems data and all the rest of it, then that information ought to be transferred between communities.

Q64 Chairman: I am still not quite clear on who is not doing that. You are saying that we have all this, but is it government, is it the WHO, is it the regional level of the WHO? Who is it?

Professor Hemingway: I am saying that for the WHO, certainly at a regional level, it is almost counter-productive trying to establish these things from ground level without getting the right people around the table to start with. The understanding is there that the information is needed. I think there is a very poor understanding at AFRO level—maybe someone else can comment on central WHO but I worry it is true of central WHO—of what ought to be

pulled together and where really the information is to be able to do that quickly and effectively.

Q65 Lord Howarth of Newport: Successful global surveillance pre-supposes, I take it, a willingness on the part of the authorities within particular countries to act rigorously and honestly. How confident can we be that that will be the case? Was I too cynical in suspecting that in the People’s Republic of China they did not want the world to know the extent of SARS—possibly they did not want their own people to know? Would there be other cases where countries would be alarmed that there might be negative implications for trade or tourism or whatever? Is it a problem to get a genuine willingness and an honesty and fullness of response from regimes in some parts of the world which we really do need to know about.

Professor Walt: That clearly could be one of the problems but it is not just a political problem, it is also a problem of capacity. The information has to be gathered from the ground and there are often simply not sufficient systems to collect that information and to feed it upwards, so there is a real problem of lack of capacity.

Dr Coker: I would like to touch on the point that you raised which was about HQ and Regional Offices and then perhaps Country Offices and surveillance. I can comment with more familiarity around the EURO office, where the TB surveillance systems in Geneva have been pretty good; they are a very strong team. EURO has a lot of technical capacity but sometimes one wonders what it is for, what does it do that adds value beyond Geneva? That question is more profound when one recognises the ECDC. In terms of surveillance do these different agencies contribute beyond what HQ could do, given that now we have very effective communication systems from when the Regional Offices were set up?

Q66 Lord Jay of Ewelme: I should declare an interest as Chairman of the Trustees of the medical NGO Merlin. I wanted to pursue the WHO point a bit, if I may. One of the points which quite early on in our inquiry has been stressed by a number of people is that there are too many organisations in the health field, but I think there is a general view that WHO is—or certainly should be—the most important among them. We have already heard evidence of a certain amount of criticism of the WHO, but we also heard from Government representatives last week a sense that under the present Director-General things were getting better and that the curve, in a sense, was upwards, certainly in Geneva (there is a question mark, I think, about the Regions). I just wondered if, from your perspective, you could say what you think the WHO is doing well and perhaps doing better, and the things that you would say are definite failings and

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what it definitely ought to do better. I know that is quite a broad question but I think it is going to be quite an important part of the inquiry.

Professor Walt: I think that the difficulty for WHO—this is one of the things that is creating major problems for all of us thinking about what is happening globally—is that WHO is not acting as an agency by itself. Where it used to be the dominant agency it is not any more. It is having to deal with the Gates Foundation, which is hugely influential, making a huge difference to the way people are thinking about health problems. I do not know what Gates is doing in relation to surveillance—I would be interested to know—but those are the circumstances within which WHO is working. What it can do well and where I think it has legitimacy is in the way it is seen by many countries around the world—especially the middle and low income countries. It is perceived as being more neutral than any American organisation or any British or European organisation. For that reason, if that one only, I think there are good reasons for supporting it. It is probably still doing too much; it probably does the normative things better than some other things. It also provides some support to countries at country level in thinking through plans and so on, which is still useful in some of the low income countries. I think it is quite difficult to say which are the clear areas where it is doing well and those that it is not; I think it may depend on the needs of the countries with which it is working.

Q67 Lord Jay of Ewelme: Thank you. I wonder if your colleagues have a different perspective.

Professor Hemingway: Clearly the landscape has changed around the World Health Organisation and I think the World Health Organisation has actually found it quite difficult and has felt challenged by that change around it. Gates is an obvious one but there are also other foundations starting to come up and it is having to share that space that it is used to being a master of. I think Margaret Chan has been a breath of fresh air in that she has clearly decided that she is going to work with the foundations rather than fight against them. I think some of those lower down the system are still intent on fighting. Anybody who read the *New York Times* yesterday, with Kochi Arata's outburst and the memos on malaria and fighting against the Gates Foundation, will be able to see that. I think there needs to be a mechanism where we are all fighting on the same side to try to achieve the same ends. The question is who really is in charge of the international agenda and how are we going to try to take things forward. The Gates Foundation and others are trying to work with the WHO; the WHO has made it quite difficult for those organisations to work sensibly with them.

Q68 Lord Jay of Ewelme: Would you say that the Gates Foundation or other foundations and their rather sudden appearance on the scene is acting as a kind of spur to make the WHO more effective? Or is it rather confusing them and making them not quite certain in what direction they ought to be going? Is it a positive or a negative development in that sense?

Professor Hemingway: I think the jury is probably out on that one. My views are coloured by malaria, because that is where I spend a lot of time working, but certainly in malaria WHO did not work well and did not respond well to what was going on externally. There was almost a feeling that, if it did not have WHO's mark on it at an early stage, then it was not good. Policy should not be driven that way; it should be driven by evidence and WHO should be able to stand above that. For a while it did not do that well in the malaria field; I think it has done it better in TB and some of the other areas.

Dr Coker: You raise an interesting point which is around this issue of closure: when is the evidence sufficient to drive the policy? I think there is a tension—or there has been a tension in the past—with WHO because it is a technical agency; at times it is an implementing agency and it is a strategic policy generation agency. I reflect on the DOTS strategy for TB, where there is still a debate in academic circles about whether that is an effective and efficient approach. WHO attempted to close the argument, saying that that was the way the strategy should be developed and it needed a WHO label to be adopted in different countries. Although the debate is still ongoing in academic circles about whether that is an effective way to go forward, the brand of DOTS is still required by countries if they want to adhere to a WHO strategy. So this tension comes out, never mind the issues around surveillance and other issues that WHO deals with.

Q69 Lord Jay of Ewelme: From what you have been saying, would your advice to our Committee be that we should not look at the WHO as one large organisation but try to disaggregate it a bit? You talked about different approaches to different diseases, different approaches in some Regional Offices. Do we need to try to look at it in a rather disaggregated fashion do you think?

Dr Coker: WHO has traditionally focused on disease specifics and therefore you have all the problems of vertical programmes and lack of integration and the on-going debate about that. But, if you look at diseases, you can look at some good programmes and then you determine how you measure whether that is a good programme or not, and there is a debate within that. Malaria may be a contrast to TB, but that does not actually tell you what are the problems

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of WHO in its entirety, it tells you about the programmes within WHO.

Q70 Lord Desai: When I hear this, hear echoes of the World Bank and IMF. Do we still think that a single organisation can rule the world in any topic? Once upon a time when WHO was set up, it was possible to imagine it, but now countries have more capacity themselves, they have different interests. So is it not time that one re-thinks how much WHO can do and what they should not do?

Dr Coker: I think that is what Margaret Chan has attempted to do: what is WHO for? What niche does it fill?

Q71 Lord Desai: What do you think?

Dr Coker: I think it should be clear what WHO stands for and I think it should focus on what it does well: it should be issues around surveillance, coordinating rapid responses, focusing on specific diseases that it has programmes and technical expertise in; it should perhaps have a focus on countries that will most benefit from that expertise.

Q72 Lord Desai: Should it get out of rich countries altogether?

Dr Coker: If it has a global surveillance programme, then that should be global and it should not be broken down.

Q73 Chairman: It is a question of decentralisation; it can be a centralised body that oversees everything but, if it decentralises, then there is a problem about how good the decentralised units are at actually feeding back up to the WHO. Have I understood that correctly or not?

Dr Coker: Yes, I think that is right. In a sense it touches on what the Regional Offices are for. If you have a very good spoke and you have a good hub, then why do you need the bit in the middle, as it were?

Q74 Lord Avebury: Is there not a mismatch between one of the answers you gave to a previous question concerning the failure to develop large-scale surveillance systems that were integrated with GIS and the suggestion that the WHO should focus on what it does well? Clearly it does not do that very well, because that was the gist of your answer to the previous question—that nobody has been looking at how you produce very large scale databases that do integrate with GIS. I would imagine that the WHO is the only supra-national organisation that would take an initiative of that sort, yet it has not done so. If it focuses only on what it has done well, then it would not be involved in that particular enterprise. I wonder if you could reconcile these two incompatible statements.

Professor Hemingway: I think we are talking about technology and I think the technology in this area has moved so quickly that the Centre within WHO in this case has not kept up with what technology can now do. It used to do it better in some ways than it does; I think it needs to take that technology on board that may not be coming from a health system itself but may be coming from others externally. We know, for example, that the Google Foundation are now getting into that area; they have a huge amount of expertise in IT systems and WHO ought to be working very, very closely with these guys, where Google is talking about putting one per cent of its staff time into those systems. I do not know whether they are; I would be interested to find out. They should have been knocking on the door, not waiting for the world to knock on their doors to say, “Come on, guys, you need to be taking this technology forward”.

Q75 Lord Avebury: Since Google is a dominant enterprise in its own field, would there not be a difficulty if WHO approached them and asked for assistance with these global IT systems? Other companies like Yahoo or Microsoft would say that this was an unfair preference being given to a particular company.

Professor Hemingway: We are talking about the Google Foundation and not Google itself. But using the free systems, in terms of Google Earth just as an external viewer, if you like, that is free, but not necessarily using Google’s products for any gain in that sort of sense.

Dr Coker: A month or two ago Google launched InSTEDD which is funded by Google, Microsoft (drawing on Microsoft’s computerisation skills), Rockefeller and WHO. This is in regard to pandemic flu, particularly in South East Asia. I think these discussions are on-going.

Lord Avebury: Could we have a note of that, please? I would be very interested to pursue that.

Chairman: If you are able to do that, it would be very helpful. I now want to move onto multisectoral initiatives.

Q76 Lord Desai: Following on from what we have said before, we are very concerned about the confused architecture of health intervention. You said something about a multisectoral initiative being adopted by people in an uncoordinated fashion. Do you think countries or agencies adopt these multisectoral initiatives because they are aware of WHO’s shortcomings or because they have a different view on how this issue should be tackled?

Professor Walt: If you are looking at low income and middle income countries who have to deal with huge numbers of donors—whether they are UN agencies,

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whether they are the Global Fund, whether they are bilateral agencies—they have a huge problem to coordinate between those. The countries which manage that well are the countries where they have reasonable systems in place and they are able to get budget support, and then they do their own thing (they have a national plan which everybody then to some extent works to). To coordinate those efforts, though, is really difficult because the donors have their own agendas, they have their own constituencies to whom they are responsible, they all want to attribute changes to their own inputs. There have been a number of examples to improve coordination and I am sure you know about them: sector-wide approaches, the attempt to have one UN Office at the country level, and the Paris Declaration to harmonise donors and so on. But each individual agency has its own particular interests which challenge any coordination attempts. I think you are right in saying that we need to look at the countries to see how strong they are in terms of being able to develop systems where they can actually take control. That is where a lot of aid might actually go and would be very well spent in doing so. In those countries which cannot do that, then you need to have the various donors trying to harmonise as best they can.

Dr Coker: A really good illustration of this challenge and of the burden that is placed on some countries is when one looks at monitoring and evaluation. We have just done some research commissioned by the Bank to look at the indicators for progress on HIV. We looked at all the indicators for determining success and there are something like 140 or 150 indicators. They vary across all the different sections between the Global Fund, between WHO, between UNAIDS, between UNGASS, and we were looking to see which ones are similar or whether there is duplication and how much coherence is there. There is a huge variety. If you are sitting in a Country Office and you have to fill in the indicators for each of these, then it is going to be hugely time-consuming and that is in large part why, I suspect, they are not filled in.

Q77 Lord Desai: Does it arise from the desire of each donor to have a kind of recognised bang for the buck? Or does it arise from a genuinely different opinion as to what causes a certain disease or what cures it?

Dr Coker: I suspect that it is both. The issue of attribution is important—that you can say that your dollar has achieved such and such—but I think also there are people who really believe that certain indicators tell you that you are succeeding and there are differences of opinion.

Q78 Lord Desai: So is the confused architecture a reflection of a confused situation and you cannot simplify it—there is no way of simplifying the

architecture of health intervention? There is no way everybody would agree on what the causes and cures for disease are and how best to approach it and, therefore, there will always be differences? Are we hoping for simplicity where there is no simplicity possible?

Dr Coker: I suppose we can talk about what is a measure of success but ultimately, if you can reach a consensus that that is the measure of success—and hope that that does not distort the response such that you are trying to meet the target rather than actually achieve the public health goal—then this would surely be a good thing. If the public health goal is achieved as well as the indicators being measured to give some insight into whether progress has been made, I would say that this was a good thing. Many of the indicators that one sees are very similar but they are slightly different.

Q79 Lord Desai: Is that because people do not differentiate?

Dr Coker: A sceptic might say that people like to develop indicators.

Professor Hemingway: Sometimes it may be sheer bloody-mindedness, basically that this group over here has set up that set of indicators and is not prepared to agree that this group over here has a better set of indicators or that the two are similar. I think there is a fair amount of that out there.

Q80 Lord Avebury: I was wondering whether an incremental approach to the reduction of these 150 indicators would be most likely to succeed. If you start by saying you are going to bang everybody's heads together and force them into accepting a common set of indicators across the board—which might reduce the numbers by half or a third of its present level—then you will meet with a lot of proprietorial opposition. However, if you look at the 150 indicators and you have, as you say, some that are barely distinct from one another, then getting the two proprietors of those indicators together and saying, “Could you two agree to harmonise and have one indicator that would cover both your fields?” That might be a more productive approach.

Dr Coker: Yes, I think that is what the World Bank is trying to do.

Q81 Lord Avebury: In what sense?

Dr Coker: They are trying to get a consensus on what would be a useful limited number of indicators. It is interesting that the Bank is leading on that.

Q82 Lord Avebury: Where can we find that information on what the World Bank is doing to enhance to harmonise the indicators?

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Dr Coker: There is a meeting in about two months' time on that.

Q83 Chairman: Presumably one of the problems here is that particularly some of the private sector who are putting money in want to solve a specific disease, whereas there is also this wider healthcare issue; you are torn between those. Is that right?

Dr Coker: Yes, what I have been talking about is disease-specific rather than health systems.

Professor Walt: That is a major problem because there are some indicators which are much easier to measure than others and the health systems indicators are much, much more difficult; they are more difficult to gather, more difficult to agree on and need to be evaluated in a completely different way from measuring whether, for example, somebody has had an immunisation.

Q84 Chairman: Measuring the specific disease might not work anyway if the healthcare system is so inadequate that you think you have dealt with the problem when in fact you have not.

Professor Walt: Indeed.

Q85 Lord Desai: I get the impression that a country receiving these visits from the donors, can handle them, it is possible it does not need their help; and those who need their help cannot handle the donors. Would that be too simple a way of looking at it?

Dr Coker: That is a useful indicator, is it not?

Professor Walt: How would you measure it though?

Q86 Chairman: I want to move onto our Government's influence on the WHO. We pour enormous sums of British tax payers' money into intergovernmental organisations and the WHO is no exception. Do you think we are getting the sort of influence we need over the WHO, bearing in mind the amount of money that we put in. Or could we increase our influence?

Dr Coker: My personal take on this is that I think the UK influences WHO quite strongly through both formal and informal channels.

Q87 Chairman: Can you say what those are? Do you mean by medical input, for example, or academia?

Dr Coker: Yes, through the strength of academia in this country; the research to policy links, although not as strong as perhaps they could be, are relatively strong from the UK in the fields that I know but that may not be the case in others. We also have expert committees. DFID is considered very highly within the WHO, the messages from DFID are not totally narrow and it does have a breadth.

Q88 Chairman: Bear in mind that Parliament has a duty about the way British taxpayers' money is spent and this is a very large sum of money going into the WHO; is it being used effectively is what I am asking to you?

Dr Coker: You are asking a question about attribution?

Q89 Chairman: Is the money being well-used?

Professor Walt: WHO has very little money in comparison with many of the other agencies that are working in health. One of the criticisms is that it spreads it too widely but the difficulty is that it is very hard to get precise agreement on what WHO ought to be doing. I think it is one of those conundrums that there will always be tensions about: should you be spending more on public health and less on disease, or more on chronic and less on infections, and so on? There are never really enough resources but WHO as an organisation, it has always struck me, has very little money and in comparison with the sort of money that is now flowing into particular diseases it is actually working with few resources. I think we may be putting money in but I do not think that we are putting too much in at all.

Q90 Chairman: It is not so much about the amount, it is how well it is used. At the end of the day that is the question you ask about taxpayers' money, is it not?

Professor Walt: Then it comes down to the question of how do you measure how it is used and that is a difficult one, I think.

Q91 Lord Jay of Ewelme: When you say that DFID is highly regarded, would you say that that high regard for DFID translates into positive influence on the way in which the WHO operates?

Dr Coker: That is the sense that I have got, particularly at HQ in Geneva and in the areas I have been working with.

Q92 Lord Avebury: One way of looking at how the money is spent in WHO is to look over a period of time at the overheads in comparison with the amount which is spent on its programmes. Is that something that anyone looks at? Or would you think it would be worthwhile examining the relative expenditure on things that happen on the ground and things that happen within WHO's bureaucracy?

Dr Coker: Where does the money end up? Does it end up in countries? Does it end up in Geneva? Does it end up in the Regional Offices?

Chairman: Maybe this is a difficult area for you. I suspect that you are not too familiar with the way the money is used at the WHO.

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Q93 Baroness Eccles of Moulton: I was just wondering whether generally speaking the arrival of Gates and Google—no doubt there will be others—with very large sums that can be introduced into this area is actually changing the balance a bit about where the funding is coming from. Previously much more of it was coming, broadly speaking, from public sector government sources and now, with this wave of new funding coming in, what effect might that actually have? I might be getting the terminology wrong but I rather gather from what has been said that WHO is more concerned with, as it were, the horizontal input and the Gateses et cetera with what I think is described as the vertical, which is the disease-specific; and whether, as the balance matures between the private sector and the public sector—to use simple terms—the private sector input might see that it will be advantageous perhaps to start to fund WHO directly itself to a certain extent. Could that be a possibility?

Professor Hemingway: When organisations like the Gates Foundation first came along they believed that the space that they needed to occupy was in the discovery and development of new products for disease control and that, if they produced those new products—ie new drugs, new vaccines—the world could take them up with no problems. The delivery mechanism was there, with WHO and others being able to pick these things up, integrate them into policy and practice, and away you go. What they have found out to their cost is that that delivery system is deficient as well as the discovery and development programme, and therefore Gates and others are now moving into that because they believe they are not going to have the impact that they want unless they get in there. I think that is where you have seen more and more tension building, because WHO do believe that the foundations are actually starting onto their territory. They need to work together rather than fight at that point in terms of how they do that.

Chairman: That is a very important point, thank you. I want to move on now to the global initiatives. Lord Howarth?

Q94 Lord Howarth of Newport: Can we come back to a dilemma which is touched on recurrently in these sessions between the disease-specific approach and the approach of developing a strong health system—the vertical and the horizontal? Budget support to assist countries to develop effective healthcare systems presupposes good governance in the sense that there is substantial administrative capacity, an absence of corruption and, I would also say importantly, an equal benevolence to all the people of country, untainted by tribal considerations or whatever. Where do you think, if you can generalise,

we get better value, in the vertical or the horizontal? Generalisation is obviously very difficult; if you want to give specific instances where one works well and the other works well, please do.

Professor Walt: I personally believe that you have to have both, that there are times when you have to prioritise a particular disease—it may be because it is a major problem at the time—and you try to tackle it through your health services or your health system, so that you address it in an integrated way. There may be a period in which you just go for that one particular issue to resolve it and later you integrate it with other activities. I think that the juxtaposition of these two as completely separate is probably a bit unreal. There are times when you need both. However, simply having largely or only vertical systems is hopeless in the long run because you cannot sustain any changes that you make, so you have to have a good system in place. But, within that system, I would argue that there would be times when the vertical programme would be justified.

Q95 Lord Howarth of Newport: Do you think it is appropriate to invest money provided for global health in the development of good governance?

Professor Walt: Yes, I do, very much so. We need to feel confident that there is managerial and financial capacity in the countries. In the end I would have thought that is what everybody wants for those countries which are struggling to build systems. The way to do it, is to build capacity at the country level. I think that is one of the things that the British have been good at doing.

Q96 Lord Howarth of Newport: Could you give us now or later any specific examples of success in one dimension or the other?

Dr Coker: I can give you an example which illustrates something else I think. We were working in Russia in the prisons and in the civil sector on TB control, multi-drug resistant TB control and HIV control. What we did was to implement the WHO vertical DOTS programme, which was probably unsustainable once funding had been removed, because it was not integrated into the broader health system. That brings me to the point that I think you do need very strong vertical programmes which are well integrated. That is a counsel of perfection perhaps, but if you do not have a good, strong vertical programme then what you have is ineffective programmes; and, when it comes to communicable diseases, one could argue that that results in a worse scenario than having no programme because you generate drug resistance; you generate it with HIV, you generate it with TB, you generate it with malaria and undoubtedly you will generate it with pandemic flu, which has huge knock-on consequences. If you

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do not have it integrated, then you do not have a sustainable programme, so there are inefficiencies. When we were discussing this issue of vertical programmes and horizontal programmes a few years ago with WHO, I think we reflected on this notion of non-negotiable elements of a vertical programme—that you absolutely have to have certain elements. If you do not have these elements, then you generate a problem in generations to come which is going to be incredibly costly. Because I am an infectious diseases specialist in the first instance, I would argue that you need good, strong, non-negotiable elements embedded first of all.

Lord Howarth of Newport: Are there examples that you can think of where horizontal programmes to strengthen healthcare systems in developing countries have been funded by international sources and have worked usefully? Can you provide models?

Q97 Chairman: If you have examples that you think give us these core issues that apply on the horizontal and vertical, it would be quite useful.

Dr Coker: The Thai 30 Baht scheme was a very powerful cross-sector health system reform programme. I do not know what the position of it is now, but it addressed issues of vaccination levels, of maternal mortality and reproductive health; it touched on a wide range of different health issues.

Professor Walt: It was built on a good infrastructure that already existed.

Chairman: I have heard some good things about that but it did have a certain basis to build onto, whereas in some countries the basis is not there. Lord Howarth's question is quite important; if, after this session, you think of examples which give factors which you think are necessary in the way that you have talked about, Dr Coker, I think it would be useful to have those.

Q98 Baroness Whitaker: I have been on the receiving end of quite heavy NGO advocacy about the Global Fund from those NGOs who are associated with it, that it is much more effective than direct budget support. I do not necessarily subscribe to their view. I rather take your balanced view, but I should be interested in your comments. They say that the Global Fund is more accountable and long term, not least because it has several representatives of civil society on it and budget-to-budget support given to a country with a weak Parliament which cannot call its own government to account—as is often the case in a developing country—for some strange reason, governments do not always want to strengthen their parliaments!), then civil society is absolutely necessary to draw in as much capacity as can be done from the regions concerned. That is one point. Of course the global fund does also attribute benefit as

part of its modus operandi; I think they outsourced malaria to Dr Kochi, whom Professor Hemingway mentioned; there was an interesting article in *The Economist* a couple of weeks ago on this point. The final point I should like your views on, going wider, is that these same powerful advocates criticise DFID's international health partnerships—which we thought was rather a useful idea to draw together all the donors so that programmes would be more coherent and less of an ordeal for the receiving countries to deal with—because there is no space, again, for civil society on the IHAs. Partly it relates to Lord Howarth's governance problem; it goes back to the weakness of the national parliaments in being able to pursue the government's use of the budgets, and obviously NGOs have a role in this vacuum. If you have any views—I hope I have made this rather convoluted argument clear—could you pick out a few points which you think would be helpful?

Professor Walt: I think the Global Fund has been amazingly transparent and has given the opportunity for a great deal of participation by NGOs in a number of ways, not least through the internet, and there has been a lot of debate about it. It has also tried very hard to involve NGOs at the country level in the CCMs (the Coordinating Council Mechanisms) with some success and some failure. In fact, there are increasing suggestions that the CCMs are not working terribly well and that they should be amalgamated into National AIDS Councils and so on. The difficulty with that is that it is very contextual and does depend on a great deal on the country that one is looking at; some countries' NGOs are weak and do not have much voice and, therefore, are not able to stand up to government or donors et cetera. I think one does have to look country to country and in that sense the Global Fund has been quite successful in trying to bring in NGOs.

Q99 Baroness Whitaker: Is it effective in reducing infectious disease by these means?

Professor Walt: We do not really know that yet. There is an evaluation being carried out now of the first five years of the Global Fund.

Q100 Baroness Whitaker: When is that going to be published?

Professor Walt: This year. It is a five-year evaluation.

Q101 Baroness Whitaker: What about Dr Kochi? Is his work completed do you know?

Professor Hemingway: I am not quite sure what the context is on that one.

Chairman: I am afraid we are going to have to adjourn for ten minutes because of the division.

The Committee suspended from 5.05 pm to 5.15 pm for a division in the House.

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Q102 Chairman: Baroness Whitaker, would you like to continue? Have you had time to think about the question?

Professor Hemingway: We have been conferring and I must say we are still struggling over the context. I think the question was around Kochi Arata and the WHO?

Q103 Baroness Whitaker: That was just one example. What I really wanted was your take on this conceptual philosophical struggle between the advocates of budget-to-budget support, which gives the governments ownership and therefore has a more long-term health effect, arguably, if they have a strong Parliament, and the Global Fund model, which is more accountable (they say), more long-term (they say), more transparent (they say). Which should our money go to? The NGO people say DFID is giving the Global Fund less and putting more into direct budget support and they think that is wrong from the point of view of the prevention of disease.

Professor Hemingway: It is difficult to turn that into an either/or. If you do not do something about strengthening the health services and health systems within a country in many of these places and all you have are vertical programmes, like the Global Fund, then in some ways you are contributing even more to what is going on in the health system.

Q104 Baroness Whitaker: People say it is the opposite with the Global Fund; it is not from the top, it penetrates much more into the health systems themselves.

Dr Coker: It is focused on AIDS, TB and malaria but it is not focused on the health system more broadly, so by its nature it has to be contributing to the vertical programme. A sceptic would say that the NGOs would say that, would they not?

Q105 Baroness Whitaker: They would say that, absolutely. I do not know whether you have seen examples of direct budget support which has reduced the incidence of, say, malaria; malaria has gone down in some places.

Professor Hemingway: It has, but how do you actually attribute where that has come from? Sometimes it is very difficult to get at that because you have multiple factors all sitting in there that interplay together. Speaking personally, where I have seen the Global Fund operating best is where the Global Fund programmes have been integrated with the health system and the health service—for example, in Zambia they are operating that very well there and that works. I have also seen it operate very badly elsewhere and I have seen budget-to-budget support not work very well, so I think it is very difficult to give

you a generalisation of what works and what does not work.

Q106 Chairman: Is there a note of scepticism about why the IGOs might be saying this, if I understood you correctly?

Dr Coker: And also why the NGOs might be saying this.

Baroness Whitaker: It sounds as if there is not a magic bullet anyway, like the rest of life.

Q107 Lord Howarth of Newport: Do we have to assume there will never be effective audit, there will never be value for money assessments that we can trust?

Dr Coker: Value for money?

Q108 Lord Howarth of Newport: We are asking where money should most usefully go. We do need answers to these questions if we are to channel our money responsibly. From what you are saying it is very hard to discern where we are getting effectiveness and value for money.

Dr Coker: Can I give you an illustration of where I think this is problematic? When I was working in Russia, an NGO was working there and the NGO had brought in its own doctors, its own laboratories, expensive systems and set up a completely parallel system to the Russian system, which was costing huge amounts and was clearly going to be unsustainable. They were arguing that this was a humanitarian crisis and we needed to respond; we were arguing, on the other hand, that we needed to develop a health system, we needed to integrate a TB control model and so forth. If you say, what is value for money? Well, some people would say that there was a humanitarian disaster unfolding and we offered value for money because in the immediacy, in that timeframe, we saved lives. We would have argued that actually over a ten-year period they would not necessarily have saved that many lives but it would have cost a lot more. It really touches on your philosophical point, over what time frame is one interested in terms of value of money?

Q109 Baroness Whitaker: Moving onto resource allocation, do you think too many resources are going to HIV, malaria and TB at the expense of others which arguably undermine the health of the whole country, like leprosy or pneumococcal disease, or eboli? Should they have more money than they get because they are not up there in lights in the same way that TB and AIDS and malaria are?

Dr Coker: You could argue that not enough money is going into those diseases because they are still a huge problem, a huge burden. Does it cause distortions? It causes substantial distortions. Does it pull money

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away from the resources that might also usefully be going to those other diseases? Yes, it does.

Q110 Baroness Whitaker: Does WHO have a good system for judging what money is going to what?

Dr Coker: WHO does not decide at a country level what resources go to what.

Q111 Baroness Whitaker: In its own programmes?

Professor Walt: It certainly evaluates its own work, so many of the programmes that it does will be evaluated by external independent evaluators and they will learn from that how successful they are being.

Q112 Baroness Whitaker: The balance of its investment between surveillance, prevention and treatment—do you find that acceptable?

Professor Hemingway: I would not know what WHO's balance is there. It is not the kind of information that we are given in any shape or form.

Chairman: Maybe we need to pursue this with the WHO.

Q113 Baroness Whitaker: Finally, I think the London School listed a wide range of blockages to better control of infectious diseases. In trying to remove some—presumably one cannot remove all of them—including upstream issues like economic development and downstream ones like investment in drugs, where you do you consider that intervention by the international organisations would be most effective? Or what are the points of maximum leverage? What should they focus on?

Professor Walt: My personal view would be that international organisations need to be building capacity within countries and you do not do that through two-week training programmes, you do it over a very long period and you train and set up systems so that people can be managed and supported through their work. I think that would be a very good long term aim for organisations to improve health.

Q114 Chairman: That seems to be the thrust of your comments, improvement in relation to this. Is that right?

Professor Walt: That was a personal view.

Q115 Chairman: Would either of your colleagues wish to add to that?

Professor Hemingway: It is also clear that health benefits go hand in hand with economic development; there is no question about that. Having worked in places like Thailand, Sri Lanka and others over a 20 to 30 year timeframe where you have seen the economic benefits move, you have seen

improvements in health systems move hugely. That goes along with improvements in housing, which brings you improvements again in a whole raft of other disease related issues. Unless there is something that tackles poverty alongside the health systems, you are fighting a losing battle in many ways. Somehow you need not to just think of health in its own silo, but ask what it is, for the region or for the country, that is going to give it the economic benefit that goes hand in hand with the health improvements that you are trying to put in. If you can tie those together, you can get something that is sustainable; if they are not tied together, then anything sustainable is very, very difficult to actually move forward. There is too much of a tendency just to think in one block and not across the breadth.

Q116 Baroness Eccles of Moulton: Is political stability a very important factor there?

Professor Hemingway: I think it helps, but if you look at Sri Lanka, in Sri Lanka there is no political stability and yet they have almost got rid of malaria and it has not been because they have swamped the place with indoor residuals, spraying or bed nets. It is because they have improved housing and they have done that against a civil war and a reduction in some ways in parts of their economy—tourism has gone—but they have had some of the key improvements that have pushed some of those diseases out.

Q117 Lord Avebury: One of the comments that was made by the London School was that without HIV control, TB control is likely to remain a mirage. I would like to ask you whether the converse of this is also true—that, if you like, without more effective treatment of TB, the death rate from AIDS is going to continue to rise. Could you say something about the synergy or lack of synergy in IGO programmes to tackle these two diseases? Could you also, in answering that, explain how the DOTS strategy fits in with the programmes for integrating anti-TB and anti-AIDS programmes in different countries?

Dr Coker: HIV lowers your immune system and makes you more susceptible once you have been infected with TB; TB does not make you more susceptible to acquiring HIV unless you are in a setting where you are likely to transmit it to each other. TB kills an awful lot of people who are infected with HIV. In terms of the response, over the last 15 years or so the focus was initially on TB control and in parallel HIV control, and never the twain met and patients did fall between the gaps. I think over the last five years, admittedly belatedly, that problem has been recognised and there are efforts to try to ensure that patients do not fall between the gaps, and there are policies developed by WHO to try to address that problem. That said, many of the vertical systems that

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deal with one disease are in a sense owned by certain professionals, and so patients continue to fall between the gaps as they move between HIV services and TB services. To some degree that is understandable, partly because professional expertise sits within those particular domains, but also, if you are an HIV-positive individual, the last place you want to be is sitting in a TB clinic. So there are real practical issues as well. The response to those two diseases is that it is easy to understand that we should have an integrated response, that we should have a coherent response that delivers professionally, good clinical care, but how one does that on the ground and ensures that a lot of people do not become cross-infected is a substantial challenge.

Q118 Lord Avebury: Why is the answer not to deliver TB treatment and care within the HIV clinical system?

Dr Coker: If we were sitting in an HIV clinical care setting and I walked in with multi-drug resistant TB, we would all be dead within six months or so.

Chairman: That seems to be quite a powerful answer.

Q119 Lord Avebury: Do you consider that, if the delivery of antiretrovirals is successful but there is no corresponding programme to change sexual behaviour, then the incidence of HIV is going to continue rising?

Dr Coker: Yes, the incidence will continue to rise and that rise will be because people who are at risk of acquiring HIV do not change their behaviour but also it will rise because the prevalence of HIV will increase, the number of people living with HIV increases and they potentially pose a transmission risk. It does raise the issue that I touched on earlier on, which is what we mean by a successful antiretroviral programme and the risks associated with a half-baked antiretroviral programme and the transmission of drug resistance and so forth.

Q120 Chairman: You cannot fully separate them out in that sense, can you?

Dr Coker: You cannot, no.

Chairman: Can we move onto the important issue of human flu versus avian flu.

Q121 Lord Jay of Ewelme: Could you help, first of all, with an analytical point because I have never been entirely clear about this. Am I right in thinking that there are actually two quite separate things here. There is avian flu in the sense that there is a risk that there may be a jump across the species barrier and we may all start communicating among ourselves what is now avian flu? Separately, quite independent of that, is there the risk of a flu pandemic of the kind that we have had every 30 years over the last 200

years or so and ought to be expecting another one? Are those separate? Is what you are saying that we are focusing too much on the former and not enough on the latter? I wonder if you could say a little bit about that and what you think international organisations ought to be doing to ensure we are properly prepared for the outbreak of either.

Professor Hemingway: You are largely correct in your analysis and I think there is a large potential risk on both sides, and it is how much you put onto both sides. What more should we be doing and how should we be geared up is a difficult one.

Q122 Lord Jay of Ewelme: By saying that there has been too much emphasis, at least in some countries, on avian flu and not enough on pandemic flu suggests that somebody ought to be doing a bit more at least on the risk of pandemic flu?

Dr Coker: We wrote that partly on the back of an analysis of national strategic plans in Africa, where substantial efforts from the international community focused on animal surveillance, poultry surveillance, in culling and protection of the poultry economy and so forth. What those national plans do, however, is that they address avian flu and they disregard almost completely pandemic human influenza. I suspect the reason for that is that much of Africa would be incapable of responding to a pandemic of human influenza. That means that the focus needs to be on stamping out avian influenza before it becomes pandemic human influenza. If we have a global pandemic, then Africa, as everywhere else, will be affected. It also means that we have no strategic plans in readiness for a pandemic of human influenza in large parts of the world.

Q123 Lord Jay of Ewelme: Is there any particular reason why pandemic influenza should break out in parts of the world where there is avian flu?

Dr Coker: The epicentre of the next pandemic of human influenza is likely to come from areas where there is substantial avian influenza, because the change in the virus will occur there. In all likelihood it will occur there because that is where the greatest density of poultry is, where the greatest number of strains of the virus are. In my view it is likely to come from South East Asia or China because of the density of poultry.

Q124 Chairman: This is the issue which we touched on earlier about the lack of surveillance between the agricultural and the human.

Dr Coker: Exactly.

Q125 Chairman: That is the key thing, and if there were more surveillance of that switchover between the agricultural and the human we would have a

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better chance of spotting when a human pandemic was beginning. When the mutation takes place, presumably you would get the first few cases of human pandemic flu; but, if you do not spot it at that stage, it becomes a pandemic a short period down the line. Have I understood that correctly?

Dr Coker: Yes, and if you go back to medical school you will ask the question “What is surveillance for?” Surveillance is information for action and, if you cannot act in response to your surveillance, then that poses the question why you are bothering with surveillance.

Q126 Lord Jay of Ewelme: Even if there was not avian flu at the moment, am I not right in thinking that we ought to be worried about a flu pandemic simply because historically these come around every generation and we have not had one for a while?

Dr Coker: There are always different strains of avian influenza circulating.

Chairman: I want to move on finally to trade versus health, which we maybe need to clarify.

Q127 Lord Howarth of Newport: If global prosperity is to increase and the benefits are to be felt throughout the world, then we need mobility. There is, of course, an enormous increase in human mobility across the globe and trade is an aspect of that. Migration of people on a very large scale is another. Unless we can produce the wealth, we will not get better healthcare systems and we will not see the other benign effects of the alleviation of poverty. On the other hand, the more people are free to move about, the more transmission of infectious diseases is likely to occur. Clearly we cannot stop world trade, but is there at least some discussion between the organisations that have leading roles in these respective fields, the WTO and WHO, for example? Do they reflect upon this dilemma together?

Dr Coker: I am sure they do. I think the question about trade is absolutely critical because, if we look at the emerging zoonoses—the emerging diseases—over the last 20 years, most of them have come from animals. They have come from animals either because of the movement of animals or because of the differences in how we look after our animals. With BSE, with SARS, with pandemic influenza, the driving force is the economy, that is what drives our changes in practice and the movement of goods. That is what threatens public health. I think there is an emerging debate about this, not just in the spheres that we are familiar with, but you just need to look at Jamie Oliver and so forth and think about how we look after food and how we deal with our relationship with food to recognise that the relationship between trade and health is inextricable. We pay £1.50 for our chickens because they come

from Thailand or wherever and the way they are looked after in some countries encourages the emergence of infectious diseases.

Q128 Lord Howarth of Newport: We can narrow the problem down to some more specific issues such as that. Can you see scope for effective international intervention via the intergovernmental organisations? The difficulty in world trade negotiations is that we are all the time dealing with the excuses that are put forward for continuing protectionism, and this would be another wonderful excuse for protectionism—to stop imports from countries where there were large question marks about the health and safety of food products. Can you envisage that there could be some useful disciplines or some useful routines applied in the way that world trade is regulated and developed to reduce the risk of transmission of infectious diseases while not seizing up trade?

Professor Hemingway: To take the example you have with chickens coming from Thailand, the way that the chickens are looked after in Thailand for that trade is now dramatically different to the way it was a few years ago because there is now a much lower tolerance, for example, of aflatoxin contamination within those broiler chickens because they are for the international market, and so the home market within Thailand has had to change the way it works. There are only two distributors of chicken feed within Thailand and both of those chicken feed manufacturers have to work within more restricted norms. In some ways, because you have opened up the international market, you have actually improved the animal husbandry that is going on over what it would normally be.

Q129 Lord Howarth of Newport: Somebody has suggested health impact assessments; is that meaningful? I am not quite sure where the idea came from.

Dr Coker: Sorry?

Q130 Chairman: There is a suggestion that, if you made a health impact assessment of certain types of food which might be at risk, for example you could say that in Thailand there is a risk factor and that might put pressure on the government to do something more about it.

Dr Coker: I can imagine that is possible.

Q131 Lord Desai: To take an example, there is a chicken flu epidemic in West Bengal and they had to slaughter very many more chickens than people would like, but I want to ask you would BSE happen here? There are certain bans on British beef exports everywhere, very instantaneous. Obviously in some

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forms of animal products there is a very tight form of prevention of trade if there is a health risk. Is it the problem again that poor countries do not have such safeguards or we cannot safeguard against imports from poor countries? Certainly whenever there is the slightest evidence of BSE or foot and mouth or anything, all countries stop importing British beef.

Dr Coker: That assumes that international trade is the driver. But, if you look, for example, at poultry density in southern China over the last 30 years, it is something like a 3000 or 4000 fold increase in poultry density. That is not just in serving the international market, it is serving a domestic market as well. The potential consequences of generating new zoonoses, they would impact on international trade but whether domestic trade responds in the same way I am not sure. One only needs to look, for example, at Thailand's neighbour, Vietnam, where most of the poultry is backyard to see the contrast.

Q132 Lord Desai: I presume one can only control poultry which is factory farming but back yard farming cannot be controlled?

Dr Coker: It is difficult, but Vietnam was very successful actually in dealing with backyard problems.

Q133 Baroness Whitaker: Does WHO make representations to national governments about animal husbandry with respect to infection? Or is there another international organisation which deals with this?

Dr Coker: FAO.

Q134 Baroness Whitaker: Do they have the same regional networks and so on? Are they active in this way?

Dr Coker: They are, yes; they are very active. Also there is a coordinating body.

Q135 Baroness Whitaker: Do they link up with WHO?

Dr Coker: Yes.

Q136 Lord Howarth of Newport: Looking at the kaleidoscopic system of international governmental organisations interested in health it is hard to see what capacity there is in the system overall to prioritise. I just wondered, coming to your own

institutions, how you have experienced that. Both your institutions are very important international resources for research. How free are you to determine your own priorities for research? To what extent do you have to scramble around to secure funding from one funder or another who have their own favourite priorities and are willing to pay you to work in one field but not in another? How possible is it for you to be selective, to be strategic, to pursue your own preferred programme of research?

Professor Walt: It is a mixture, but we can be strategic. It depends on our relationships with the various funders, because we can go to them and we often have policy dialogue about issues that are emerging and so on and, therefore, can suggest areas to look at. At the same time, obviously, we are extremely dependent on those particular funders; if they are not interested, then we may not be able to pursue something. That would be my view; I am in a different disciplinary field from my colleagues.

Professor Hemingway: I think it is actually easier now than it was five years ago. I think it is easier because there is more money in this area. We certainly decide strategically from Liverpool's perspective what we are going to do and, more importantly, what we are not going to do; which areas we are not going to get involved in and where we are going to put forward a very strong market and say that these are the areas that we are good at, that we are internationally competitive at and where we should be pushing. We have been fairly restrictive then in terms of making sure that those are the areas we are going for. I think we have also tried to make sure that we are well enough connected in the system that we understand that that money is not going to dry up in the next few years and that we are covering a broad enough area so that we are balanced, and that there are enough funders in those areas to be able to go for that. I do think it is easier now than it was a few years ago.

Chairman: That is encouraging. Thank you very much for that. If you get any more thoughts on any of the questions that have been asked or indeed anything that we did not ask that you think maybe we should have done in relation to intergovernmental organisations, please contact the Clerk. You will get the transcript of evidence, as I have said, and you can correct any factual errors or make anything clearer if you wish to do so. Thank you very much indeed for coming today and giving us your time.

MONDAY 25 FEBRUARY 2008

Present	Avebury L Desai L Eccles of Moulton B Falkner of Margravine B Geddes L	Howarth of Newport L Soley (Chairman) L Steinberg L Whitaker B
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Memorandum by the Health Protection Agency

1. *A recent report on Communicable Diseases by the UK Department of Health stated that “post-war optimism that their conquest was near has proved dramatically unfounded”. What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis?*

1.1 It is clear that they have not been “conquered”. The introduction of effective vaccines, antimicrobial therapy and improved sanitation over 100 years has had a significant beneficial effect; while increasing levels of international trade and travel, emergence of new infections (particularly zoonotic infections), emergence of antimicrobial resistance, changes in societal behaviour (eg sexual behaviour, uptake of vaccination, urbanisation and the extension of human settlements into new ecological settings), geopolitical factors, and war/strife with mass population movement, have increased the risks of transmission and the impact of these diseases. Some risks have never gone away, eg the risk of pandemic influenza. The emergence of antimicrobial resistance, and the potential lack of new antimicrobials, is probably the greatest single “natural” threat, along with the emergence of new infections and the threat of deliberate release.

2. *What reliable data exist regarding the numbers of people infected globally with the four diseases¹ on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?*

2.1 WHO malaria figures are approximately 500 million cases, with at least one million deaths (approx 90% of them in sub-Saharan Africa), per annum. There are around 1,750 imported malaria cases in the UK each year.

2.2 The WHO declared TB a global emergency in 1991. The most recent assessment suggests that the epidemic may be on the threshold of decline. Tuberculosis remains a major cause of death with over 1.6 million deaths in 2005. The number of new cases is still rising with about 8.8 million new cases estimated to occur annually. This increase has been attributed to the HIV pandemic, failures in TB control programmes, emergence of drug resistant strains, poverty, conflicts and in certain countries the dismantling of TB control infrastructure due to the perception that it is a disease of the past. There are also significant funding short-falls globally, and recent reports of the emergence of multi-drug resistant TB.

2.3 Estimates of the total number of people that have been infected with avian influenza H5N1 in humans are made available by WHO. From 2003–07, 349 cases were reported with 216 deaths. Although the possibility of person to person spread has been reported in a few incidents, the virus currently appears to be very inefficient in transmission to and between humans.

2.4 The 2007 UNAIDS/WHO AIDS Epidemic Update estimated that in the previous year 2.5 million became newly infected and 2.1 million had died, and that there were 33 million people living with HIV. It is also thought that the rate of increase in the overall numbers living with HIV may be slowing as the numbers of new infections has fallen, from an estimated peak of three million annual infections in the late 1990s. In the UK estimated numbers living with HIV is now 73,000, with up to a third remaining undiagnosed. Much of the

¹ HIV/AIDS, Tuberculosis, Malaria and Avian Influenza.

recent rise in HIV in the UK is due to continuing migration of HIV-infected persons from sub-Saharan Africa. Sexual behaviour together with the increasing complexity of sexual networks in a globalised society continues to drive HIV transmission.

3. *What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? And what improvements might be made?*

3.1 At a global level, formalised international surveillance systems to give early warning of outbreaks of infectious disease are largely managed or coordinated by the WHO (for some parts of the World the WHO also provides the main focus for regional surveillance). Within Europe, the recently established European Centre for Disease Control and Prevention (ECDC) is increasingly taking the lead in the operation and coordination of surveillance that extends across national borders. The growing importance of zoonoses as emerging infections, and the importance of internationally distributed foodstuffs as vehicles of infection, mean that international surveillance of animal infections, coordinated by the OIE², and rapid international reporting of significant food contamination, through the WHO Infosan³ network and the EU's RASFF⁴ system, also have an important role in the early warning of outbreaks of infectious disease.

3.2 The implementation of the 2005 International Health Regulations has formalised and enhanced the level of exchange of early warning information between countries. The shift of coordination of EU surveillance networks to ECDC has yet to demonstrate any added value, and for some diseases there is concern that the capacity for effective assessment and response to potential threats has been diminished.

3.3 Beyond these European and global non-governmental systems there are few formalised international surveillance systems. EuroMed partners (non-EU countries surrounding the Mediterranean) should be encouraged to actively support and strengthen their participation in existing ongoing activities, such as EU networks (eg Communicable diseases surveillance) and regional projects (eg Episouth, Shispan, Public Health Border Management) and consider sustainable long term cooperation for the Region. There is one system within the EU, RASBICHAT, that provides an early alerting capability between member states. There is a similar system with the GHSI (Global Health Security Initiative) of G7.

4. *Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years?*

4.1 For HIV there is a huge effort by UNAIDS and by government to provide treatment, but surveillance of drug resistance is poor. An increasing proportion of HIV cases in the UK are migrants from high prevalence countries who acquire HIV there. It is expected that an increasing proportion of such migrants will be infected with resistant HIV. Increased survival will increase transmission risk.

4.2 Although no increase in TB case numbers was reported in the UK in the most recent year for which data are available (2006), the underlying trend of the last two decades remains one of increase. Future trends will depend on patterns of immigration and the success of the tuberculosis control programme outlines in the Chief Medical Officer's Action Plan.

4.3 No reliable prediction can be made about the occurrence of either avian or pandemic influenza in future years. History suggests that a new pandemic strain of influenza virus is likely to emerge at some time and cause widespread human illness. The extensive spread of the avian influenza H5N1 in wild birds and poultry (despite control measures), and its ability to cause severe disease in humans, has raised concerns about the emergence of a new pandemic strain derived from the current H5N1 virus.

4.4 The global malaria situation will remain very serious for at least the next 10 years. Eradication is extremely unlikely at present. The extent to which malaria is controlled will depend on the success of current programmes to roll out insecticide-treated bed nets and artemisinin combination therapy, supported by parasite-based diagnosis.

² OIE—World Organisation for Animal Health

³ WHO specified the International Food Safety Authorities Network (INFOSAN) in 2004

⁴ The Rapid Alert System for Food and Feed (RASFF) is a system which has been in place since 1979

5. *What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?*

5.1 Sharing experience, knowledge and expertise is a key component in global efforts to prevent and control the four diseases. The UK has considerable technical expertise in a range of scientific aspects of disease control and prevention, and the potential to contribute substantially to this. TB is used here to illustrate the issues posed.

5.2 Trends are determined by factors outside the UK and control measures must include interventions applied globally. This might be helped by better coordination of UK funded TB work carried out in the UK and overseas. Consideration should be given to the funding of an international group/section whose remit is primarily to work overseas in countries with a high incidence of TB, and/or drug resistant TB with the aim of supporting their national TB control efforts i.e assist in solving the problem at source. Such a group exists within the USA Centers for Disease Control (CDC). The USA supported the Mexico TB programme through the CDC, and was cost effective. This approach would work best with direct co-operation between DH and DFID and agencies such as the HPA.

5.3 Emergence of drug resistant strains including those resistant to virtually all effective anti tuberculosis drugs is a serious problem. More rapid identification of drug resistance is now possible for many drugs but further research is needed to develop better diagnostic systems for many second line drugs and for new agents. Better co-ordination to plan and implement phase 1, 2 and 3 clinical trials of new drugs is needed across the EU and in countries where the need is greatest but which have the poorest resources. Improved joint co-ordination and implementation between DH and DFID and UK agencies could assist in this regard as current activity is largely left to USA organisations. Despite considerable funding to the WHO the UK has relatively little influence on the direction of WHO activity compared to other countries who frequently contribute less but take an active role in influencing global policy.

5.4 Lack of a new drug (since the 1970s) or a vaccine (since BCG, which is not particularly effective). A number of new candidate drugs and vaccines are currently being developed. Further funding of this work will help in which UK expertise and funding is joined to current international activity funded through the Gates or Global Fund or Wellcome Trust.

5.5 Poor markers of cure in drug resistant TB patients eg, although guidelines exist, in practice it is a long and uncertain process to determine when such a patient is truly non-infectious and cured.

6. *What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?*

6.1 The HPA's role in combating communicable disease in general includes: infectious disease surveillance; providing specialist and reference microbiology and microbial epidemiology services; co-ordinating the investigation and response to outbreaks and other communicable disease threats and incidents; providing evidence-based expert advice and guidance to government, health professionals and others with a responsibility for the control and prevention of infectious disease, and to the public, undertaking research, teaching and training; and providing the national focal point and competent body functions for the UK in meeting international obligations and coordinating international collaborations in communicable disease control and prevention. The continuing emergence of new or re-emergent infectious disease and growing expectations on the protection of health at the individual and population level are putting significant strains on the Agency.

6.2 Key partners in the work of the Agency in combating infectious diseases are the NHS, Local Authorities, Department of Health, the Food Standards Agency, DEFRA and the VLA, and international bodies such as the WHO, the EU and ECDC. The degree of synergy varies.

6.3 Funding to enable the HPA to engage more in international work to track infections that threaten our population is needed. This issue was addressed by a previous Lords Committee (The House of Lords Science and Technology Committee, 4th Report of 2005–06 session on Pandemic Influenza published 16 December 2005. <http://www.parliament.uk/hlscience/>). To quote: The Government should also make every effort to ensure that the efforts of United Kingdom departments and agencies in both animal and human health are fully co-ordinated. We therefore recommend that the Government review the current rules governing funding of HPA activities overseas.

7. *What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient “joined-up” thinking in approaching the problem?*

7.1 Poverty, international migration, conflict leading to dispersal and displacement of populations, increased ease and rapidity of travel and behavioural changes (see also 1.1) all contribute to spread. Alleviation of poverty attacks the root cause of TB and malaria. Successful TB control can be achieved through TB programmes such as those operated in some parts of Africa and Asia, but co-infection with HIV compromises these efforts. Better integration of TB and HIV control measures will assist in the control of both diseases. Laboratory support for diagnosis is identified currently as a major weakness, and increasing funding to the sustainable development of new laboratory facilities globally is important.

7.2 For AIDS in particular there is a need to further address social drivers, notably the low status of women, homophobia, stigma and inequalities.

7.3 Avian influenza is primarily a zoonosis spread by birds. The two main routes of spread are migration and commercial poultry operations; smuggling of wild birds also presents a potential route. Improved surveillance and the sharing of these data amongst countries would enable better preparedness and response. Improving compliance with regulations relating to animal husbandry to identify diseases early and the registration and accurate transit documentation of farm animals would enable potential sources and routes of infection to be identified.

8. *Cases of Tuberculosis fell progressively in the UK until the mid-1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of Tuberculosis infections in Britain? And how could intergovernmental action help to reverse the trend?*

8.1 The annual number of TB cases reported in the UK now exceeds 8,000 (8497 in 2006). The main factors responsible for its re-emergence TB are immigration from high incidence countries and the rise in HIV infection. Other factors include ongoing outbreaks in population sub-groups such as the homeless, injecting drug users and prisoners. Although travel to high incidence areas, poverty, poor housing and health infrastructure on UK trends is likely to be small, enlargement of the EU encompassing countries with a high TB incidence or high rates of drug resistance poses new risks. A greater integration of social and health services to create a “one-stop approach” in which residency, accommodation and health issues can be addressed simultaneously is needed.

9. *Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions—eg HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?*

9.1 The global rise in cases of tuberculosis is primarily related to the HIV pandemic, especially in sub Saharan Africa. Other factors such as poverty, lack of or breakdown in health care services/infrastructure, conflicts and migration have played an important role. The most recent global assessment of the WHO’s Directly Observed Therapy—Short Course (DOTS) strategy for tuberculosis suggests progress is being made worldwide. Diagnostic and treatment facilities are, however, lacking in many parts of the world. This is especially the case for drug resistant forms of tuberculosis. A short fall of \$1.1 billion in funding was estimated for 2007. Global diagnosis of TB remains seriously short of international targets; such delays permit a greater spread of infection and in the case of drug resistant TB leads to a higher mortality particularly in individuals co-infected with HIV. Improvements in laboratory diagnosis and treatment facilities are required.

10. *To what extent do you believe that the 2004 Stockholm Convention limiting the use of DDT against Malaria-carrying mosquitoes has been a factor of increases in the spread of the disease? Has any risk analysis been carried out comparing the relative dangers to human health posed by DDT and Malaria?*

10.1 In the pre-amble to the Stockholm Convention on Persistent Organic Pollutants, there is mention of the desirability of replacing DDT house spraying against malaria mosquitoes by equally effective and affordable alternatives, if and when these become available. However, there is a detailed amendment in the Convention which specifically authorises continued indoor use of DDT against disease vectors using WHO approved

methods. The amendment accepts that outdoor use of DDT against agricultural pests should be banned because of the evidence that DDT harms wildlife. There is evidence that lack of use of DDT contributes to increases in infection.

10.2 After 50 years of successful use of DDT in South Africa from 1945 to 1995 they switched to pyrethroid spraying. Within four years, one of the two important malaria transmitting species in southern Africa, *Anopheles funestus*, evolved resistance to pyrethroids, and incidence of malaria cases increased four-fold. Switching back to DDT spraying in 2001, and adopting Artemisinin Combination Therapy as first line anti-malaria drug in 2002 led to a 91% decline by 2004 (Maharaj et al, 2005, S.Af Med J 95: 871–4). With South African assistance parts of Zambia and Mozambique have successfully taken up indoor spraying with DDT.

10.3 There have been numerous published reviews of the evidence about possible adverse effects of DDT on human health. Most show no convincing evidence of such adverse effects. A long term detailed study in Guyana showed the beneficial effect of DDT on maternal and infant survival and on live birth rate over three decades (Giglioli 1972 Bull WHO 46: 181–202). The implications are that the beneficial effect of DDT used to eradicate malaria far outweighs any adverse effects.

11. *What intergovernmental action is planned or in hand for early detection of the transmission of Avian Flu from birds to humans and of human-to-human transmission in potential source countries? Is this proving sufficiently effective to prevent an Influenza pandemic? What more could be done?*

11.1 WHO is the principal coordinator of global intergovernmental action in relation to the human aspects of avian influenza; the OIE coordinates the animal aspects of avian influenza. WHO, in addition to coordinating action with OIE, has taken action in three areas; surveillance, investigation and management of incidents and international control measures. The WHO Global Influenza Surveillance Network, comprising four collaborating centres and 121 institutions in 93 countries, established to collect data on circulating strains of influenza to inform the composition of influenza vaccine each year, now serves as a global alert mechanism for the emergence of influenza viruses with pandemic potential eg, the current avian influenza H5N1.

11.2 International investigation and support to avian influenza incidents affecting humans is channelled through the WHO Global Outbreak Alert and Response Network (GOARN) established in 2002.

11.3 The 2005 revision of the International Health Regulations (IHRs) includes specific provisions for reporting and response to public health threats, including avian influenza. In June 2007, the HPA became the National IHR Focal Point for alerting the WHO of UK incidents of international significance. In addition to WHO, the ECDC, is increasingly becoming a focus for the coordination of action on avian influenza in Europe. The Global Health Security Action Group (GHSAG) of the G8 countries, of which the UK is a member, is also committed to coordinating intergovernmental action on pandemic and avian influenza in the G8 countries and is currently identifying research gaps with a view to developing a combined and coordinated research effort in this area.

11.4 Strengthening and supporting the analytical and epidemiological capability of the HPA contribution to WHO and ECDC could improve further the exchange of information and contribution that the UK can make to effective intergovernmental working.

12. *To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?*

12.1 Between 5 and 10% of cases of tuberculosis worldwide are caused by drug resistant strains. Increases in the numbers of drug resistant cases are being seen, including increases in multi-drug resistant cases. The current global cost of treating cases with resistant strains exceeds that for all the remaining cases combined. Poorer countries with a significant case load have insufficient resources to effectively provide care for these patients. Such patients have a high mortality particularly if co-infected with HIV.

12.2 *Plasmodium falciparum*, which now accounts for over 75% of the malaria cases seen in the UK is the most pathogenic species of malaria parasite and, if untreated, can give rise to potentially fatal cerebral malaria and other severe and complicated forms of malaria. It has become resistant to chloroquine (CQ) in all but a few malarial areas. Resistance to antifolate drugs has been reported in Africa, and to those and many other drugs in SE Asia, including worrying early reports of possible emerging resistance to the new artemisinin based drugs. Resistance to CQ is also now reported in *Plasmodium vivax*.

12.3 Intergovernmental action against malaria (including drug-resistance) includes the WHO Global Malaria Programme (previously “Roll Back Malaria”), the Global fund to Fight AIDS TB and Malaria (set up by G8 in 2001) and the Medicines for Malaria Venture (MMV) which receives funding from a variety of international sources, including Dfid.

13. *In a number of countries, including the UK, there is a problem with hospital-acquired infections. What intergovernmental sharing of knowledge is taking place to help bring this problem under control?*

13.1 There is a lack of a co-ordinated information sharing system directly between governments on healthcare associated infections. This will become increasingly important as healthcare provision within the EU becomes a common market. There are a number of significant barriers such as which infections are counted (including the definitions used for infection types and the different ways in which rates of infection are calculated), and the differing levels of mandatory reporting between countries. The differences between healthcare systems (eg state, insurance based, private) also complicate matters.

13.2 Most European countries submit data to the EARSS (the European Antimicrobial Resistance Surveillance System); this provides useful comparative data between countries on the extent of antibiotic resistance in bacterial pathogens associated with healthcare associated infections. This information is distinct from the rates of different types of healthcare associated infections.

14. *Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?*

14.1 Intellectual property and effective patents are an essential mechanism in providing an incentive for companies to invest in new anti-infective drugs and vaccines, and indeed there is some evidence that the current period of patent protection may not be sufficiently long to make drug development attractive to investors. Certain pressure groups and governments of lower income countries have taken the view that patents inherently impede the flow of cost-effective medicines to those infected. This has proved particularly controversial over the past decade in the case of HIV drugs, resulting in a series of compromises in which pharmaceutical companies have drastically reduced prices in lower income countries. In the case of fast-moving scientific areas such as pandemic influenza vaccines, patents covering “enabling” technologies could hinder development if not effectively developed or licensed to others by the owner and, on rare occasions, this might give rise to a case for compulsory licensing. This is an area that might usefully be kept under review by an intergovernmental forum.

14.2 It would be inappropriate to tackle individual isolated problems by introducing general intergovernmental measures that may well be counterproductive. There may be scope, however, for agreement on “best practice” to underpin a responsible global approach to the development and use of intellectual property. This might include, for example, discouraging attempts to patent the sequences of newly emerging viruses or virus strains in a way that restricts the development of counter measures, or encouraging public sector organisations to adopt patent licensing strategies that ensure competition and that favour developing countries.

15. *What interchange exists between States in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?*

15.1 Intergovernmental knowledge and training is largely facilitated by the WHO. Furthermore, within Europe, the ECDC co-ordinates activities which support the exchange of knowledge between member states. For TB, informal networks such as the International Union against Tuberculosis and Lung Disease and its European branch and the European Respiratory Society all contribute to the exchange of knowledge and training.

16. *The International Health Regulations 2005 are intended to provide a global framework for the rapid identification and containment of public health emergencies. How effective do you consider this response system to be? Do improvements need to be made?*

16.1 The new reporting arrangements under the 2005 IHR have been in operation since June 2007. The system appears to provide a more sensitive and focussed mechanism for alerting WHO and member states to potential threats than previous systems operated by the WHO. There is, however, room for improvement, both in the speed with which WHO undertakes its risk assessment of reported incidents, and in the mechanisms used for

alerting countries to potential public health events of international concern (PHEICs). Improvements are also needed on harmonisation of quality of risk assessment to inform whether IHR reporting is warranted, and if warranted, to better inform recipients of the alert.

17. *What intergovernmental planning has been undertaken to cope with the impact of an outbreak of infectious disease caused by deliberate release of micro-organisms into the environment? Is there adequate liaison between the various agencies involved, including intelligence, law enforcement and health care professionals? How could action by intergovernmental bodies help further?*

17.1 The intergovernmental planning to reduce the impact of an outbreak of infectious disease caused by the deliberate release of microorganisms into the environment has taken place through initiatives led by the Health Security Committee of the European Commission (ECDC is a member), and through initiatives led by the GHSI of G7 (of which WHO is a member).

17.2 There has been adequate and indeed very good liaison between the agencies involved including intelligence, law enforcement and the Health Protection Agency in the UK. Intergovernmental actions include the UK hosting a forensic epidemiology workshop for G8 member states and the design of a training course for the EU. The WHO has also been active in this field and published a response manual. The UK has an excellent record in using exercise scenarios to test and improve plans. The EU has commissioned the UK to provide exercises. Future action by intergovernmental bodies should build on this UK experience by utilising the exercises in many more countries.

17.3 The threat of smallpox has been reduced by the actions of WHO and intergovernmental initiatives in the Global Health Security Initiative (GHSI) of G7 through measures to improve recognition and response and stockpiling of vaccine.

18. *Though our remit is focused specifically on known infectious diseases, we would be interested to know how you view the global threat from new or previously unrecognised ones and from the transmission of infections from animals to humans*

18.1 All of the issues raised under Q1 are also factors here (see also New and Emerging Infections—the Threat to Europe. Borriello, P Eurohealth 11:7–8). Roughly one new disease emerges each year, nearly all from contact with animals. Some of these have the capacity to form global epidemics (HIV), others cause locally significant outbreaks of disease with human and economic consequences (Nipah).

19. *What resources (subscriptions, staff, training, medicines etc) does the UK Government commit to intergovernmental bodies to help in the fight against the four diseases listed?*

No response.

20. *Do you wish to provide any other relevant information in addition to what you have said in answer to the above?*

No.

January 2008

Examination of Witnesses

Witnesses: PROFESSOR PETER BORRIELLO, Director of the HPA Centre for Infections, PROFESSOR MIKE CATCHPOLE, Deputy Director (with special responsibility for public health), PROFESSOR FRANCIS DROBNIEWSKI, Director of the National Bacterium Reference Unit, and PROFESSOR PETER CHIODINI, Head of the Parasitology Reference Laboratory and Director of the HPA Malaria Reference Laboratory, examined.

Q137 Chairman: Welcome to the Intergovernmental Organisations Select Committee. Thank you for your time. You ought to know that this session will be webcast. Also, you will see a transcript of the evidence, so if there is anything you want to correct of a factual nature you will have an opportunity to do so. Although questions might come directly to individuals, all of you should feel able to add

something if you think you have something important to say. If after this hearing you think there is something important that has been left out, perhaps you could tell us about that and write to the Clerk. That would be useful. When exactly were you set up?

Professor Borriello: We were formed in 2003 and I think the Act was 2005.

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Q138 Chairman: You were born before your conception!

Professor Borriello: Some people have a different interpretation of that.

Q139 Chairman: From your evidence, you seem to take the view that the middle two quarters of the last century were very good on international health but that now some of those gains are being offset. I think you pick out globalisation, urbanisation and drug resistance. Am I understanding you correctly in saying that? And, secondly, what about the resistance issue, the resistance particularly of animal to human microbes? We want to have a clearer understanding of that.

Professor Borriello: It is easy to forget that primarily we are in a golden age of health protection. It is very easy to look back and think things must have been better because we now have new, emerging infections. SARS obviously caused a lot of public and governmental concern but we responded very well to that. AIDS is still a major problem. It dominates people's view of risk. When most of the population's concern about infections risk is more about the possible side effects of the vaccine than the disease itself, I think that tells us something. When parents no longer worry about polio or diphtheria and many other diseases that used to just lay waste to our population—smallpox is now eradicated—then I think it is a little easy to think all the problems are now and not in the past. I think we have overcome many problems but there are increasing pressures that increase the risk of the emerging new infections spreading quickly as well as some existing infections, which of course are not fully eradicated, re-emerging. One is, of course, complacency on those that we no longer consider dangerous and therefore people are more willing not to have a vaccine or take other protective mechanisms. The other issue is increased globalisation, so it genuinely is the case that what you ate for breakfast today might have been in another country yesterday. There is also increased travel. That mobility, that flexibility, increases the risk of transmission of an infectious disease happening much more quickly than it used to in the past.

Q140 Chairman: And drug resistance?

Professor Borriello: Drug resistance has always been with us. Of course it would not emerge as readily and become as apparent until you had drugs you were using to kill the germs with, almost by definition. Otherwise, nobody would be interested in looking. There is increasing concern—I think rightly so—that the spread of resistance between germs is now so fluid and so capable, particularly multiply antibiotic resistance capability, where increasingly we are learning that those bits of the DNA that give

resistance can be transferred as a block with lots of different resistance in it, not just one at a time, that it is causing people concern. The ability to create new classes of antimicrobials that work in an entirely different way to regain the upper hand becomes increasingly more difficult.

Q141 Chairman: Do you foresee a particular problem on the HIV-TB one or not?

Professor Borriello: Of course, resistance is a problem in both organisms and becoming an increasing problem. One of the lessons we learned from antibiotic resistance in bacteria was that you are better off giving more than one antimicrobial at the same time, because that minimises the risk of one resistance appearing and then the other one. In crude terms, you just bash it hard and big. That has been quite successful for HIV so far but of course there is resistance emergence.

Professor Catchpole: As I am sure Committee members are aware, resistance to the HIV drugs that we have has developed but the alarmingly rapid progress in the early stages would seem to have been slowed at least by the use of multiple therapies and it may well be that, as pharmaceutical advances move on, we can add to that multiplicity. It remains a concern but I think prompt action when it was recognised and the role of surveillance in recognition are important. It has helped us to perhaps slow down what we thought was looking like an alarmingly rapid process in the early days.

Professor Drobniowski: For TB the situation is perhaps more grim. Certainly we have seen a year-on-year increase in the numbers of cases of multi-drug resistant tuberculosis, globally which is a benchmark for the most severe form of drug resistance in tuberculosis, and there are relatively few new drugs under development. There have been a number of international initiatives to try and bring new drugs to market and some of them are reasonably successful. It is very safe to say that the numbers of drugs are relatively small, particularly in terms of new classes which were mentioned earlier on, so we are seeing high rates of multi-drug resistance, particularly in Eastern Europe for example, and also in parts of China and parts of India.

Q142 Chairman: Although it has to have an understanding of the diseases concerned, this Committee's primary focus is on the Intergovernmental Organisations and the way the UK Government can work through them. Do you think either the World Health Organisation or the Intergovernmental Organisations could make any changes in the way they are working at the moment in order to deal with the problems that you have just been talking about?

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Professor Borriello: There may be a need for more interaction on accepting common approaches to antimicrobial prescribing. One of the things that is very different throughout the world is antimicrobial prescribing as well as access to antimicrobials. A number of countries have over-the-counter, unrestricted sales and a number of countries do not. The hard evidence as to the extent to which that difference in access contributes to the resistance seen in those countries is not as readily available but some agreement and discussion based on evidence that should be generated to better inform prescribing practice could be useful at an intergovernmental level because, just like germs now can travel easily on a human host, so can their resistances.

Q143 Lord Avebury: Which International Organisation should be doing that work?

Professor Borriello: From my understanding of it, I would suspect the WHO would have an immediate mandate to at least raise the issue and try to convene such meetings through its Regional Offices.

Professor Drobniowski: Certainly the WHO has taken a significant initiative in addressing multi-drug-resistant tuberculosis, speaking specifically on that. For example, a global task force was called about a year and a half ago and that created a blueprint for further activities and action that were needed. This was a mix of strategic implementation but also technical implementation and technical requirements that were felt essential to achieve the strategic goals. For example, the ability to diagnose drug resistance much earlier was considered to be something of great importance. The WHO certainly has taken a lead along with other organisations: for example, the Foundation for Innovative and New Diagnostics, which is based in Geneva and has a close relationship with the WHO and in terms of new drug developments, the Global Drug Alliance, based in New York and, more broadly in terms of new TB vaccines, the AERAS Foundation. Certainly there has been a broad, strategic examination and leadership from the WHO in that area.

Professor Chiodini: I wonder if I can add a little bit on antimalarial drug resistance because this is the single biggest factor in the severe malaria situation which we face at the moment.

The Committee suspended from 4.25pm to 4.35pm for a division in the House

Drug resistance is a major factor in the deteriorating malaria situation. We lost Chloroquine in the Far East in the 1970s, in Africa through the eighties, which was associated with increased child mortality as treatments were failing and now it is effectively useless in sub-Saharan Africa. Similarly, sulfadoxine pyrimethamine is essentially unhelpful in that area, so the WHO is

moving now to combination therapies. We have few drugs coming through the pipeline and that creates a big issue for us. There are some useful Public Private Partnerships, and indeed Baroness Chalker from this House chairs the Medicines for Malaria venture. I am sure you will be speaking to her about it later in the course of this. That is an example of an excellent Public Private Partnership. It is fair to say that even with that the need for new drugs to come through when the current treatments fail, as all treatments eventually do with malaria I am afraid, is an imperative.

Q144 Chairman: They all fail eventually?

Professor Chiodini: The parasite that causes fatalities from cerebral malaria or severe anaemia in children is very adept at becoming drug resistant. Once it has become resistant to one drug, its ability to become resistant to others seems to be more rapid. For example, in South East Asia after Chloroquine we had multi-drug resistant malaria. All we were left with at that time was Quinine. SP (Sulfadoxine plus Pyrimethamine) and Chloroquine had essentially gone. There are already reports of possible resistance to the Artemisinins and those await confirmation, but it is unfortunately a fact of malariology that eventually drugs do fail and we have to be prepared for that and have other drugs in the pipeline. It would be a shame if what is currently an excellent treatment giving dramatically good results were to lull us into a false sense of security. We need a continuing pipeline of drugs to back that up.

Q145 Chairman: If you think of any further ways in which the WHO or the Intergovernmental Organisations can address the concerns you have raised, please let us know.

Professor Catchpole: Can I add a thought on the role of the European Commission? I was at a meeting of the European Centre for Disease Control, which I know we are going to talk about, at their Advisory Forum last week with the representative of the European Commission, DG Sanco. It was mentioned that antimicrobial resistance has been flagged up at a meeting of the three countries that have the next three Presidencies. They have all indicated a particular interest in antimicrobial resistance as a public health issue. That does present an interesting and exciting opportunity because the Commission, of course, has competences and responsibilities not only in the area of health but also in terms of industry. That is what we need to tackle. This problem is where health and industry are working together.

Q146 Lord Howarth of Newport: Professor Chiodini, whose responsibility is it? Where does responsibility lie for commissioning the next

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generation of drugs, for ensuring that that research and development occurs?

Professor Chiodini: It is a very good point because, unlike, if one were looking at a Cholesterol-lowering drug for example, the market for antimalarials is overwhelmingly in the Tropics, where there is little money to pay for the drugs. Thus, for a pharmaceutical company looking at the product they want to develop, an antimalarial would not be a big money-spinner for it. There is some money to be made from antimalarial prophylactic drugs but, again, that market is not enormous compared, say, to Cardiovascular drugs. Thus, I think this is one area where intergovernmental cooperation combined with the WHO should be involved in the kind of public private partnership that I have mentioned, so that funding can be put in to make it more attractive for manufacturers to produce drugs. At the same time, we already have good examples of the pharmaceutical industry donating drugs, for example for filariasis control. Thus, with some imaginative funding up front to get the thing running, developed and then put through the various clinical trials, thereafter there is an element of *pro bono* that one might hope for from industry in there. I do not think they are ever going to make very big money out of antimalarials, so there will always have to be some incentive for that.

Q147 Lord Howarth of Newport: I think you are saying to us that, with the present structure, that decision is not going to be taken. It is not foreseeable going to happen. Is that correct? If so, how do you think structures should be reformed to ensure that a new generation of antimalarial drugs is developed?

Professor Chiodini: I think the situation is now much better. I did mention the Medicines for Malaria venture, which is hoping to get a new antimalarial out by 2010. It is with that kind of model that I think the compounds can come through. There are many basic scientists looking at antimalarial chemotherapy and plenty of promising new compounds, and the mechanisms through public-private partnerships do exist. I think they could do with more support. Everybody makes a plea for funding but until very recently malaria has always been very much a poor relation and yet more needs to be put into that.

Q148 Chairman: Professor Catchpole, you led us on rather neatly to the European Centre for Disease Prevention and Control. I note you are a member of it and I note also that the evidence from the HPA is quite critical of this organisation. I know it is fairly new but I would be grateful if you could spell out what that criticism is. What is the link between the ECDC and the WHO. Is it good? Is it bad or is it just not functioning? Is it not built up yet? It is hard to get

a picture from what you are saying as to how this is working or whether it just needs time.

Professor Catchpole: Just to provide a little context to our response, which I think very much focused on the “areas for improvement” question that was put to us, the important thing is that the response is paraphrased in the “likely areas of questioning” paper: “. . . ECDC has yet to demonstrate any added value . . .”. The point we were making is that in one of the areas of ECDC’s activities, which is surveillance, there have been some issues. I will come back to those but I think it is important to make the point that ECDC has delivered added value in some of its other areas of work. For example, in the provision of scientific advice, it did a very good job of summarising the evidence for the effectiveness of the many different interventions that we might need to look to to deal with pandemic influenza. It has done a lot of work in developing training to improve the capacity of some of the newer Member States in their epidemiological response capacity. It has also done a lot in terms of improving some of the communication processes we have by managing information systems. But in the area of surveillance ECDC was not created in a vacuum. For the last two decades there have been a number of European-wide surveillance collaborations largely funded by the European Commission for diseases such as Legionnaire’s Disease and Salmonella. Those have provided a lot of added European value over the years. With the creation of ECDC, the strategy is to move the coordination function for those surveillance initiatives from the host institutes which are based around Europe—some of them were hosted by the Health Protection Agency—to Stockholm. In a way, it is a tall order to ask ECDC to provide additional added value for networks that were already there. ECDC’s main challenge is to improve the standard of all those surveillance networks. What they have yet to do is bring up all surveillance networks to the same standard.

Q149 Chairman: Your criticism is that this is work in process but they have not demonstrated they have done it yet. Is that right? Or are you saying that they have not quite got their act together and thought about it?

Professor Catchpole: They have clearly thought about it. They have not yet got the systems and structures in place. I think it has taken them longer than probably they had anticipated to put some of those systems and structures in place. You quite rightly picked up on a comment about degrading assessment and response. There have been a couple of examples in the early days of their establishment where we felt that we had to push them on the response to, say, salmonella outbreaks, but I think things are moving

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on. Just to put it in context, given the word limits we had, we focused on the areas for improvement. In terms of the interaction with the WHO, that is an interesting question. I have been involved in a couple of joint exercises which involve both the World Health Organisation European Office particularly and ECDC, looking at how they would respond to an emergency, such as a Viral Haemorrhagic Fever case coming back on an airliner with people from all over Europe. They are running exercises together which are helping flush out both the synergies and tensions between the organisations, and there have been tensions. They are putting in place shared surveillance activities, on, for example, TB with HIV. There will be a single managed surveillance system, as there has been, but that will be hosted in ECDC, collaboratively run with the World Health Organisation European office. There are clear examples of how they are working together.

Q150 Chairman: Is that working at the international level of the WHO or the European level?

Professor Catchpole: That is working at the European level but ECDC, I believe, also has contributed to discussions at the global level. For example, there has been a recent need to review some of the procedures and protocols around dealing with multi-resistant TB passengers on airlines. An area which is clearly an area of unresolved tension, for want of a better phrase, between the World Health Organisation and ECDC is the area of the new International Health Regulations and the reporting requirements that those place on all signatories, which include ourselves, to report public health emergencies of international concern to the World Health Organisation. At the moment, interestingly, ECDC does not have access to the World Health Organisation's information website where it displays all reports because ECDC have to be a national Member State. They are not a recognised, legal, international entity or something like that. It may be that with the passing of a European declaration ECDC may then take on that mantle which will allow them to have access. There is a line in the International Health Regulations which was expressly put there so that the European Commission and the European Union could potentially be a fully signed up member of the international regulations. That is the one important area where I see that there is still some tension about whose role within Europe it is—whether it is the WHO European Office's or the ECDC's role to deal with this.

Q151 Lord Geddes: Professor Catchpole, an extremely direct question: on balance and from a global perspective, would we be better off without the ECDC?

Professor Catchpole: No.

Q152 Lord Geddes: What is it contributing?

Professor Catchpole: Do you want me to answer that purely from a UK perspective? What it is contributing for us is that it facilitates considerably our ability to communicate with colleagues around Europe, particularly the newer Member States and the Baltic states, where for example we not too long ago had a case of an individual from this country who unfortunately died of an infectious disease in one of the Baltic states. We needed to undertake a risk assessment where they acquired their infection, in this country or in the Baltic state, and who would need to be offered appropriate prophylaxis and treatment. ECDC greatly facilitated making sure that we could communicate with them, putting us in contact with the right people. If we had an issue about not getting a response, they pushed on that. From a UK perspective, that is one small example. There are others. More broadly from a European Union perspective, if you put that question to someone from one of the smaller states in Europe they would say they absolutely feel that they get huge value from knowing that ECDC is there. We are fortunate in this country. We have a tremendous resource of experts and expertise that can provide us with information and advice on how to deal with SARS or other emerging problems. They do not have that expertise and depth in other parts of Europe.

Q153 Chairman: Including the Euro Office of the WHO? Lord Geddes, in a sense, is right. Why two? Why ECDC and the WHO Euro?

Professor Catchpole: If you compare ECDC to the WHO's European office, ECDC has more resources in some areas, particularly in terms of its ability to provide resources on infectious disease issues, than are available in the WHO European office. It provides additional capacity and competence and it provides additional capacity and confidence in areas where it is needed.

Q154 Lord Avebury: I have a question about RASBICHAT, which is mentioned as providing an early alerting capability between Member States of the European Union. Does that belong to ECDC? Or is it entirely separate from it?

Professor Catchpole: It belongs to the Commission. Even the system that is operated by ECDC for communication on purely infectious disease issues, although it is technically managed by ECDC, is owned by the Commission. It is formally the system for the Commission to communicate with Member States and for Member States to communicate with each other. All of these systems are owned by the Commission.

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Q155 Lord Avebury: Similarly to Lord Geddes's question, I wonder why we need to have RASBICHAT, when you say it is a similar system to the Global Health Security Initiative. Surely there ought to be one worldwide system for early alerting of incidents which may lead to serious infectious diseases spreading?

Professor Catchpole: We agree with that.

Q156 Lord Avebury: You do not think there is a need for these two organisations?

Professor Catchpole: I agree it is helpful to have a common communication system but what then follows on in terms of the risk assessment, the provision of expert advice, the coordination of response may not mean that it is just one organisation.

Q157 Lord Avebury: Are you talking about IT systems in these two acronyms here?

Professor Catchpole: Yes.

Q158 Lord Avebury: Do the IT systems have common protocols?

Professor Catchpole: They do not at the moment.

Q159 Lord Avebury: How appalling.

Professor Catchpole: There has been a lot of discussion about the system that the European Commission and ECDC operate called EWRS, Early Warning and Response System and about countries like ours being able to use that to report to the WHO under the International Health Regulations. The WHO have said they are prepared to receive reports in that way but all further communication under the International Health Regulations requirements they would not make through that system. They would choose to communicate back to the Member States through a different system.

Professor Borriello: I feel quite strongly that there is an intergovernmental role in looking at all the different early warning and response systems that exist and also their interoperability. There are some cases where there do need to be some separate systems and more dedicated, different access because the customer base may be different. For the ones on security and bio-terrorist response, they would need a particular group of users and reporting lines and also each of the nation states would wish certain offices to be alerted and not others, for example. There are also the food ones. They have been set up. Even within Europe there are food alerting systems which are not the same. If you have a food-borne outbreak and there is Salmonella in food affecting multiple countries, as a focal point both the International Health Regulations and the EWRS, which is the role the HPA plays for the UK, do we go to EWRS and

then IHR? Or do we go to both? Is there such a circumstance when it would only be one and not the other? Whose role is it to alert the food alerting systems if it is a food-borne pathogen? One can see why these systems arose. Although there is some complication, it is important to remember that we are in a much stronger position now than we were to the extent that in the early days you needed some refining to take the noise out of the system.

Chairman: I have picked up from elsewhere that there is a concern about the international surveillance system and some restructuring needed. If you want to give some thought to that, as to what sort of organisation would be required, we will be taking evidence on that on a further date down the line. If you have any views, I would like the Committee to see them.

Q160 Lord Desai: If the only point of ECDC is that the Euro section of the WHO does not have enough resources, would it not be better to give resources to the WHO and not have ECDC? That would save duplication.

Professor Borriello: ECDC was established by the European Union to which all nation states have an input and a vote and they agreed to its establishment. The debate as to whether or not those functions could have been discharged by an existing body—I would be surprised if that was not debated—I think is above my level to respond to. They do discharge slightly different functions.

Q161 Lord Desai: Do they interfere? Do they make it more difficult to coordinate response?

Professor Borriello: The issue that we have already alluded to is that there needs to be some clarity in certain areas between the WHO Europe and ECDC. They are in those discussions but the debate on the extent to which another body that already existed could have undertaken those functions must have taken place elsewhere. It was not one that we were engaged in.

Baroness Falkner of Margravine: I slightly disagree with the premise of your question. In addition to the political or institutional factors which you pointed to in terms of how it was set up and why, would it not also have a logic in its existence, ECDC, in the future direction of travel, which is to have a more integrated Europe-wide healthcare approach? As our systems are becoming more integrated, as people are travelling across the boundaries, there is a more Europe-wide national health market being created and that would seem to me to be the logical direction.

Q162 Chairman: I understand your point but we are in danger of drifting into the European Community here. Do you have a quick response to that? I am not

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saying it is irrelevant but there is a distinct dividing line between what the House's European Union Committee does and what we are doing.

Professor Borriello: At the intergovernmental level, as healthcare provision becomes more plural within Europe, there does need to be a body that looks at healthcare acquired infections for example, and their associated risks at European level. ECDC as a body could and probably should do that.

Q163 Baroness Eccles of Moulton: The core of my question is the integration of animal and human disease surveillance as a result of the increasing emergence of new infections which are transmitted from animal to human. But, before we get on to the core of the question, I think it would be interesting and useful to know why it is that this particular form of transmission from animal to human is becoming of increasing importance and is an emerging source of infection and, very quickly, what the reasons are. We probably do know them but I think it would be helpful if we could just have that clarified.

Professor Borriello: Zoonose, transmissions from animals to humans, are not new. TB was probably one of the first that we can have some accurate records on. In essence, we need to view ourselves as part of the mammal population of the planet and transmission is not one-way; we also infect animals. In essence, we are part of a big, major, common reservoir but for centuries our concentration on identifying the pathogens and/or combating them has concentrated on ourselves as a species and ignored the rest of the mammal population and others. New diseases emerging? The classic example has to be HIV and probably that is an example of things that have happened many times in the past with other infections. The converse is also true. The reason it happens probably more commonly now is just that we now recognise them more but of course there is increased exposure to wild animals by what you might consider naïve populations. Earlier in our existence there was not a lot of contact. For centuries then there was none other than with domesticated animals. Now there is increased contact either in zoos or with exotic pets or by foreign travel, going to these sorts of places to see wild animals. Then there is pressure in Africa and other parts of the world, the use of bush meat and encroachment. It is increasing the risk. It is considered or thought that SARS probably arose that way by association with bush meat.

Q164 Baroness Eccles of Moulton: It comes much more from animals in the wild than from domestic animals?

Professor Borriello: CJD would be a classic example where that was not true but, by and large, that is probably the case because we have been with domestic animals and husbandry for so long that what is there we have already been exposed to and what is new would be picked up very quickly if it affected animals because of the economic impact on livestock.

Q165 Baroness Eccles of Moulton: If we come to the surveillance point, it says that the two bodies that are mainly responsible for animal and human surveillance are not very integrated. They tend to operate separately. Would you support that?

Professor Borriello: No. I will qualify the no. The animal side and the human side for known zoonose work very closely together. Of course they could work closer still but within this country at least they work very, very closely together. I can give you many examples in writing later if you wish. The one area where that interaction is not sufficiently strong is on what you would call fully integrated surveillance where we can match patterns of human disease and newly emerging syndromes in humans to newly emerging syndromes or diseases in animals and to have the two bits of intelligence in some way brought together, analysed and undertaken at that level. Analysis does take place but it is at the sharing of intelligence around a table level, not at the IT supportive level and that is the next step where we would like to see some improvement. Of course the problem with zoonose in general is that it always falls between two areas of responsibility and it always begs the question who is meant to fund which bit. It is not quite so easy. If it is health, whatever answer we get, we know where to go. If it is animals, whatever answer they get, they know where to go. If it is zoonose, it is so easy to end up being batted backwards and forwards.

Q166 Baroness Eccles of Moulton: Even without that, surely the fact that the emerging infections on the animal side of the equation are in the wild must make it incredibly difficult to track down and get hold of?

Professor Borriello: Absolutely, which is again a totally different thing. By and large, on the veterinary side, it is for the analysis of current livestock.

Q167 Baroness Eccles of Moulton: Very little of it is generated on the domestic scene. It comes out of the wild?

Professor Borriello: Absolutely.

Professor Chiadini: Certainly from my point of view, I deal almost exclusively with parasites and here I am talking about parasites other than malaria, which is not a zoonosis. In many cases the synergy between

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the veterinary specialist and the medics is crucial to control. For example, hydatid disease requires good animal husbandry, de-worming of farm dogs etc. Trichinosis is another good example. Parasites over millennia have taken advantage of the proximity of humans and their domestic animals to infect us. As parasitologists, we rely greatly on liaising with our veterinary colleagues in order to work out control programmes and so on.

Q168 Baroness Eccles of Moulton: It is fascinating, and obviously we could go on talking about sources and all that. But perhaps we should get back to what we are here about, which is what you can see as a way forward in getting closer integration between the animal side and the human side.

Professor Borriello: A number of committees are already now in existence which have full representation of the animal, the human and the food side. The National Expert Panel for Newly Emerging Infections has that plus the Devolved Administrations, so it is fully intergovernmental within the UK. Across the board, though, it is not quite so true in a number of countries abroad where the health, the vets and the food have no linkage whatsoever.

Q169 Chairman: That is a major part of the problem, is it not, in some developing countries?

Professor Borriello: It is, and in some developed countries they have evolved separately. To be blunt, if you went back 20 years in the UK outside parasitology—Salmonella etc.—there was not that much interaction. The Memorandum of Understanding between what was then the PHLS and the VLA, the Veterinary Laboratories Agency, is only about 12 years old. Even for us it was a recent awareness, and structures were put in place to improve that. In many other European countries it does not exist at all.

Q170 Chairman: There is a lot of work to be done there?

Professor Borriello: There is.

Q171 Lord Geddes: What vehicle could be used to achieve that objective?

Professor Borriello: The OIE.

Professor Catchpole: It is the animal equivalent of the WHO.

Professor Borriello: Possibly it is to look at the existing international, intergovernmental bodies and to get them to agree to the creation of fora. In the UK the Chief Veterinary Officer and the Chief Medical Officer meet. I cannot say that was a consequence of BSE.

Q172 Chairman: This might be the question about a new structure for the international surveillance issue. That is what I was asking you to look at and come back to us on, if you could.

Professor Borriello: Yes. Within that we may need to bring in plants as part of that whole environment of disease, infection and transmission.

Q173 Chairman: We want to ask you about bio-terrorism. Can I ask if any of you are constrained on this issue by the Official Secrets Act?

Professor Borriello: I do have clearance but there are no obvious constraints. I will not know if there are any constraints until I hear the question.

Q174 Chairman: If you indicate to me, there is a number of ways I can deal with it. The Clerk is pointing out to me, quite rightly, that you must know at the moment that we are in public session. If that causes you a problem, perhaps you could indicate to me.

Professor Borriello: I will do so.

Q175 Baroness Whitaker: I was interested in not only bio-terrorism but also the International Health Regulations. My neighbour, who was anxious to ask the question originally, says that there was a lot of fear in regard to the Iraqi war in Kuwait that there would be biological attacks made. I am aware that there is quite a powerful convention for chemical weapons. Of course, it does not completely eradicate capacity and the suspicion is that there are chemical weapons around. But at least there is an international norm about chemical warfare. As far as I know, there is no international norm to deter biological warfare. Do you think it would be useful to have one? And would you recommend we take any further steps than those we may be taking to combat the threat of potential biological warfare?

Professor Borriello: My answer to the first part of the question is quite simple, in that I was unaware that there are not any existing criteria on limitations or restrictions on biological weapons for warfare, but that would be my ignorance, not anybody else's. I certainly know that there are committees in existence, international and intergovernmental, that discuss these issues as well as agree on removal of stockpiles and agree on no use of certain agents.

Q176 Baroness Whitaker: International agreements?

Professor Borriello: That is my understanding. Certainly there is an expert in the HPA, among the other experts you have access to, who could clarify that directly, if you wish to put that question, directly in writing.

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Q177 Baroness Whitaker: That would be helpful.

Professor Borriello: The second part of the question was?

Q178 Baroness Whitaker: Was there anything else that we ought to be doing in the absence of a convention?

Professor Borriello: The use of infective agents as weapons, we know, is not new and has happened throughout warfare to varying degrees. The real question is the extent to which natural agents could be used, particularly if there were a fear, of course, of smallpox because the population is now naïve: could somebody release smallpox? The same could be true in the future, say, of polio. As the world eradicates certain pathogens, the population becomes naïve, there are no vaccinations, therefore the release of such an organism, if it is retained, could have quite devastating effects. There is then the issue of the extent to which people could engineer pathogens, could create an animal pathogen to become a human one. Increasingly, our knowledge and the science take us to the position where that can be achieved. That is a slightly different set of control regulations and considerations, the creation of something damaging, to make it more dangerous, more virulent, putting in lots of antimicrobial resistance, putting in masking agents and all sorts of things, but that is quite a degree of sophistication. The fact that that degree of sophistication existed within countries and was developed at State level shows it is possible to do. Could any of that still exist and be made available to terrorists? Or could terrorists ever commission somebody to make such organisms? I think it is on those grounds that there is a fairly concerted global intergovernmental response, saying “How can we control this problem and how can we be better alerted to spot it if it starts to happen?”

Q179 Chairman: There are some agreements on biological weapons actually, but the key bit in a sense, as Baroness Whitaker was highlighting, is that some could be produced on a relatively small scale, almost by individuals; some could be produced in a way that would constrain their development geographically, i.e. they could only spread so far; others could be spread on a much wider basis. I suppose the key question here is how much are the Intergovernmental Organisations looking at that, in your understanding?

Professor Borriello: They are looking very carefully, and one of the surprising things that comes out of most of the analysis is how difficult it is to deliver an agent to cause a massive problem quickly. It is the delivery end which is where most of the sophistication is needed. To be blunt, growing anthrax, even with the restriction of transfer of

anthrax organisms between countries—and there are great restrictions—any microbiologist could go and dig up some soil in country Z and stick it in some broth and grow the thing. It is not that they do not exist; they are all over the place. Growing it to a sufficient level and then weaponising it is where the limitations are. It is certainly true that the risk is high, the desire to pursue such developments is high, and the consequences could be high.

Q180 Baroness Whitaker: The desire to pursue such developments on the part of terrorists?

Professor Borriello: Yes, absolutely.

Q181 Baroness Whitaker: Do you think we would be correct if we devoted attention in our inquiry on how to control this particular risk of infectious disease? Is it a subject of real concern, would you say?

Professor Borriello: I think yes, for two reasons. The key reason actually is a public health one more than a security one, in that any improvement in detection, alerting and responding that might be put in place due to an interest in the threat of bioterrorist release of a pathogen is very good and useful at improving the structure for response to any natural infection.

Q182 Chairman: Can I just summarise that, because it is a very important point? My understanding, certainly the conclusion I have reached so far, without committing myself, is that the natural spread is a greater danger than the unnatural spread or the spread by terrorists but the spread by the latter is a very real danger that we should not under-estimate. Is that a fair analysis of the situation?

Professor Borriello: That is absolutely right and, again, one of the problems is that consequential to any outbreak that has been induced artificially is the associated fear, panic and concern. It is fearful enough in response to a natural outbreak, but the fear then of somebody purposely trying to infect somebody else just adds another dimension to the problems of control and dealing with the public response to such an incident.

Q183 Baroness Whitaker: Are you aware of the Intergovernmental Organisations having a good hold on all this?

Professor Borriello: G8 are actively involved, in which the UK has a very strong presence, of course, and G7. There is also a European Commission global health response based around bioterrorism. One of the alerting systems that was referred to, in saying “Why do we have that?” is put in place exactly because of this issue, which is to analyse the intelligence, to look at natural outbreaks to determine whether or not they really are natural or were a failed bioterrorist threat attempt.

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Chairman: Thank you very much. I want to move on to International Health Regulations.

Q184 Baroness Whitaker: This is meant to help with the surveillance problem, among others. People from the Government have told us about weaknesses they see, that there is no provision for enforcement and that there were problems, for instance, in the case of Indonesia's refusal to share influenza viruses, and you yourselves have said that there is room for improvement. Would you like to tell us what more could be done to improve the implementation of the regulations? Why has this Declaration empowering the ECDC to access WHO data not been made? What is holding it up?

Professor Catchpole: A major role for us is in risk assessment and surveillance and so on. I am going to focus perhaps a bit more on that than on the response side. Clearly, we very much welcome the new regulations. They are a much more all-hazards, risk assessment-based approach, which is much more suited to the patterns that have emerged in recent years—there have been new emerging infections—assessing the risks, determining what a proportionate response is. It is a clear step forward on what we had before. The principle that lies behind those international regulations is that rapid reporting, before it is clear what the risk is, so that the WHO and the reporting country can then rapidly undertake a risk assessment, should allow us to be in a position to try and control something at the source rather than wait for it to be disseminated around the world. All that is good, and clearly there is a lot of support for that, both within the WHO and certainly within Europe, in the Member States I have spoken to. We flagged up that we felt that there was a bit more to be done, particularly around the slickness with which information is moved around and the speed with which risks assessments are undertaken. I was delighted to hear at a meeting in November/December last year that in fact the World Health Organisation are investing quite a lot of time and effort into putting in place a new information system that will actually address some of the issues that led us to say that we felt there was some room for improvement. However, that is largely around the alerting process, the process for rapidly gathering information, the risk assessment, which may then lead to a response. I got the impression that in some ways some of your questions were more about the response side and touching on the Indonesian question. I do not feel so well qualified to comment in detail on that. I do not know whether other colleagues do. I think that in terms of the surveillance and alerting side, the risk assessment side, we very much welcome what we have seen, which is that the World Health Organisation has taken a little bit of

time to get up to speed with their own system but they are clearly getting better at that and we are better off now than we were a year ago.

Professor Borriello: I would like to see the evolution of the IHRs to have a more rapid and broad-based risk assessment. I would like to see more guidance at the front end for people in terms of what is reported in there. What is the definition of a public health event of international concern? I have not seen the definition of that so-called PHEIC. By definition, that is what it is, by its terminology. It is something that potentially could or already has started to affect more than one country of the world within the WHO that we at the moment would be reporting as we have major Salmonella outbreaks, but WHO would do an assessment to say "Maybe that is not that critical and we won't post it." It means there is quite a lot of noise in the system; that is inevitable until the system starts to mature but I think one needs to actively manage that, to have a rapid risk assessment so that the bulletin comes out, you receive it, you read it, and you think, "Ah, that's what it means for me." It is not just a statement and you think, "So what? What does that mean for me?" So the messaging could be looked it.

Q185 Baroness Whitaker: This is lack of capacity within WHO that you are referring to?

Professor Borriello: I think it is simply a learning process but, like all learning processes, unless you flag up issues to be learned early, it means they are not learned till too late or downstream. One of the areas where things could be improved and would involve intergovernmental action, in my view—as well as other bodies with international roles, NGOs and others—is that the International Health Regulations make it quite clear that to have maximum effect you must be able to detect the thing that needs to be alerted in the first place. If you cannot detect it, you cannot alert about it. So you have to be able to detect it, and you then have to have systems in place so that detection results in a message going to the right people for some analysis to be done so it can then go into an international alerting system. Many of the countries where people believe dangerous things could emerge are places where they are weakest at being able to diagnose dangerous things. The WHO has put in place a laboratory twinning programme, for example, so less developed laboratories will twin with more developed ones. They are matched, and then there is some interchange to try and improve the capacity, which must be improved in a sustainable way—not go in, have a chat, have some visits, take some material away and then it is finished. It has to be associated with some form of accreditation or improvement which is sustainable. It is terribly difficult to secure funding

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for that. There must be lots of bodies around the world who are all trying to do the same. One could argue that there be some improved coordination so that through the laboratory-twinning process the WHO has in place, they could say, “We’d provide all the governance, we’d provide all the accreditation read-out and the security. Give us the money. We will do what you are trying to do.” I think things could be improved from within existing resource and it does take intergovernmental interaction.

Q186 Lord Howarth of Newport: We have lamented the deficiencies of coordination between Intergovernmental Organisations but your evidence at 5.3 suggests that there are also deficiencies inside the UK in terms of our capacity to deal effectively with these IGOs. In particular you suggest that our influence with the World Health Organisation is not commensurate with our contribution. Would you expand on those thoughts?

Professor Borriello: Yes, I am happy to. It is similar to the comment about the ECDC, where, due to the page constraints, we did not put all the very positive things; we just picked up on areas where we felt there could be some improvement. Of course, being at the operational end of the business, our definition of policy might be somewhat different to Government and Government Departments. Certainly it seemed to us, at the level of implementation of policy or putting the detail into policy, when at the strategic level there has been in our view very good influence from the UK, in many areas some countries, particularly the United States and others, take a very coordinated, joined-up approach to trying to influence the detail. The detail, of course, can have effects on any given country. We have raised this with the Department of Health and we are already in discussions on how we can improve the way we interact on understanding what is trying to be achieved and to ensure that, when some of our staff and other agency staff in the UK get involved at that flesh-on-bones, dotting—Is and crossing—Ts level, there is a better understanding of what the overall strategy is and what the UK Government position is on some of that. We also mention the DFID issue. I know at the moment, as for all Government agencies, there is a review on how it sources its evidence and makes use of evidence. We do believe that DFID could make more use of the expertise in the Health Protection Agency in forming some of its own decisions on infectious disease, maybe also chemical and radiological areas, and certainly for those areas I think it could draw on the HPA more. Whether it chooses to accept or ignore or modify our advice is a separate issue but I think it could draw on the Health Protection Agency more than it does.

Q187 Lord Howarth of Newport: Can I press you to be as precise as you possibly can and perhaps give us an instance of where the Department of Health’s efforts are falling short, and where in DFID. And are there particular cases where, as you just now suggested, the HPA is not enlisted and involved as it might most effectively be by these departments? Can you give us some examples?

Professor Borriello: Firstly, examples of where it works well, which would be on global security, international bioterrorism, that sort of level; global warming, climate change. There are lots of very positive interactions there. But there are other areas, and we particularly flagged up TB as the example, where, with both DFID and DH involvement on some of these activities, we felt that, if we had been engaged a bit earlier in some of the issues, and then had been as a consequence of that better apprised, we might have had stronger representation at the implementation end with WHO. As I said, those discussions are now in place. Exactly where that should have happened is difficult to say but we are having that discussion now with the Department.

Q188 Lord Howarth of Newport: The Government suggests that one can sometimes be more effective if one is not too keen to be seen to be pulling strings or calling the shots and if you work through others.

Professor Borriello: That is absolutely right, and again there is the issue, particularly in the public perception in the UK; they would not make any differentiation between international interactions and national in that we are an arm’s length body and the reason the Health Protection Agency is respected by the public is that it is believed to be independent of government and its departments. The way we manage that close working relationship actually has some issues within it and we do have to be careful on that.

Q189 Lord Howarth of Newport: In your evidence at 6.1 you suggest that it is down to you to do much of the coordination. You talk of your role in combating disease and so forth; coordinating the investigation and response to outbreaks and other communicable disease threats and incidents; giving guidance to government, health professionals and others responsible for the control and prevention of infectious disease; providing a national focal point and competent body functions, et cetera. Who is supposed to do what? Are you waiting for the Department of Health or DFID to tell you what to do? Or are they waiting for you to take the initiative?

Professor Borriello: These are our UK responsibilities, and it is not fully UK in all areas. Certainly for infectious diseases, that is not the case for Scotland, although it is for International Health Regulations. So there are complexities within the United Kingdom

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in terms of our national role, but all of those issues are functions that we discharge on behalf of the UK Government for our population. Of course, with an infectious agent, using the hackneyed phrase, germs know no barriers, and it is not possible not to have international linkages, particularly when the sources of infection can so frequently be abroad and vice versa. We have international relationships; we do not have international responsibilities. So even our role as the focal point for the International Health Regulations is to notify the WHO on behalf of the UK and its territories and dominions, not on behalf of Spain or to blow the whistle on Poland.

Q190 Lord Howarth of Newport: You suggest that you should be resourced to carry out more international work to track infections that threaten the UK population. What do you have in mind?

Professor Borriello: I will pick up a particular issue on TB, but in general, we did a big study on migrant health and looking at not just the inequalities but of course the demographics of infections in particular groups and where they arise. On that basis, our view is that that should help to inform our international strategy in terms of risk to the UK population over and above just general improvement in global health. So there are areas in which we have to be involved and work closely, and a classic example on TB and, Francis, you had one which you alluded to.

Professor Drobniowski: Yes, indeed. I think there are a couple of ways to pick up some of the questions that you raised, a specific example, but also some examples of how that interaction might occur in an intergovernmental way. For example, USAID, the United States development agency and the Centers for Disease Control in Atlanta have a very strong synergistic interaction through the International Division of the Centers for Disease Control. So USAID sees CDC as one of the principal sources of impartial, unbiased advice at a technical and policy implementation level.

The Committee suspended from 5.31 pm to 5.39 pm for a division in the House

Q191 Chairman: You were in midstream, I think, were you not?

Professor Drobniowski: I was. I had mentioned the close links between USAID and CDC but there is, for example, an umbrella programme that the USAID funds. It is called TB CAP and I think that is a TB Community Assistance Programme. It is a \$150 million programme over five years, where USAID co-ordinates eight major implementers, of which CDC is the largest partner, and in that way USAID is able to nudge those particular implementers in the direction that it wants to go while at the same time learning from them how in fact to actually deliver the

particular strategy that they want. You asked us if there was an example at the WHO where this is important, that we should be intervening at a policy and at a more technical level. Last year the WHO changed quite dramatically the strategy used for diagnosing tuberculosis. The problem that was faced was how do you diagnose tuberculosis in an HIV-positive person? The conventional techniques were very insensitive, were not doing the job and they do not tell you about drug resistance either. So, if you want to know about drug resistance and you want to be able to diagnose TB in that population, you needed new technology. The WHO, through its Technical Advisory Group, endorsed a new rapid technology, and I think it was the right decision. But the immediate two consequences of that were the need to suddenly train hundreds, and indeed thousands, of technicians in what was a fairly complex technology within a short-ish period of time, and also to develop the necessary bio-safe infrastructure in parts of the world which until now had perhaps just used a light microscope in a small room. Those are the two big challenges. How do you now train hundreds of thousands of people in more of a civil defence mode rather than the philanthropic mode that we have tended to use? I and my colleagues in Europe are often asked whether we can we take one or two or three or four people to train them up, but in this sort of problem you really need a strategy that will train a vast number of people or your overarching strategy is going to be derailed, it seems to me.

Chairman: Thank you. We do need to move on.

Q192 Lord Avebury: You said in your evidence in Paragraph 6.1 that WHO is one of your key partners in combating infectious diseases. I wondered if for that purpose you think the WHO is effectively structured and whether its Regional and particularly its Country Offices do their job to your satisfaction.

Professor Borriello: Francis and Peter, you have quite a few interactions from a personal point of view in specific areas.

Professor Chiodini: Yes. I would like to start, if I may, and take the example of malaria and then other parasitic tropical diseases. Beyond the level of the Country Office there is then the run-off through which policy and control programmes need to be implemented and, unfortunately, what we are dealing with in many areas is a very rudimentary and in some areas absent health service. So there is no basic health structure, certainly not diagnostics. Francis mentioned tuberculosis but most malaria cases in the tropics are diagnosed clinically. That is now changing with new methods coming in but it will still be slow, and the ability not only to diagnose but then to implement control measures requires a delivery

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system, and in many areas control is being frustrated simply because those measures which are effective are not getting out to the people that need them. My own experience of WHO has been a positive one. I am a laboratory person rather than a field worker, but my own experience with them has been positive. I think many of the projects to control malaria are not going to be easy to implement without the detailed run-off into a health service that can receive the measures that are required, and I think that is common to many diseases, not just malaria that I am here to talk about today, but many other tropical diseases.

Q193 Lord Avebury: In that case, would you have a view about the WHO's balance of investment between improving the basic health services in developing countries and treating specific diseases such as malaria?

Professor Chiadini: I do, and I think they are in an almost impossible situation because there are simply not the resources to restructure the health system in every country they support at the same time as providing these control measures. I think people are going to have to look again at the level of funding—I will talk specifically about malaria now, where we need over the next three, four or five decades a sustained investment and the maintenance of those control programmes. That is all dependent upon actually getting them delivered. There is now the international will to do it and there is indeed much more funding than there was but, until we can see it getting out to where the cases are, I am still worried about the situation. I do not blame WHO for that. I think they are under-resourced for the problem that they face across the board.

Q194 Lord Avebury: We have had a lot of evidence about the multiplicity of organisations that are involved in these matters. There is WHO and other health-related IGOs, business partnerships and so on. Do you believe that there is any call for a rationalisation of these efforts?

Professor Chiadini: I do, very much so. I think that there is a danger of parallel tracking. That is wasteful of resources. Duplication of administration should be eliminated as far as possible. One model would be for the WHO to take the lead, obviously with the governments of the countries concerned, because it is their responsibility to have their internal plans for health but I do think some rationalisation and better coordination between all these bodies with good intent and, in some cases, extremely good funding would be beneficial. It would save duplication of resources and probably get more money out to the periphery, where it could do most good.

Professor Borriello: I would very much support that but there are two sides to it. Firstly, that the bodies, many of whom are independent, need to agree that there is value in them being coordinated, and then there is going to have to be acceptance by the WHO that they have a role in coordinating them. It has to be signed off across the board, but it is certainly the case in many countries that there will be a number of organisations undertaking the same activities unbeknown to each other. The idea maybe of a central registry which could then have benefit to each of the component parts which are trying to be active in this area could be a useful way forward and something on which Intergovernmental Organisations could stimulate the debate and maybe have some conclusion.

Q195 Lord Avebury: Is there a call, then, for a change in the WHO's mission statement to include the coordination of activities with all other IGOs and to provide for them to have the responsibility of initiating the central registry?

Professor Borriello: I can only answer in a personal capacity: it would make sense to me. The WHO may have a different view for very valid reasons, as may others.

Chairman: This whole area is a very important one actually and we are paying some attention to it, so those remarks are helpful.

Q196 Lord Avebury: Finally, you say the WHO is always short of resources. Are there any areas in which resources could be better deployed? Are there some areas that you would prefer to see them investing in now? Could they have a shift in resources to make better use of them?

Professor Borriello: I think probably the prioritisation of resource has so many variables to it, not least of which is the country in which the actual problem exists, as well as their do-ability, because some of the things that have a high priority are not easy to actually make happen. I gave an example of where some sort of coordination potentially could have a huge beneficial effect, which is the lab-twinning project, a role in improving capability in a sustainable way throughout the world, otherwise the IHR do not mean very much. For that there are lots of different bodies all trying to do the same thing. A simple register of that with some central coordination in my view would be invaluable.

Professor Drobniowski: Just following on from that point, one of the real difficulties that the WHO has, and indeed countries and then the particular cities and facilities that have expertise brought to them, is often that the expertise is conflicting. There may be a British expert for a couple of days this month, there will be an American next week, perhaps a French

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person, and if they are working to different technical standards and so on, that may cause more confusion. So I think there is clearly a role for the WHO to streamline what actually goes on and to take perhaps a greater leadership in terms of the bigger picture. You mentioned training and twinning; we are also talking about training hundreds of people as opposed to training the twelve that twelve or so particular NGOs could do. That could perhaps also be an intergovernmental aspect where you are using funds to say “We are going to leave you to decide how best to do it but here is the money to train across this larger area, but we are looking for something imaginative, bold, and that will actually try and address the problem, perhaps across a wider swathe of Africa than one small portion of it.”¹

Q197 Baroness Eccles of Moulton: Can I ask one very quick question? Where does the WHO’s authority come from which would enable it to actually create a coordinated system? It cannot just march in and say “You do this, and you do that.”

Professor Catchpole: It would have to do it through the World Health Assembly, would it not?

Professor Drobniowski: I take it your question in a more broad sense is that it has the authority because of its particular position globally but also I think it would feel more confident about taking that role if it had a multiplicity of technical expertise so that it could say “We are an authoritative source of global advice” in exactly the way its title suggests.

Q198 Baroness Eccles of Moulton: That is what it needs?

Professor Drobniowski: Yes.

Professor Borriello: Those to be coordinated need to accept that coordination is useful and the WHO needs to be given the mandate to be able to coordinate.

Chairman: The WHO does come under the United Nations at the end of the day, so that is an important point. We must finish, I am afraid, but pandemic influenza does need a question here.

Q199 Lord Howarth of Newport: We are told we must anticipate another influenza pandemic with consequences that will be devastating in terms of lives lost, and in terms of economic and social disruption. In that kind of situation surveillance is obviously extremely important. In your view, are the intergovernmental arrangements that are intended to detect the first signs of such a pandemic coming towards us adequate, and the measures that have

been planned to act rapidly to counter this? Is the structure going to do the job?

Professor Borriello: It is one of those areas where there has been the most long-standing intergovernmental action, so the surveillance for influenza to help inform vaccine policy has been established by the WHO since 1952 and is still very effective. They used that network to deal with SARS; it was the influenza network of the WHO. Since 1996 there has been a very good European-wide surveillance scheme also looking for putative emergence of antiviral resistance. The pandemic influenza issue that is the concern amongst the population now is—is it all trailer and no big movie? And, having to deal with that, sustaining a high level of response when people have been waiting for something to happen and it has not happened yet? The point with pandemic influenza is that it is not an “if”; it is a “when,” but the scientific understanding will not allow us to tell you when. All we can say with certainty is that, if the current avian influenza strain, which is killing people when it gets into them, had been able to transmit regularly between people, we would have been in the midst of a pandemic now. We still do not really understand why it has not happened. In terms of preparedness, we are better prepared than we have ever been globally. Alerting, even at the syndromic level, without a lab diagnosis is much enhanced. Our ability to respond is much enhanced but where the problems lie—I am not sure you can have excellent plans in place for it; the UK has a global reputation for being one of the most pragmatic and best prepared and, in fact, is helping to train other countries—is the logistics issue. If there is a pandemic, who is going to deliver the antivirals? Even if they are not affected, they are going to be at home looking after relatives, family etc. The whole logistics issue, that whole infrastructure issue is a major problem which I know governments, at least the UK Government, is paying a lot of attention to. I do not know the extent to which those plans will hold tight in the face of a pandemic.

Q200 Lord Howarth of Newport: There is nothing that we should be doing that we are not doing?

Professor Borriello: I do not think so. One of the key areas of major interest and activity, of course, has been whether we can develop a vaccine very quickly. So yes, we might catch the first phase but can we have a vaccine soon after that? The answer is, technically, probably yes; but, again, scale-up and distribution is where the issue is. That is why governments around the world, including the UK, are saying “Should we stockpile one that might work just in case, which will give us a breathing space to hit that first phase or not?” It is a dilemma to which there is not actually a

¹ *Note by Witness:* For example, Lord Crisp, in a recent paper, estimated that the WHO AFRO Region alone was short of 1.5 million health workers.

25 February 2008

Professor Peter Borriello, Professor Mike Catchpole,
Professor Francis Drobniowski and Professor Peter Chiodini

clear-cut, evidence-based answer, to be honest. It is the best view based on the evidence available.

Q201 *Baroness Falkner of Margravine:* There has been quite a lot of reporting around Tamiflu, which we know of, but is there scientific research going on across the world, not just in the UK, to develop a range, to anticipate the virology and to develop a range? In other words, should Tamiflu fail, are there back-ups that we know of already?

Professor Borriello: Yes, if I understand correctly, there are three classes of antivirals for flu which hit different targets, so that if you get a mutation in one gene to a particular target, it is less likely, or it is very unlikely, to confer resistance to some of the other antivirals which hit it at a different place. In crude terms, one goes for the head, one goes for the heart and one goes for the legs, so if you develop the hard head, you still can hit it in the heart. The problem with flu is

that—and I will not go into the detail—because of the nature of the organism, it does not have a method to quickly and readily correct mistakes, so the downside is that, if mistakes in its genetic armoury are bad for the organism, it kills itself, but if they confer just by chance a survival capability or a resistance, that can also happen very quickly. So, because it does not correct its errors, it is always making them, and frequently it can be to its advantage. That is what makes it such a hard target.

Chairman: That is a very cheerful note to end on. Thank you very much for that. I am very grateful. My apologies for the interruptions, which are an occupational hazard here. Again, it enables me to say that, if there are issues which we have not covered that you think we should have covered, or indeed one or two where I asked you to come back on anyway, please do so. Thank you very much again for your time.

MONDAY 3 MARCH 2008

Present	Avebury, L Desai, L Falkner of Margravine, B Geddes, L Hannay of Chiswick, L	Howarth of Newport, L Jay of Ewelme, L Soley, L (Chairman) Whitaker, B
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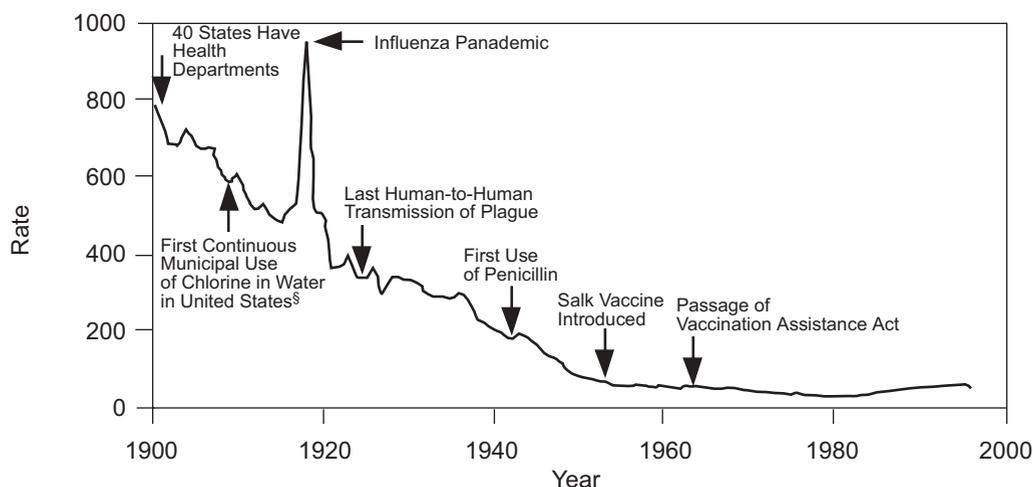
**Memorandum by Michael Marmot, Professor of Epidemiology and Public Health,
UCL—Department of Epidemiology and Public Health**

The principal issues on which the Committee would welcome your views are:

1. *A recent report on Communicable Diseases by the UK Department of Health stated that “post-war optimism that their conquest was near has proved dramatically unfounded”. What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis*

Over the long-term, arguably a positive trend globally (Figure 1; relating to changes in social determinants of health—poverty, living/working conditions, as well as health care and vaccines). This does not address resurgence (TB, malaria) nor does it account for 49 new or re-emerging infectious diseases declared a global health crisis by WHO in 1995. It does not address the issue of pandemics either.

Figure 1: Crude death rate* for infectious diseases — United States, 1990-1996†



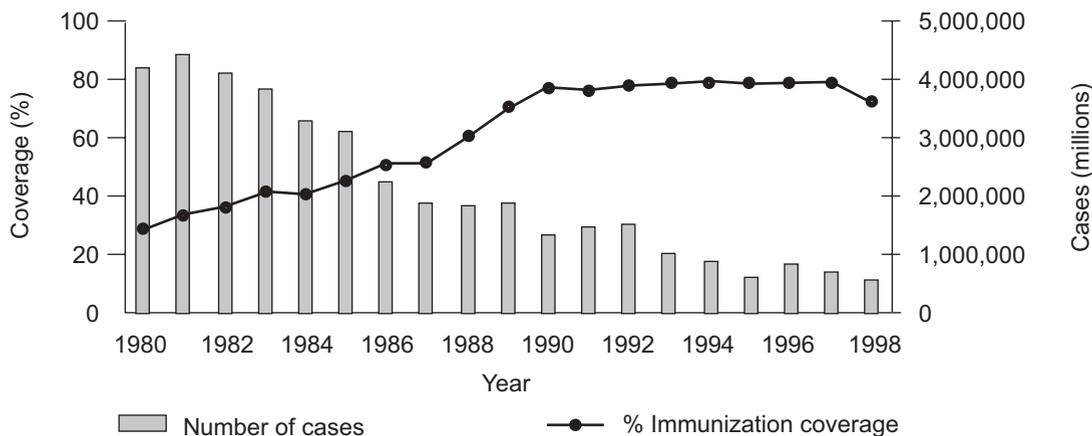
* Per 100,000 population per year.

† Adapted from Armstrong GL, Conn LA, Pinner RW. Trends in infectious disease mortality in the United States during the 20th century. *JAMA* 1999;281:61-6.

§ American Water Works Association. Water chlorination principles and practices: AWWA manual M20. Denver, Colorado: American Water works Association, 1973.

Disease specific impacts are also positive in many cases (see measles, Figure 2).

Reported global measles vaccine coverage and measles cases, 1980-1998



These data include only those countries that have reported data as of 14th August 1999

A problem to consider from the point of view of health care, vaccines development and the role of the Extended Programme on Immunisation (EPI) is both the weakness of health care systems to deliver locally, effectively and equitably (see Figure 3), and the potential for selective PHC emphasis on vertical single-disease control programmes to alienate populations adversely affected by much wider conditions of poverty and disempowerment (relative health care but also to the wider social determinants), leading to falling rates of vaccine uptake (or active refusal) with consequences for herd immunity (see Figure 4; Case example: “The Congolese are dying of such diseases as kwashiorkor, which are easily treated. Why vaccinate against polio instead of curing the real killer diseases? Today, the priority of the Congolese children is not vaccination of any kind. It is first of all and especially to control the malnutrition caused by the war of the multinationals and the pro-American invaders of the Congo.”)

Figure 1A: Full Immunization Rates among Poorest and Richest Population quintiles - Regional Averages

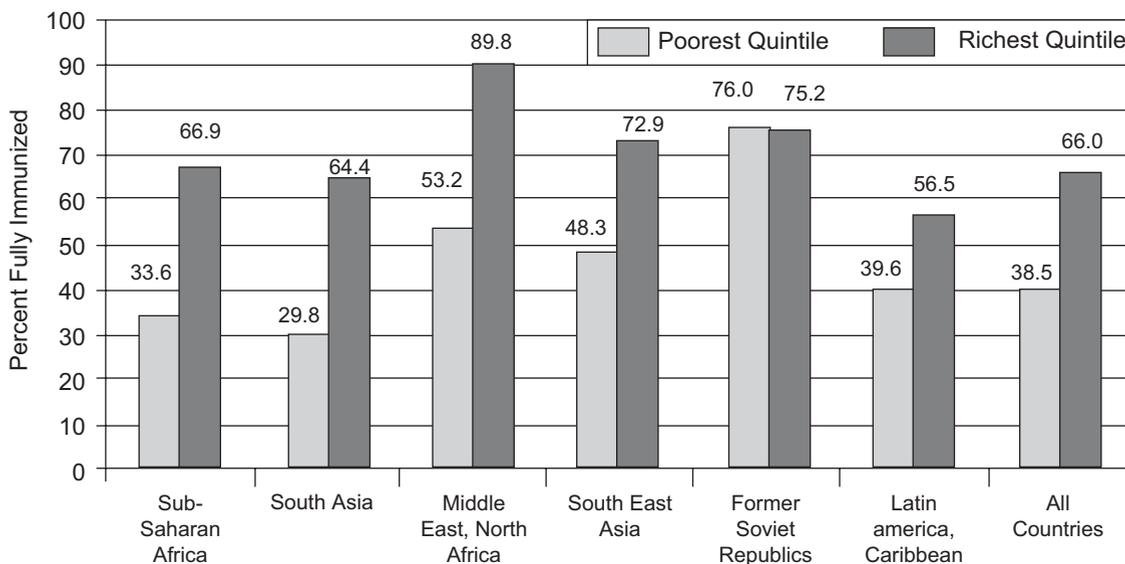
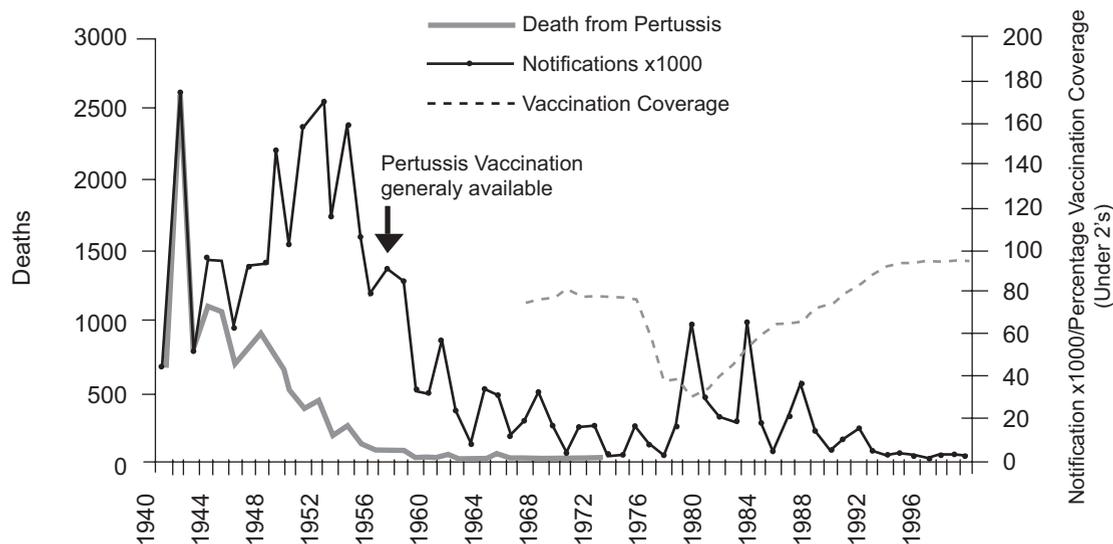


Figure 2: Pertussis deaths & notifications (Eng. Wales) (22)



The positive trends in the global picture reflect progress in some regions, and may conceal or mitigate stagnation or actual reversal of disease control gains (for example with TB and HIV/AIDS in the former Soviet Union and Sub-Saharan Africa).

2. *What reliable data exist regarding the numbers of people infected globally with the four diseases¹ on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?*

WHO (probably) houses reliable data on trends and numbers; it is arguable that patterns (especially regarding main underlying causes of infection) could be substantially strengthened—e.g. through the establishment of a global observatory (under consideration and planning in WHO HQ), and/or the establishment of the more robust monitoring and reporting framework and mechanism—focusing on health equity and the determinants of health (see CSDH recommendations).

TUBERCULOSIS

There were an estimated 8.3 million (5th–95th centiles, 7.3–9.2 million) new TB cases in 2000 (137/100 000 population; range, 121/100 000–151/100 000). Tuberculosis incidence rates were highest in the WHO African Region (290/100 000 per year; range, 265/100 000–331/100 000), as was the annual rate of increase in the number of cases (6%). Nine percent (7%–12%) of all new TB cases in adults (aged 15–49 years) were attributable to HIV infection, but the proportion was much greater in the WHO African Region (31%) and some industrialized countries, notably the United States (26%). There were an estimated 1.8 million (5th–95th centiles, 1.6–2.2 million) deaths from TB, of which 12% (226 000) were attributable to HIV. Tuberculosis was the cause of 11% of all adult AIDS deaths. The prevalence of M tuberculosis–HIV coinfection in adults was 0.36% (11 million people). Coinfection prevalence rates equalled or exceeded 5% in eight African countries. In South Africa alone there were two million coinfecting adults.

PPHC under CSDH has been conducting analysis of the factors relating to TB infection (Tables 1 and 2).

¹ HIV/AIDS, Tuberculosis, Malaria and Avian Influenza.

Table 1**RELATIVE RISK, PREVALENCE AND POPULATION ATTRIBUTABLE RISK OF RISK FACTORS FOR TB, IN 22 HIGH TB BURDEN COUNTRIES**

	<i>Relative risk for active TB disease (range)</i>	<i>Weighted prevalence, total population, 22 HBCs</i>	<i>Population Attributable Fraction (Range)**</i>
HIV infection	8.3 (6.1–10.8)	1.1%	7.3% (5.2–9.6)
Malnutrition	4.0 (2.0–6.0)	17.2%	34.1% (14.7–46.3)
Diabetes	3.0 (1.5–7.8)	3.4%	6.3% (1.6–18.6)
Alcohol dependence	2.9 (1.9–4.6)	3.2%**	5.7% (2.8–10.3)
Active smoking	2.6 (1.6–4.3)	18.2%	22.7% (9.9–37.4)
Indoor pollution	1.5 (1.2–3.2)	71.1%	26.2% (12.4–61.0)

(Source: WHO 2007)

* Based on global estimate of 6% for men and 0.4% for women (Rehm *et al* 2007).

** Note that sum of PAFs should normally be < 100%, since most causal pathways requires presence of two or more risk factors simultaneously or in sequence. The sum is less than 100% in Table 1 simply because only a few selected factors are considered.

Table 2**POPULATION ATTRIBUTABLE FRACTION IN SIX WHO REGIONS (HIGH TB BURDEN COUNTRIES ONLY)**

<i>WHO region</i>	<i>HIV</i>	<i>Malnutrition</i>	<i>Diabetes</i>	<i>Alcohol dependence</i>	<i>Smoking</i>	<i>Indoor air pollution</i>
Africa	28%	47%	3%	–	10%	28%
Americas	4%	17%	9%	–	18%	6%
Eastern Mediterranean	1%	42%	10%	–	17%	27%
Europe	7%	8%	14%	–	32%	3%
South East Asia	5%	37%	6%	–	23%	27%
Western Pacific	1%	28%	5%	–	29%	28%

HIV/AIDS**Table 1****TRENDS IN HIV INFECTIONS BY REGION**

<i>Region</i>	<i>No of people living with HIV (end of 1998) [39]</i>	<i>No of people living with HIV (end of 2003) [40]</i>	<i>% increase 1998–2003</i>
Sub-Saharan Africa	22,500,000	25,000,000	11%
South and South-East Asia	6,700,000	6,500,000	–3%*
Eastern Europe and Central Asia	270,000	1,300,000	381%
Western Europe	500,000	580,000	16%
East Asia	560,000	900,000	61%
Oceania	12,000	32,000	167%

<i>Region</i>	<i>No of people living with HIV (end of 1998) [39]</i>	<i>No of people living with HIV (end of 2003) [40]</i>	<i>% increase 1998–2003</i>
North Africa and Middle East	210,000	480,000	129%
North America	890,000	1,000,000	12%
Caribbean	330,000	430,000	30%
Latin America	1,400,000	1,600,000	14%
Total	33,372,000	37,822,000	13%

* This apparent decrease is due to inconsistencies in data collection methods between earlier and later years, as well as revised estimates by UNAIDS.

Table 2

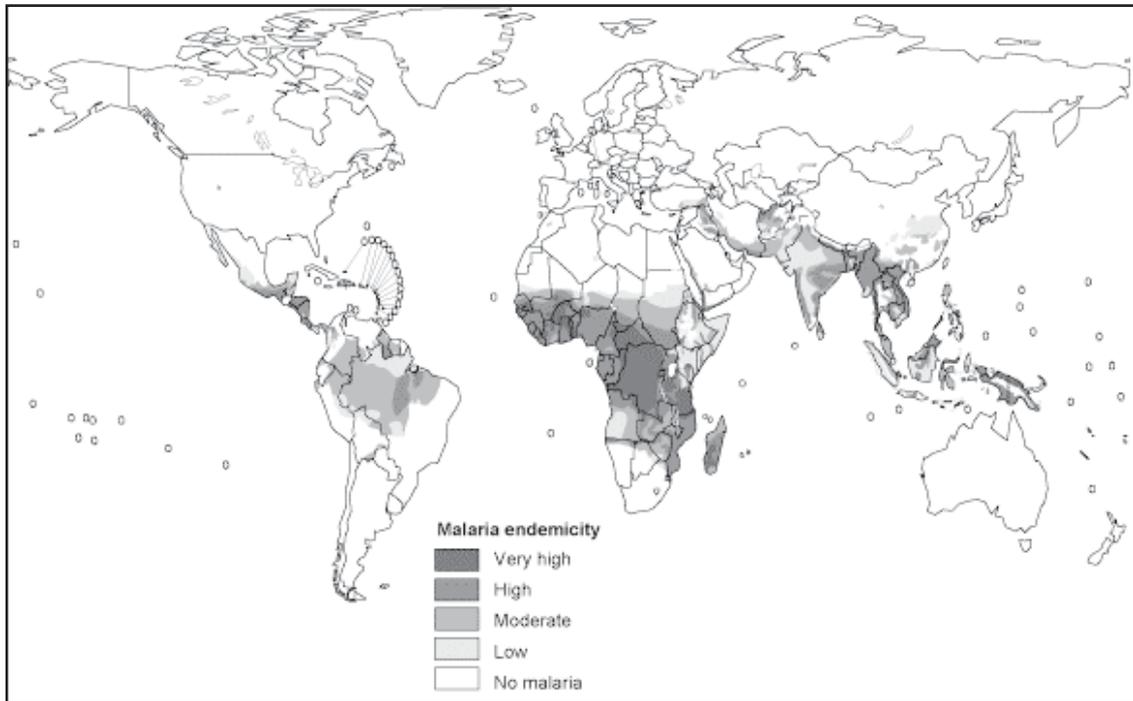
SUMMARY OF DEMOGRAPHIC IMPACTS OF AIDS

<i>Demography [9]</i>	<i>Without AIDS 1995–2000</i>	<i>With AIDS</i>	<i>Without AIDS 2010–15</i>	<i>With AIDS</i>	<i>Without AIDS 2020–25</i>	<i>With AIDS</i>
Life expectancy at birth (years)	63.9	62.4	68.4	64.2	70.8	65.9
Number of deaths (millions)	159	170	174	207	193	231
Crude death rate per 1,000	9.0	9.6	8.1	9.8	8.0	10.1
Infant mortality rate per 1,000	66.4	67.5	49.8	51.3	40.9	42.1
Child mortality rate per 1,000	93.9	98.8	68.9	75.8	56.1	62.3
Population size (millions)	3,666	3,639	4,310	4,204	4,805	4,599

* UNAIDS Population Division, 2003.

One of the major reasons for the apparent ineffectiveness of global [HIV/AIDS] interventions is historical weaknesses in the health systems of underdeveloped countries, which contribute to bottlenecks in the distribution and utilisation of funds. Strengthening these health systems, although a vital component in addressing the global epidemic, must however be accompanied by mitigation of other determinants as well. These are intrinsically complex and include social and environmental factors, sexual behaviour, issues of human rights and biological factors, all of which contribute to HIV transmission, progression and mortality. An equally important factor is ensuring an equitable balance between prevention and treatment programmes in order to holistically address the challenges presented by the epidemic (Coovadia & Hadingham, 2005).

MALARIA



As of 2004, 107 countries and territories have reported areas at risk of malaria transmission. Although this number is considerably less than in the 1950s, with 140 endemic countries or territories, 3.2 billion people are still at risk. Present estimates are that around 350–500 million clinical disease episodes occur annually (2). Around 60% of the cases of clinical malaria and over 80% of the deaths (1) occur in Africa south of the Sahara. Of the more than one million Africans who die from malaria each year (1), most are children under five years of age. In addition to acute disease episodes and deaths in Africa, malaria also contributes significantly to anaemia in children and pregnant women, adverse birth outcomes such as spontaneous abortion, stillbirth, premature delivery and low birth weight, and overall child mortality. The disease is estimated to be responsible for an estimated average annual reduction of 1.3% in economic growth for those countries with the highest burden (3).

The wide variation seen in the burden of malaria between different regions of the world is driven by several factors. First, there is great variation in parasite–vector–human transmission dynamics that favour or limit the transmission of malaria infection and the associated risk of disease and death. Of the four species of Plasmodium that infect humans—*P falciparum*, *P vivax*, *P malariae* and *P ovale*—*P falciparum* causes most of the severe disease and deaths attributable to malaria and is most prevalent in Africa south of the Sahara and in certain areas of South-East Asia and the Western Pacific. The second most common malaria species, *P vivax*, is rarely fatal and commonly found in most of Asia, and in parts of the Americas, Europe and North Africa. There are over 40 species of anopheline mosquitoes that transmit human malaria, which differ in their transmission potential. The most competent and efficient malaria vector, *Anopheles gambiae*, occurs exclusively in Africa and is also one of the most difficult to control. Climatic conditions determine the presence or absence of anopheline’s vectors. Tropical areas of the world have the best combination of adequate rainfall, temperature and humidity allowing for breeding and survival of anophelines.

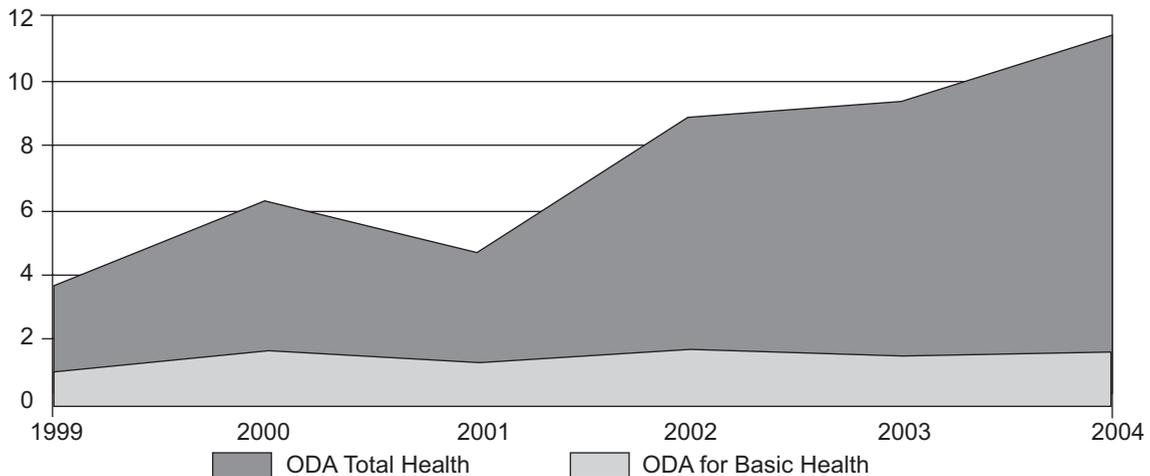
The second major factor contributing to regional and local variability in malaria burden is differences in levels of socioeconomic development. Determinants include general poverty, quality of housing and access to health care and health education, as well as the existence of active malaria control programmes providing access to malaria prevention and treatment measures. The poorest nations generally have the least resources for adequate control efforts. In many poor countries, exposure to malaria of vulnerable populations is enhanced by migrations enforced by poverty and/or conflict. <http://www.rbm.who.int/wmr2005/html/1-2.htm#box2>

5. *What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?*

Emphasis of concept, policy, finance and action on treatment over prevention (HIV/AIDS (PEPFAR, see below), TB (DOTS—see Vietnam/Morocco case studies where over 85% case detection and 70% treatment (Stop TB criteria for effective control and elimination) have not satisfactorily affected trends in infection downwards—Mario Raviglione, CSDH, October 2007).

The money appears to be available (see below, G8 financing to health), but it is not being channelled in the right direction (e.g. towards effective action on the underlying causes of vulnerability).

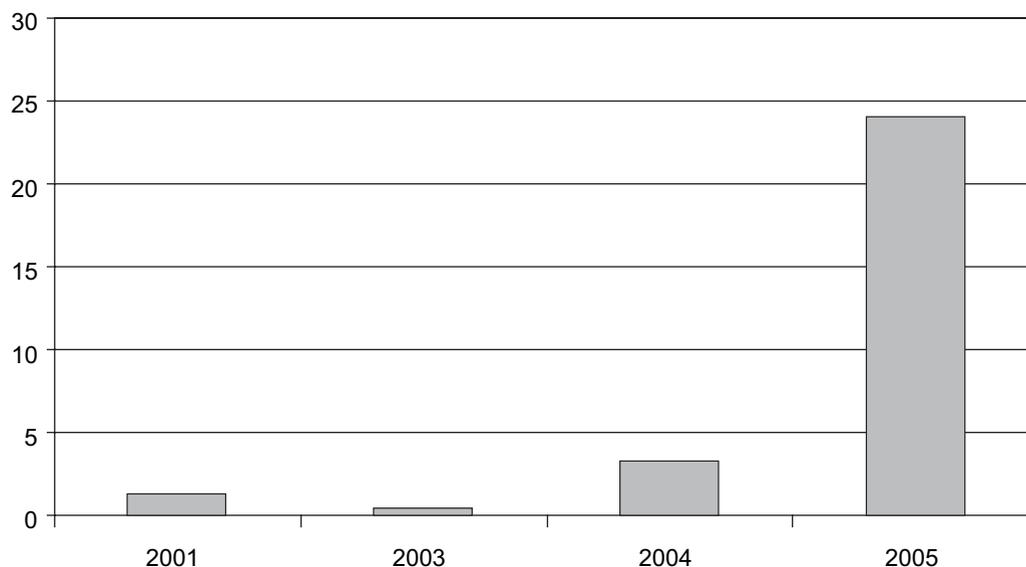
Figure 2: ODA Commitments for Health, 1999-2004
(US\$ billions, 2003 constant prices)



Source: OECD DAC

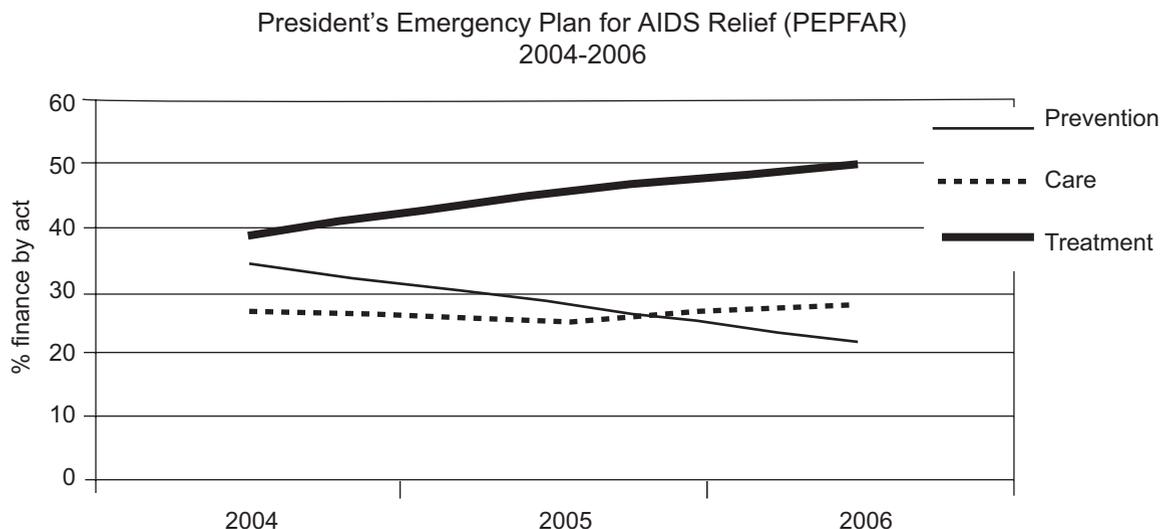
PEPFAR (President Bush's Emergency Plan for AIDS Relief) - offering around USD\$15 billion over 10 years, provides a good example of a trend in financing action moving away from investment in prevention.

Financial Commitment (USD bn)



Much of the aid flowing to “Total Health” goes to the large single-disease global programmes—these arguably limit and distort coherent national and local level coherence of action across the determinants of health, whilst in some cases establishing parallel structures to the national and local health care system, and drawing off health workers from that system.

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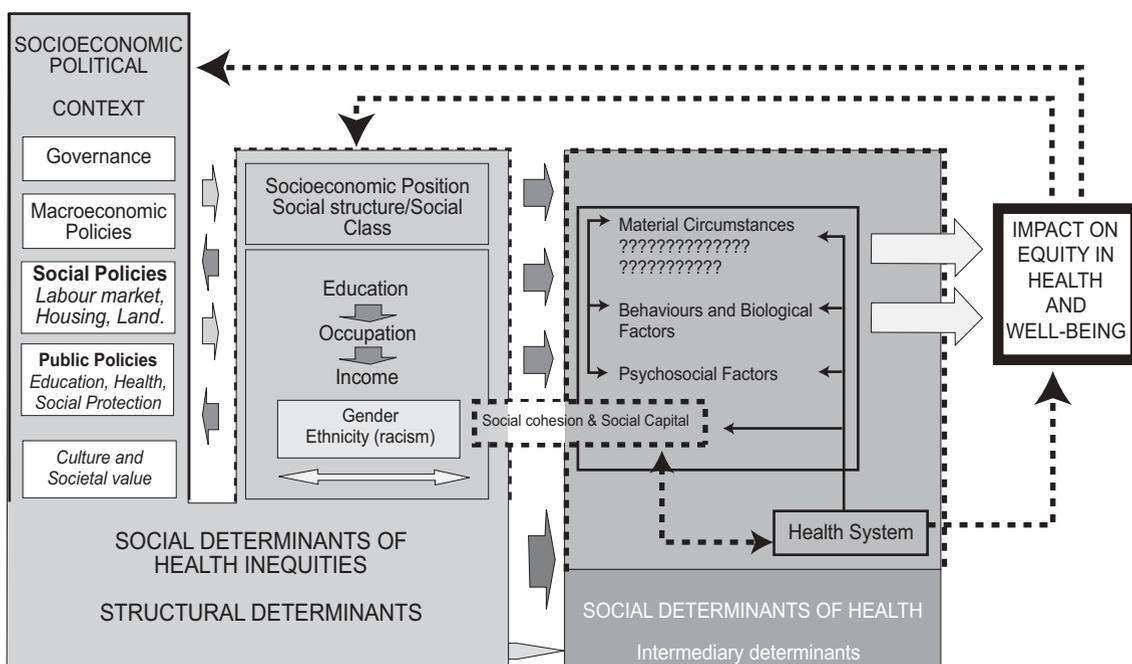


6. What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?

THE COMMISSION ON SOCIAL DETERMINANTS OF HEALTH; UCL INSTITUTE

The CSDH marshalls global evidence on what causes poor health—including both structural factors of social, economic, political and cultural arrangements (locally, nationally and internationally)—and on what kinds of interventions are effective in maintaining good health equitably across populations.

7. What are the main non-health causes (e.g. global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient “joined-up” thinking in approaching the problem?



¹ Diagram of social determinants of health inequalities elaborated EQH/EIP 2005 (OPSI)

9. *Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions—e.g. HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?*

A lack of cooperation between tuberculosis and HIV/AIDS programs is causing deaths from the two diseases in many countries, Alasdair Reid, HIV/TB adviser for UNAIDS, said on Friday at the 38th Union World Conference on Lung Health in Cape Town, South Africa

Up to half of reported HIV/AIDS-related deaths are caused by TB, according to Reid. He added that in 2005, about 7% of people with TB worldwide were tested for HIV and that fewer than one in 200 people living with HIV/AIDS were tested for TB. According to Reid, testing people who have TB for HIV and vice versa could lead to earlier detection, increased access to antiretrovirals and the prevention of “thousands of deaths”.

World Health Organization data indicate that 90% of HIV-positive people in Africa die within months of contracting TB.

IUATLD has proposed a program—called “Integrated Care for TB Patients Living with HIV/AIDS”—to simultaneously address both diseases. Central components of the strategy include increased collaboration in addressing TB and HIV, and testing for the two diseases. The strategy is being tested in various countries, including the Democratic Republic of Congo, Uganda and Zimbabwe. According to Reid, a new funding model should be developed to address the two diseases. “Currently, money is raised for either HIV or TB, and funds dedicated for HIV can’t be used for TB or vice versa,” he said, adding, “This has to change. When you want to tackle HIV you need to tackle TB, especially in Africa where so many people are co-infected” (Inter Press Service, 11/11).

Early data from worldwide monitoring of joint TB/HIV activities have indicated some progress compared with previous years, according to the SAPA/Independent Online. Since 2005, there has been a threefold increase in the number of HIV-positive people who have been screened for TB and a sixfold increase in the number of people with TB who were tested for HIV. However, Reid said that without immediate action, “it will be very, very difficult” to achieve the HIV/AIDS targets in the UN Millennium Development Goals and that “thousands of people with HIV will continue to die of preventable, treatable” TB (SAPA/Independent Online, 11/9). *TB Alert*, 2008.

OVER-EMPHASIS ON TREATMENT: DOTS

DOTS programmes are not reaching the very poorest in communities; there is inadequate monitoring, using socioeconomic position, to assess equity in access to DOTS programmes.

14. *Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?*

Two well-known WTO agreements directly commodify health. GATS (General Agreement on Trade in Services) may accelerate health care commercialization or at least preclude efforts to reverse it; TRIPS (Agreement on Trade-Related Intellectual Property Rights) extends patent protection that already limits some developing countries’ access to essential medicine and may eventually limit access more broadly, while creating perverse incentives in medical research.

Crucially, until governments have demonstrated the ability to regulate private investment and provision in health services in ways that enhance health equity, they should avoid making any commitments in GATS or bilateral or regional agreements that involve health services. It is not clear that any government, anywhere in the world, has yet met this test, leading some analysts to urge cancellation of all existing GATS commitments on health services (most of which were from developing nations) and removing health services from the scope of the Agreement. Some progress toward allowing easier access to cheaper generic drugs under TRIPS was made in 2003. The amended rules, however, remain cumbersome and costly,¹² leading to calls for moving intellectual property rights out of binding trade treaties into some other forum for resolution, such as the World Intellectual Property Organization (WIPO) where such disputes were once settled diplomatically. A more far-reaching change would involve multilateral agreement on alternatives to financing pharmaceutical research through private investment in anticipation of patent protected returns (Labonte & Schrecker, 2008).

17. *What intergovernmental planning has been undertaken to cope with the impact of an outbreak of infectious disease caused by deliberate release of micro-organisms into the environment? Is there adequate liaison between the various agencies involved, including intelligence, law enforcement and health care professionals? How could action by intergovernmental bodies help further?*

N/a

18. *Though our remit is focused specifically on known infectious diseases, we would be interested to know how you view the global threat from new or previously unrecognised ones and from the transmission of infections from animals to humans.*

There is a strong argument for greater attention to neglected infectious diseases:

Table 1

THE BURDEN OF THE 13 NEGLECTED TROPICAL DISEASES IN TERMS OF ESTIMATED MORTALITY, MORBIDITY AND POPULATION AT RISK

<i>Disease</i>	<i>Abbreviation</i>	<i>Mortality (annually, thousands)</i>	<i>Morbidity (annually, million)</i>	<i>Disability adjusted life years (annually thousands)</i>	<i>Population at risk (million)</i>
Buruli ulcer	BUR		Incidence: 0.003		
Chagas disease	CHAG				
Cholera	CHOL	Incidence: 120	1–2	N/A	
Dengue fever *1	DEN	Incidence: 19		528 (2001)	
Dracunculiasis	DRAC		Incidence: 0.016 (2004)		11 African countries
Human African trypanosomiasis	HAT	49 (2001)		1,332 (2001)	
Leishmaniasis *2	LEISH	Incidence: 59	Incidence: 0.5 VL & 1.5 CL	2,357	> 350
Leprosy	LEP		Prevalence: 0. 225	177	
Lymphatic filariasis	LF	N/A	Prevalence: 120	5,644	
Onchocerciasis	ONCHO	N/A			
Schistosomiasis *3	SCHISTO		Prevalence: 193	1,759	652
Soil-transmitted helminthes *4	STH	N/A?	Prevalence: 2,000	4,705	3,195
Trachoma	TRACH	N/A	Prevalence: 81 (Trichiasis 7.6, blindness 1.9)	3,997	10% of world's population

There is also a very strong case for much closer international attention to non-communicable diseases, since they are, if anything, the major critical threat to global health.

February 2008

Memorandum by University College London

1. *A recent report on Communicable Diseases by the UK Department of Health stated that “post-war optimism that their conquest was near has proved dramatically unfounded”. What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis?*

Post-war optimism was founded on declining death rates from infectious diseases due to improved social and housing conditions, vaccines and antimicrobials. Despite these improvements, infectious diseases remain a major cause of morbidity and mortality and the decline in disease burden in the developed world has not been matched in many parts of the developing world. Globally infections cause over a fifth of all deaths and a quarter of all illnesses and disproportionately affect resource-poor countries. Worldwide it is estimated that around 5.5million people die from HIV, TB and malaria and over a million children die from vaccine preventable diseases. Should an influenza pandemic occur the vast majority of deaths would be in resource-poor countries. In the UK infectious diseases account for over 10% of deaths and a third of consultations in Primary Care.

In the last few decades, we have witnessed the unpredictable emergence of major new public health threats such as HIV, SARS and antimicrobial resistance. Globally, we have failed to achieve comprehensive vaccination coverage (or achieve eradication eg polio) or deliver effective therapeutics. This has resulted in a failure to control transmission and/or effect cure eg TB, Malaria, Hepatitis B. The continuing emergence of new classes of antimicrobial resistance in a range of infections (eg MRSA, TB, Malaria and more recently HIV) and the absence of discovery of novel classes of antibiotics for common bacterial infections present further threats. The ever present possibility of a major flu pandemic, while not new, poses real challenges for control, clinical management and potential social and economic impact

2. *What reliable data exist regarding the numbers of people infected globally with the four diseases² on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?*

Surveillance data are collated from State surveillance systems by WHO. For HIV, data are also collated by UNAIDS. Significant investment goes into providing estimates of the burden of disease based on a variety of sources (eg diagnosed cases, sentinel laboratory data, ad hoc surveys). For example for HIV this includes incident cases of AIDS and AIDS deaths, new diagnoses of HIV and community surveys of the prevalence of infection.

The incidence of flu is highly seasonal and much infection never comes to the attention of health care professionals. Knowledge of the particular type of virus circulating is based on a network of participating laboratories coordinated by WHO. Ultimately, even the best surveillance systems will not record all cases and the quality and completeness of surveillance data varies considerably around the world. For example, case definitions may vary according to available resources, eg smear vs culture-confirmed TB. Surveillance data are also limited in terms of the risk factor and outcome data collected. International figures are therefore “best estimates” of the burden of disease and take into account assessments of the completeness of data etc. Of the surveillance systems for the four diseases, that for HIV/AIDS is probably the most comprehensive.

We do not present here detailed trends for the four infections as these are best reported and are widely available from those specifically responsible for national and international surveillance.

In the case of HIV, we note the continuing transmission in all parts of the world. Transmission of all infectious agents depends on the interaction between the biological properties of the organism, particularly its ease of transmission, the characteristics of the population into which it is introduced (size, density, living conditions, sanitation etc) and human behaviours, individually and collectively.

The HIV epidemic, for example, is driven primarily by patterns of sexual behaviour, particularly unprotected sex and rates of partner change as well as the high incidence of untreated sexually transmitted infections in the worst affected parts of the world. Underlying trends in sexual behaviour are many social and economic factors including poverty, migration, conflict, social position of women and education. These problems are compounded by the lack of health systems infrastructure to deliver prevention and treatment programmes.

² HIV/AIDS, Tuberculosis, Malaria and Avian Influenza.

3. *What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? And what improvements might be made?*

Warning of outbreaks of infectious diseases are largely coordinated by WHO through their international surveillance systems which draw data from State surveillance systems. Recent UK reports recognise the importance of investment into coordinated international surveillance systems. The Office of Science and Innovation Foresight Report “Infectious Diseases: Preparing for the future” emphasised the importance of harnessing new technologies for detection, identification and monitoring (DIM) systems for early detection of the appearance of disease, rapid and accurate identification of infectious agents causing outbreaks and monitoring of control programmes. Foresight also recognise the importance of interdisciplinarity in the surveillance and control of infectious diseases “*Understanding the future risks of infectious diseases, and how best to use DIM to help manage those risks is an interdisciplinary problem. A key challenge is to bring together relevant skills expertise to deliver properly integrated scientific research and development and to provide suitable opportunities for capacity building*”; “*How DIM technology is used is just as important as the technology itself and considerable benefits are foreseen from improving the systems in which the technology operates*”.

Both WHO and Foresight identify a need for greater investment in surveillance capacity in poorer countries. Similarly the recent Nuffield Council on Bioethics Report on Public Health: Ethical Issues recommended that “*countries such as the UK should seek to enhance the capacities of developing countries to conduct effective surveillance of infectious diseases*”, a recommendation guided by the ethical framework of the stewardship model.

4. *Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years?*

Infectious disease will continue to be driven by existing burden of disease in different populations, as well as the level of immunity to specific infections through vaccination or natural infection. Despite massive investment in prevention and treatment programmes in many parts of the world HIV transmission continues at high levels. Even in the UK where prevention and treatment programmes are well developed compared with parts of the world most severely affected such as Africa, transmission of infection is continuing, particularly amongst homosexual men.

While great progress has been made in the distribution of antiretroviral therapy to reduce morbidity and mortality from HIV, there remains an urgent need for greater integration of prevention and treatment efforts to reduce transmission and recent spread to parts of the world that previously had limited epidemics. The emergence of antiretroviral resistance is a further concern. This will need both careful surveillance and monitoring of roll-out of antiretrovirals for maintenance of appropriate drug supplies and effective clinical management programmes.

Reliable predictions about the timing or extent of an influenza pandemic cannot be made and there remains great uncertainty about our ability to contain the spread of the emergence of a transmissible and virulent new strain, although significant progress has been made in the development of pandemic plans. These plans tend to be more poorly developed in resource poor settings. Many predictions are based on mathematical models. These are important in exploring future scenarios but are based on a range of assumptions, themselves using incomplete surveillance and/or behavioural data and often have wide uncertainty limits.

5. *What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?*

Control is likely to be influenced by wider global issues, eg economic conditions, political imperatives, religion, climate change, war and conflict. Blockages to progress need to be considered in the context of the broader agenda of health inequalities. Social and economic determinants of transmission are key factors in the transmission of all four diseases. That said, blockages to progress include the lack of health infrastructure in many parts of the world to institute population programmes for control, the need for integrated prevention and treatment services. In the case of HIV there is a need for continued and population-wide prevention programmes accompanied by high level commitment from governments, and the availability of effective distribution systems for the delivery of both prevention and treatment interventions. Generally, intergovernmental support to make affordable drug and vaccine supplies available are critical.

6. *What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?*

University College London is a multi-faculty university. Our primary role is in research and education. We undertake multidisciplinary research, exploring pathogen, host and societal impacts on the spread of infections both through our large Faculty of Biomedicine, as well as through anthropology, economics, geography, the built environment etc. Our work has a particular focus on HIV and TB and more recently on influenza. Our clinical scientists, in addition to their clinical care of infectious diseases (with a strong focus on HIV), undertake observational and experimental studies of the impact of therapy on the clinical outcomes. Our laboratory scientists are engaged in a wide range of research including vaccine development and the national and international surveillance of antiretroviral resistance. We have an international programme of studies into the behavioural determinants of HIV acquisition through studies of sexual behaviour in high risk and general population groups and behavioural intervention studies in both a UK and international setting. We are involved in international trials of tuberculosis treatment. With the Medical Research Council clinical trials unit we participate in trials of HIV antiretroviral delivery in UK and Africa and of evaluation of the efficacy of vaginal microbicides in preventing HIV transmission. We are undertaking studies in the UK to better understand the transmission of seasonal influenza and developing collaborations with international colleagues.

In recent years we have enhanced our interdisciplinary collaborations. Through our newly formed Institute for Global Health, we are promoting cross-faculty links within UCL and wider international collaborations to extend our educational and research programmes in effective interventions for the control of infectious diseases.

Many staff at UCL contribute to national and international policy through engagement with Government advisory bodies (eg National Expert Panel on New and Emerging Infections (NEPNEI), Specialist Advisory Committee on Antimicrobial Resistance, Expert Advisory Group on AIDS, Foresight), advice to funding bodies (eg MRC, Wellcome Trust, DFID) and to international groupings (eg WHO, CDC). We collaborate closely with colleagues at the Health Protection Agency and undertake joint programmes of research.

7. *What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient “joined-up” thinking in approaching the problem?*

As indicated in our previous responses, social and economic factors are major influences on the spread of infectious diseases. Sexual behaviour patterns are critical to HIV spread, but these in turn are driven by demography, migration, status of women etc. War and Civil conflict have a major impact on disease control programmes. Migration facilitates the transmission of all four diseases but is particularly important in the rapid dissemination of emerging outbreaks such as pandemic flu where early detection is critical to control.

The interaction between the HIV, TB and malaria epidemics exacerbate one another and greater joining up of programmes is needed which take greater cognisance of social, economic and behavioural drivers. Alleviation of poverty is important in all these conditions but there is a particular need to focus on raising education levels and training clinical and public health personnel to implement effective evidence-based programmes.

In some settings drug use and addiction related problems exacerbate the problem eg as a direct risk factor for disease or complicating management.

Global warming is likely to impact directly on the transmission of some infections, eg the geographical extension of malarial zones. It is also likely to create the social and economic conditions which will result in food insecurity, population migration and national disasters which enhance the spread of infectious agents and hamper control programmes. All these are major challenges which require the engagement of many disciplines (eg economics, political science, geography and the built environment), government departments, and intergovernmental working in identifying sustainable solutions.

Greater interaction between experts in animal and human health is needed in tackling some of the newly emerging infections, eg SARS, avian influenza to ensure that early warning systems are in place, to limit the risks of outbreaks and to improve control measures.

8. *Cases of Tuberculosis fell progressively in the UK until the mid-1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of Tuberculosis infections in Britain? And how could intergovernmental action help to reverse the trend?*

The majority of tuberculosis cases in the UK occur in those born abroad. Migrants to the UK tend to come from areas with high tuberculosis incidence: of the top 10 source countries of recent immigrants to the UK, six have a tuberculosis incidence of over 150/100,000 population. In addition, there is considerable travel from the UK to visit friends and family abroad, particularly to the Indian Sub Continent.

It is tempting to think that the solution to the problem lies in screening of new entrant groups but there are difficulties with this approach. The majority of foreign-born patients who develop tuberculosis do not have active disease on arrival and may only develop this years later. Identification of TB risk may perhaps be better tackled by a process that begins with the new entrant check when individual register with primary care and by ensuring ready access to high quality tuberculosis services when needed.

Work published in the New England Journal of Medicine demonstrates the “Enlightened Self Interest” phenomenon whereby rich countries can achieve greater reductions in their domestic levels of tuberculosis at a lower cost by investing in control overseas than by screening new migrants. Schwartzman K, *et al*, N Engl J Med. 2005 Sep 8;353(10):1057–9. Intergovernmental action to strengthen tuberculosis control in resource poor countries is fundamental to global control.

A relatively small but very important group of patients with overlapping risk factors of illegal drug use, homelessness and imprisonment make a significant contribution to transmission particularly in major urban settings. Such patients tend to be diagnosed late, have highly infectious disease and poor compliance with treatment leading to transmission and the development of drug resistant disease. More action is needed to ensure that tuberculosis services can engage effectively with this group.

9. *Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions—eg HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?*

Maintaining drug supplies for TB is an essential pre-requisite for control but clinical delivery is difficult because effective treatment requires at least six months of uninterrupted treatment and adherence is often poor. Directly Observed Therapy (DOTS) has been widely adopted as a strategy globally to ensure patients take their treatment but there remain challenges in delivering effective DOTS programmes in different settings

Tuberculosis incidence has risen sharply in countries with severe HIV epidemics. HIV increases the risk of TB, through immunosuppression, but also indirectly, through onward transmission of *M tuberculosis* from the increased caseload. Wide scale rollout of antiretroviral therapy (ART) is needed. However this alone is unlikely to reverse the rising incidence of TB, since the increased risk of TB occurs soon after HIV seroconversion, before ART is likely to be given. Enhanced active case finding, for both HIV positive and HIV negative individuals, needs to complement a sustained TB control programme based on the DOTS strategy. HIV and tuberculosis programmes need to work together, including screening for symptoms of tuberculosis as part of HIV counselling and testing. The impact of innovative approaches, such as mass isoniazid chemoprophylaxis and novel diagnostic methods, need to be investigated. Only with a shift in paradigm, while continuing measures that have been shown to be effective, are we likely to reduce the risk of tuberculosis in HIV-infected individuals, and reduce transmission in the population as a whole.

10. *To what extent do you believe that the 2004 Stockholm Convention limiting the use of DDT against Malaria-carrying mosquitoes has been a factor of increases in the spread of the disease? Has any risk analysis been carried out comparing the relative dangers to human health posed by DDT and Malaria?*

No response.

11. *What intergovernmental action is planned or in hand for early detection of the transmission of Avian Flu from birds to humans and of human-to-human transmission in potential source countries? Is this proving sufficiently effective to prevent an Influenza pandemic? What more could be done?*

Although there is relatively intensive activity to identify spread from birds to human and subsequent human to human spread it is possible that identifying and acting around such incidents may delay rather than prevent a pandemic. If a strain that is well adapted to humans emerges and spreads efficiently from person to person then intergovernmental co-operation may ameliorate impact but is unlikely to stop it.

Stockpiling of antivirals is a key part of many countries' pandemic response but emergence of antiviral resistance threatens to limit their impact. Better international surveillance of antiviral resistance in influenza is needed. Even in the absence of antiviral resistance their use may have limited impact on disease transmission. Antivirals have however been found to be effective at preventing contacts of influenza from developing active disease but their use in this capacity does not seem to be being considered. Better understanding of how non-pharmaceutical interventions can interrupt transmission (eg hand hygiene, surface cleaning, mask use etc) needed. This could be addressed through large scale community studies of interventions to prevent influenza transmission using seasonal influenza as a model.

International co-ordination of the key data-sets and specimens that should be collected around early cases of avian influenza in humans is needed. There are also political and "scientific" sensitivities about sharing of such data which need to be overcome if we are to understand the problem better.

For example, the Nuffield Working Party on Public Health Ethics drew attention to the issue of sharing virus isolates internationally in the control of pandemic flu. "*WHO should not merely facilitate access to virus isolates for commercial companies, leaving the question and availability of vaccines to market forces. It should use its authority to impress on pharmaceutical companies their social responsibilities. We urge WHO to explore, in liaison with Governments and relevant industries the notion of viewing virus isolates as a form of "public good" and to take a flexible approach to patenting and intellectual property protection*".

Investment in planning for research that would be conducted in the event of a full-blown pandemic is needed. Without such planning it will be difficult to conduct clinical research in a pandemic situation, especially within modern research governance structures.

12. *To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?*

In these four diseases antimicrobial resistance is an important problem but is unlikely to be a key driver of increases in cases. It can however, make cases substantially harder to treat. Although outside the scope of the four diseases, antimicrobial resistance in common bacteria such as *Staphylococcus aureus* infection and *Escherichia coli* is a major emerging threat. Antimicrobial resistance has been a problem in hospitals for many years and there is increasing evidence that resistant strains are now becoming important community pathogens. Surveillance systems are often not well equipped to identify this because they tend to focus on isolates from secondary care settings. The problem of antimicrobial resistance in resource countries poor countries where prescription of antibiotics is unregulated has not been adequately studied.

13. *In a number of countries, including the UK, there is a problem with hospital-acquired infections. What intergovernmental sharing of knowledge is taking place to help bring this problem under control?*

Although there have been initiatives to encourage sharing of ideas in infection control between countries and there are a number of EU funded projects in this area it seems that more could be done to understand international variations in hospital acquired infections and to develop research networks that are able to investigate these in a more systematic way.

14. *Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?*

See response at 9 and 11. We also note the important rolls of community organisations, NGOs etc in campaigning for the equitable delivery of affordable medicines for eg the African Treatment Action Campaign for access to antiretroviral therapies.

15. *What interchange exists between States in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?*

Recent reports have highlighted the need for international cooperation in training and capacity development in resource-poor settings (For example Crisp Report and Chief Medical Officer's report on global health). There is undoubtedly a need for capacity and infrastructure development in this area in developing countries. Research funding agencies are beginning to address this through new capacity development funding initiative encouraging North-South and South-South research partnerships (eg Wellcome Trust, MRC).

16. *The International Health Regulations 2005 are intended to provide a global framework for the rapid identification and containment of public health emergencies. How effective do you consider this response system to be? Do improvements need to be made?*

No response.

17. *What intergovernmental planning has been undertaken to cope with the impact of an outbreak of infectious disease caused by deliberate release of micro-organisms into the environment? Is there adequate liaison between the various agencies involved, including intelligence, law enforcement and health care professionals? How could action by intergovernmental bodies help further?*

18. *Though our remit is focused specifically on known infectious diseases, we would be interested to know how you view the global threat from new or previously unrecognised ones and from the transmission of infections from animals to humans.*

Whilst there has been much pandemic planning in relationship to flu it should be recognised that other pathogens possibly new to human-pathogens could lead to a pandemic. There is therefore a need to consider "generic" pandemic plans that would be of use whatever the infection.

19. *What resources (subscriptions, staff, training, medicines etc) does the UK Government commit to intergovernmental bodies to help in the fight against the four diseases listed?*

20. *Do you wish to provide any other relevant information in addition to what you have said in answer to the above?*

No.

February 2008

Memorandum by the University of Oxford

3. There are the WHO systems: GOARN, the global influenza surveillance network and FluNet.

Many countries now have thermal scanners at points of entry. For example UAE will scan entrants and give febrile individuals a rapid diagnostic test (looking particularly for malaria). Infected individuals will be offered treatment. It is not clear what an infected individual's options will be for entry thereafter.

Proper consideration of the role of migration on the spread of infectious disease is needed. It is not sensible to let considerations of political correctness stop us from detecting and treating infected and infectious migrants. Both for their own good and for the good of the societies they join.

4. HIV/AIDS depends on how good drug distribution programmes are and how at-risk populations change their behaviour. The emergence of highly transmissible multi-drug resistant strains will also have a high impact.

Avian influenza (or any emergent influenza). The acquisition of the ability to transmit easily amongst humans is a process so poorly understood that it has to be treated as stochastic. It is not the case that H5N1 avian influenza is the only threat, a new pandemic strain might arise from a different genetic background that currently does not infect humans.

TB The increase in XDR TB needs to be followed very carefully to assess the global threat.

Malaria. Discussion of eradication is widespread. The problem is financial, not anything else. The Global Fund has dispersed 2.4bn in the last 5 years with a reasonable match to malaria prevalence. In terms of financing what is needed to move towards eradication things are in a good position. If The Gates Foundation follows up their apparent interest in eradication with substantial funds it may become a possibility.

7. For malaria global warming is often cited as a risk factor for extensions in the range of spread. This is probably a red herring and drug resistance has been a much more important risk. Now that a new family of drugs (the artemisinins) is available prevalence is falling across Africa.

The thought that global warming would bring malaria back to N Europe pre-supposes a complete breakdown in the health infrastructure.

9. TB has always been hard to treat. The drugs have to be taken for a long time, including long after the patient feels well. Many countries use directly observed treatment strategies (dots) in which health workers visit patients every day to watch them take their medicine. This is costly in terms of man power, but can be very effective.

10. The adverse effects of DDT were from agricultural applications, not malaria control. For malaria control you would perform residual spraying to the inside of a hut. Janet Hemingway at the Liverpool School of Hygiene would know about this.

12. Different answers for different pathogens

HIV drug resistance is not yet the major reason for continued spread.

TB drug resistance is an important contributor to continued spread.

Malaria drug resistance has been the most important factor in the past. If drug resistance to the new family of drugs arises it will have enormous impact. MMV the medicine for malaria initiative considers this possibility and seeks out new drugs for the pipeline. Again we are in a better position than 5–10 years ago.

Avian influenza is not spreading amongst humans yet. However, I think it is extremely likely that an avian influenza that became capable of efficient human-to-human spread would very rapidly acquire drug resistance which would then render useless our proposed drug-based control strategies.

16. The 2005 IHRs allow WHO to “use” unofficial sources although it states that it will “verify with countries before taking any action”. This is an important step forward as it allows WHO to (at least partially) benefit from internet based sources of information. I assume you know about Promed www.promedmail.org. However the IHRs are largely about sharing information and expertise. It would be a mistake to rely on them to prevent the spread of infection. We would just know about it sooner and be able to help a source country with interventions. That could stop a pandemic for some infections but almost certainly won't for something like pandemic influenza.

18 We think there is a real threat from Dengue. Bacterial infections of childhood and from food are an important and growing threat to health. Our past vaccines have mostly remained effective for a long time. Newer vaccines may be much less durable (because of differences in the underlying biology of the pathogens they protect against). It would be prudent to be aware that vaccine resistance may become a public health problem in the future.

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Examination of Witnesses

Witnesses: PROFESSOR SIR MICHAEL MARMOT, Head of the Department of Epidemiology and Public Health, University College London, PROFESSOR ANNE JOHNSON, Director of the Division of Population Health University College London, PROFESSOR ANGELA McLEAN, Director of the Institute of Emergent Infections, University of Oxford, and PROFESSOR NEIL FERGUSON, Director of the MRC Centre for Outbreak Analysis & Modelling, Imperial College London, examined.

Q202 Chairman: Welcome to the Select Committee on Intergovernmental Organisations. First of all, these sessions are being recorded. You will have an opportunity to send in any written corrections, factual corrections, that you think need to be made. I would also want you to feel free to send in any other additional comments that you feel need clarifying or you need to add something totally new. Please do not feel that this is the end of your contribution. Each of

you does not have to answer every question but, if you want to come in on something, do please indicate. Let me just say to you, because of your particular backgrounds, that we are primarily interested in the intergovernmental organisations and the effectiveness at dealing with communicable diseases and the British Government's involvement with that. In order to do that we do need a better understanding at times of the medical side. We

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particularly need, and are beginning to get, having taken a certain amount of evidence now, an idea of where the problem areas are. We are not expecting you to have great knowledge of intergovernmental organisations per se, but it would be very, very useful if you flag up where you think things are not being addressed on an international level, if you like, as well as they could be or where the UK Government might be able to make its contribution more effective. Be fairly flexible in how you deal with this, do not worry if most of your knowledge is medical and not so much of the intergovernmental type. Just understand that is the bridge we are trying to cross here. Can I perhaps start by asking you to introduce yourselves so we have got a better understanding. Perhaps you could start, Professor Marmot?

Professor Sir Michael Marmot: I am Michael Marmot, Professor of Epidemiology and Public Health at University College London. I also chair a commission set up by the World Health Organisation, the Commission on Social Determinants of Health, of which Amartya Sen is a member. I have a little bit of experience of how one particular intergovernmental organisation works, the WHO.

Q203 Chairman: This is very useful, Professor. Professor Johnson?

Professor Johnson: I am Anne Johnson. I am a Professor in Infectious Disease Epidemiology at University College London. I have a particular interest in HIV and sexually transmitted infections and also some interest in other areas, such as influenza and tuberculosis. I am involved to some extent in international research programmes in HIV in an African context.

Q204 Chairman: Professor McLean?

Professor McLean: I am Angela McLean. I am Professor of Mathematical Biology in the Zoology Department in Oxford. In that department I direct something called the Institute for Emergent Infections of Humans. My research interest is the evolution of infectious diseases.

Q205 Chairman: Thank you. Professor Ferguson?

Professor Ferguson: I am Director of the Medical Research Council Centre for Outbreak Analysis and Modelling at Imperial College. Again, I have a background in mathematical epidemiology. I have worked for many years on novel infectious disease epidemics ranging from BSE to foot-and-mouth disease on the animal side, but most recently on SARS, bioterrorism and preparation for a flu pandemic. In all of those contexts I have worked quite closely with both governmental and intergovernmental organisations. Until the

introduction of the International Health Regulations I was a member of the World Health Organisation Global Pandemic Task Force, which would advise the Director-General on when to call, say, a Phase 4 pandemic. My group worked quite closely with Margaret Chan, who is now Director-General of the World Health Organisation, during the SARS outbreak. Whilst I would not say I am an expert in WHO, I am there about every two-three months or so.

Q206 Chairman: Thank you. We will have some questions on terrorism and biological threat. If you have problems, if you are affected by the Official Secrets Act, which I suggest you may be, let me know and indicate that.

Professor Ferguson: Not in the context of the WHO.

Q207 Chairman: Let me know if there is a problem anyway. Thank you very much for that. Let me start by asking you this. We have been made aware of what seems to be a very crowded and fragmented architecture between the various intergovernmental organisations, both the voluntary private bodies and, indeed, the international organisations. One of the things we are trying to work out is, whether there is a need for some sort of rationalisation of these organisations. Do they overlap in a way that is productive? Or is there overlap which actually causes confusion? I wonder if any of you feel able or not to talk about that particular area.

Professor Ferguson: I would just say I find it unsurprising given the numbers of actors involved and given the scale and number of challenges involved.

Q208 Chairman: You do not find it surprising?

Professor Ferguson: I do not find it surprising at all. I also think scope for rationalisation is somewhat limited because those different actors have different funding, different constituencies, and answer to different interest groups. I am encouraged by the degree of co-ordination now compared with ten or 15 years ago, and maybe we will come back to the drivers for that. I think there is an implicit sense in the question perhaps of global health being something which is more akin to a centrally planned economy, whilst I think really it is a free market of different interest groups interacting. My perception is that it is a market working quite well generally at the moment, at least in the areas I have dealt with. It is not perfect but it works quite well and arguably better than the alternative of a more directed approach, even if that were feasible.

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Q209 Chairman: If there is not too much fragmentation or the interaction is good enough, if you like, in a way the question is: who is making sure it is good enough? Is that the role of the WHO as you see it? And is the WHO doing it well enough?

Professor Ferguson: It has varied over time and there was a hiatus, under the last Director-General. Some things went very well and some things went backwards. But under the current Director-General they have really picked up the gauntlet of co-ordination. I think the other big player on the scene, which is an NGO but it has got a far larger budget than WHO, is the Bill & Melinda Gates Foundation. Those two organisations working together, which has not been a perfect interaction, have achieved a good deal more co-ordination than has been seen in the past.

Q210 Chairman: Before I bring in my two colleagues who want to come in on this, just let me ask whether your comments are affected by a different approach to the regional structure of WHO or the central structure of WHO? One of the things we hear is that the regions are very variable.

Professor Ferguson: I think that is true. First of all, I should say most of my interaction is with the centre and I have been specifically, mostly in the recent past, interacting on acute outbreaks and things like avian flu, where there has not been as much mismatch between regional interests and central interests as is sometimes the case. So in that sense I have seen co-ordination, not necessarily at its best but close to its best. I have also been quite impressed that, compared with a few years ago, WHO and other key players are willing to be rather more confrontational of Member States than they used to when faced with lack of openness, for instance. In the past that did not occur partly because of the effect of regional offices' representational nature of WHO.

Q211 Chairman: So you see it as more of a country-level problem or a regional-level problem?

Professor Ferguson: I honestly do not see it as a problem. Things are evolving over time. In other disease areas there are issues about different agendas at the centre versus regions, and probably my colleagues can talk more about that. Particularly in the acute planning for a pandemic, the next SARS emerging infections, those issues are a little less acute. They may be more acute when we get other issues, for instance, like the interaction between WHO and OIE and FAO where there are some more fundamental challenges, but within WHO I see less of an issue, at least on that side.

Q212 Chairman: Before I bring in Lady Whitaker and Lord Geddes, would any of the other three witnesses like to add anything?

Professor Sir Michael Marmot: I see it slightly differently, I have to say. Looking from a country perspective, my Commission met in Nairobi, for example, before the recent disastrous chaos there and the impression we were given was of a huge bewildering variety of specific programmes from specific sources, each with a demand for "Do it this way. Account for it this way". The countries did not have the resources for the accounting that was required by this bewildering variety of specific programmes. Looking at it from a country point of view, what they saw was total lack of co-ordination and they found it very difficult.

Professor Johnson: In the field of AIDS I think there is some similarity with what Professor Sir Michael Marmot has described insofar as there are great gains that have been made by some of the vertical programmes, for example in the roll-out of anti-retroviral therapy. But in one area you may have several different programmes operating in one town. That may have advantages but it may have significant disadvantages if they are operating in different ways as described. The second thing is how do we build capacity within those countries. We are talking about intergovernmental agencies, the role of WHO. But there is, of course, the whole question of the role of governments within country and the capacity of governments to develop their own health services, to develop the skilled people capacity. This is critical, to deliver programmes over which they have some greater degree of autonomy, which I think has to be a long-term aim.

Q213 Baroness Whitaker: In a way my question is just another way of putting Professor Johnson's point. Professor Ferguson, when you mention actors and interests, I quite see that there are a number of what in some contexts would be called producer interests, very many professionals and very many organisations. But from the point of view of the people who are going to get ill, would you say there was an integrated set of organisations?

Professor Ferguson: I am not sure if anybody speaks for the people who are going to get ill in those cases. We have governmental representation and WHO is an intensely political organisation. The thing I have had most dealings with recently has been the Indonesian controversy over virus-sharing and the response to that. There has been concerted action by individual countries and groups of countries achieve changes relating to intellectual property, and to get more investment in certain basic infrastructure, although I have to say with a lot of political edge to the whole controversy. These actors are countries,

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they are not people speaking for the individual. Turning to Professor Johnson's point, it is perfectly true that, if you actually look on the ground—not necessarily in avian flu, which is an exception, but in many control programmes for well-established diseases, such as malaria and HIV—you will see a bewildering variety of programmes in many countries. I would not necessarily say that this is WHO's responsibility or fault, however. They attempt a degree of co-ordination, but really the situation is that lots of individual NGOs are coming to agreements with individual Member State governments to put in yet another programme without necessarily any degree of co-ordination. The failure of governance, if there is one at that level, is really with the individual country involved.

Q214 Lord Geddes: I am homing in on very much the same point as Lady Whitaker. In your opening remarks, Professor Ferguson, you kept referring to "interest groups" and I wonder what you meant by "interest groups". Do you mean the people who are funding? Or political interest groups? Or, as Lady Whitaker said, is it what I call the recipients? They are all interested groups.

Professor Ferguson: It is a combination of both. Because global health is almost a synonym for the health of developing countries, quite often the funders and the people behind them, have the controlling interests in those discussions. The sectional groups within organisations such as the UN and World Health Organisation are other interest groups. By sectional interests I mean they are very technical organisations fundamentally, so you have people with backgrounds in particular disease areas who advocate those disease areas. There is not necessarily the overview of scope, a truly comparative assessment of, say, the cost benefit of interventions for different diseases across disease areas which you might wish if you were planning this from scratch. The data do not exist to allow one to balance investment in a malaria programme versus investment in another vertical programme, such as HIV. So what you get are very powerful interest groups which are almost built organically between scientists, professionals, policy people within those organisations and partner organisations, NGOs, academic units, which typically advocate particular vertical programmes. In my view, the things which suffer in this are arguably the less sexy horizontal programmes which are much more difficult to implement because they involve much more challenging interactions with Member State governments on the ground and are more difficult to motivate. That is why it is encouraging in the last few years that organisations like Oxfam have got more involved in interactions with Gates and the WHO,

and also organisations like MSF which is growing in importance. These interactions are on both the vertical and the horizontal sides. So overall, interest groups are rooted in subjects and diseases. That is what it is easy to raise money for and people are trained in specific areas.

Q215 Lord Geddes: If I may do a follow-up, and I would be interested to hear from our other three witnesses. One of the great advantages of being a member of this Ad Hoc Committee is I have never met so many professors in such a short space of time in my life. It is a bit awe-inspiring for us on the Committee.

Professor McLean: We are delighted you think that is a good thing.

Q216 Lord Geddes: Be that as it may, what you have just said, Professor Ferguson, frankly frightens me because, if these interest groups are as powerful as you say they are, and I can understand the logic of why they are, is that not by definition a recipe for disorganisation overall?

Professor Ferguson: I do not want to paint too bleak a picture. People are aware of this and there are attempts to join the dots horizontally. There are some big initiatives. One of them is funded by Gates, which is a follow-up to an earlier study by somebody called Chris Murray on *The Global Burden of Disease*. Whilst it has its methodological flaws, the current study and the previous study have the big advantage of being the only attempts to compare across all disease areas the relative importance, impact and severity of different diseases and also, to some extent, how easy it would be to mitigate that impact. That inter-sectorial comparison is starting to happen, but part of the challenge is lack of crucial data. Part of the challenges overall in this area are for the non-research intervention programmes. The research programmes have well recognised metrics of success though even these could be better defined because, but for the intervention programmes quite often measurement of success is done in a very ad hoc manner and not in an easily comparable manner between programmes.

Q217 Lord Desai: Professor Ferguson, you gave a very good analogy that it is not like a central bank, it is like a market. But at the same time Professor Marmot said what we have heard, and there are lots of other specific things. It seems to me that specific agencies and programmes give money which is non-fungible and it is like a market with different foreign currencies operating, but there is nobody to trade between foreign currencies. Do you think that reduces the effectiveness of the resources because people cannot transfer money. They have to do it the

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way X tells them to do it and, although Y may tell them to deliver the same, it is in another way? Is that a problem with the architecture?

Professor Ferguson: Yes, in part. There are some finite resources and the finite resources are the capacity of the global community at any one time to implement a certain number of programmes. There is a limited number of people with the technical background and experience to put in place certain programmes on the ground and quite often those people have worked on a whole range of different programmes in different disease areas, so there is a degree of competition there. I would agree in general with your remark. Officially, NGO funding is earmarked for particular areas, and different NGOs raise their money from the grass roots and they want to implement their own thing. But, if you tell them “this is not necessarily the best way of investing money”, it is not a zero-sum game—the money will disappear.

Q218 Lord Desai: Would it be better if all the money was put in a nice big pot and then spent?

Professor Ferguson: You could try to do that.

Q219 Chairman: I think Professor McLean wants to come in.

Professor McLean: I was going to say I think Professor Ferguson has just touched on a very important issue which we have not discussed yet, which is local manpower, local healthcare worker power. There are just not enough people to deliver all of these things. As I am sure you all know, the problem is getting much, much worse with healthcare workers leaving developing countries to go and work in wealthy countries, and that is a huge issue.

Professor Sir Michael Marmot: Lord Desai said it as if it were an off-the-cuff suggestion, putting all the money in one big pot, but surely that is what governments do. I do not pay my taxes towards the NHS or education, I pay my taxes to the Government and the Government decides what to do with them. The idea that I would pay my taxes only for HIV/AIDS control and not for anything else we have decided is an unworkable proposition, and yet so much of the money coming in for healthcare in developing countries is hypothecated. Not only does it take away from local people to decide what is important to them, it takes away from governments to decide what is important. Take the issue in Nigeria: 2,000 women die for every 100,00 live births and in Sweden it is three; so that is the range. If you have a programme for HIV/AIDS, it does not touch that maternal mortality at all. If a country says, “We have got these billions coming from PEPHAR and Gates and everywhere else for HIV/AIDS but we are not doing anything about the fact that a majority of women who give birth are not attended by skilled

personnel, sorry, there is no money for that. You can’t decide what to do because there’s all this specific money coming in”, we would not run our government that way and why should other countries run their systems that way. I think Lord Desai’s point is really a very good one. It may not be just throwing it into one big pot, but it may be working with governments to decide how best to use the resources for their needs.

Lord Hannay of Chiswick: I want to follow up on this point because I think quite a lot of what one hears is that, indeed, it is the lack of health infrastructure in many developing countries which means that, however many resources you pour into targeting particular infectious diseases, you are not going to have terribly good outcomes. Having described that as the problem, I think one of the questions we are asking people like you is, in that case, how do we get it better? Should a committee like this be saying that too much money is going into specific, very high-profile diseases and not enough is going into less well-known ones? That is perhaps the more straightforward problem. The most difficult problem of all is that nothing like enough is going into healthcare systems in poor countries and, if you put more money into healthcare systems, then a smaller quantum on the individual diseases might actually produce better results. I do not know what the answer to that is, but if you are able to guide us I think this is one of the biggest issues we are looking at.

Chairman: I am going to bring in Lord Jay on this because in a way this is very much the question you were going to ask and it is a very logical follow-on.

Lord Jay of Ewelme: That was the question I was going to ask and I do not think I need to re-ask it.

Q220 Chairman: That is fine. This is the horizontal versus the vertical, as we understand it.

Professor Johnson: I think this is an absolutely critical issue. I think it is very easy to throw out the vertical programmes completely, and one should not do that. The vertical programmes have, undoubtedly, achieved a great deal in certain areas—anti-retroviral therapy is making a difference and so are TB programmes, vaccination programmes, and so on. But the difficulty that arises is, if they are being set up without the underlying horizontal infrastructure with which they can interface, you begin to distort the health economy, so you get people coming out of what little infrastructure exists, which is often very little indeed, and further pushing resources into the vertical programme. To give an example, HIV programmes are being rolled out, HIV screening is being undertaken in ante-natal settings, because at least part of maternal mortality is due to death from HIV and neo-natal problems due to transmission of

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HIV. But then people stopped screening for the entirely treatable condition syphilis, and therefore you get the reappearance of congenital syphilis, to give an example. To develop that infrastructure in health systems it does seem to me to have the need to work very closely with Member States and governments, as Professor Marmot has said we have to build the kind of infrastructure which may be less glamorous for certain NGOs that are single-focused, to build district health services and systems. That requires huge investment in the training of individuals. In Malawi, for example, there are very, very few doctors. In other countries, as you know, we are seeing net importation of trained staff into developed countries, into the Western world, so we have to invest quite heavily in that, and I think Lord Crisp has written about how we can assist in the UK in doing this. People are now talking about diagonal programmes. That is, of course, trying to invest in vertical programmes but making sure that they interface with horizontal programmes. We have vertical programmes, remember, in this country which work like that. We have vertical programmes for tuberculosis control in this country. It could not be done just by managing in primary care; we need to use the primary secondary interface and specialist services.

Professor Mclean: I think there is reason to be hopeful, because all that vertical money could leave a legacy. Remember, the ultimate vertical programme was the eradication of smallpox, and for some time after smallpox was gone the childhood vaccination programmes that have been set in place by it functioned well, and in many places they still do function well, so we do have a model where a vertical programme leaves a legacy behind it that can do other things too.

Q221 Lord Jay of Ewelme: Developing the same point a little bit further. The consensus I get is that you need both: you really need some vertical programmes, you need some horizontal programmes. Do all of you think that at the moment, the way that funds are being allocated, there is either a risk of, or there is, an actual distortion of priorities away from what you would think would be the right balance between the building up of basic healthcare systems and the focus on individual diseases?

Professor Sir Michael Marmot: I think there is another issue that I am sure you have come across in your deliberations. In 1978 the World Health Organisation had its Alma-Ata Declaration on Health for All and said that the means to achieving health for all was comprehensive primary healthcare. That meant building health systems—not a new idea. 1978 was the Alma-Ata Declaration. It will be revisited this year in Alma-Ata, 30 years on. What

happened, in practice, was that health system reform essentially meant marketising health systems. It was seen as a very bad thing to have everything controlled by the state, by the centre, “public” was a bad word, and the structural adjustment programmes that were foisted on low-income and middle-income countries also affected health systems. So the bold declarations of Alma-Ata did not happen by and large. They were vertical programmes and countries were told to privatise everything in sight to do with health systems. In most low-income countries the majority of healthcare expenditure is out of pocket. There is good empirical evidence that, the higher the out of pocket expenditure, the worse the health figures. Whether that is a causal link between out of pocket health expenditure or there is some common factor to do with poverty and disorganisation. But it is, nevertheless, the case that, the greater the proportion of healthcare expenditure that is out of pocket, the worse the health record. Rich countries do not do it that way, by and large. In Europe we do not do it that way, very little of our healthcare expenditure is out of pocket, and we have good health records. But, when you hear about Nigeria, two-thirds of its healthcare expenditure is out of pocket and the majority of women, as I said a moment ago, do not get skilled care during their maternities. The whole idea of developing a health system just foundered after 1978. We have had the vertical programmes but there has been almost nothing else, and, at long last, WHO is rediscovering the importance of primary healthcare, and that is one of the things Dr Chan is hoping to make part of her legacy in WHO and that is why this year’s World Health Report will be on primary healthcare, to bolster it. It is not just that there is a mix. I would say the only game in town has been vertical programmes and we need to rediscover how important health systems, primary healthcare must be to make vertical programmes work better, quite apart from the fact that they are needed for all the other things that are left out of the vertical programmes.

Professor Ferguson: I would agree with much of that. I think there are some positive steps to be taken in a gradualist approach rather than tackling health system reform head on. Organisations like the Gates Foundation are deliberately forcing 90 per cent or so of funding of their big programmes to be in-country and increasingly are moving to enforcing that there is a transitional hand over from initial governance of those programmes, typically in academic or other expert institutions in the West, moving to being sustained on the ground without necessarily that same input. The transition from a sustained, self-directed, if not self-funded, vertical programme to a horizontal programme is an easier one to see than, in essence, flying in experts who run a programme for

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four years whilst they have funding and then fly out again. So, for instance the Schistosomiasis Control Initiative, which is run out of my department, has treated 45 million people with a very simple drug against one of the so-called neglected tropical diseases. It has been a relatively cheap programme, but it has been effected by nearly all the delivery being done through local healthcare systems rather than a single one-off additional programme with additional staffing. There are other examples along those lines. Also, there is the rediscovery of simple interventions rather than necessarily complex therapeutic interventions—for instance, going back to bed nets and vector control for malaria, gives programmes which can be implemented easily on the ground—similarly, some of the ones for diarrhoeal diseases. They are not necessarily the programmes that scientists in the West want to get involved in and other people want to advocate though.

Chairman: Can we move on to WHO leadership, which we have touched on in a way already, but it is becoming relevant.

Q222 Lord Geddes: We have, indeed, Lord Chairman. It is difficult now to know how to phrase the question. If I can put words into your mouth, the pendulum has swung too far into vertical and you would like to move back a bit to horizontal. Those are my words and not your words. If that were to happen (and the consensus of opinion from the evidence we have had so far all points towards the WHO), is the WHO geared up to take on that role? And, as has come out in a question, there is a big difference between WHO centrally and WHO in the regions. There are two parts to each of my two questions, and I would very much appreciate hearing from all four of our witnesses.

Professor Sir Michael Marmot: In answering that, can I raise another issue. We have been talking about vertical programmes and horizontal programmes, but there is a third issue which relates to the commission that I am chairing, the Commission on Social Determinants of Health, which is based on the understanding that the main drivers of the health status of the population lie outside the healthcare system.

Q223 Chairman: In poverty, and so on, you mean?

Professor Sir Michael Marmot: Yes, it is arguable that the best intervention to improve infant and child health is education of mothers, not more healthcare, and it is actually cheaper. I would never, for one moment, argue that we should not have healthcare for infants and young children; we should have it, but we should also have education of mothers. It would make a huge difference. When you talk about lack of

joined-up architecture, it is not just the lack of joined-up thinking among the various actors interested in healthcare, but it is lack of joined-up action in the various actors concerned with the main factors that affect health. There are good reasons for dealing with child poverty, apart from poverty being a bad thing, because poverty affects the health of the next generation. But it is not being combined, it is not being sorted out, it is not being co-ordinated to, for example, invest in early child development, which is very important for subsequent health. One of the areas that my Commission is going to emphasise is the importance of early child development, not just child survival but physical development, linguistic and cognitive development, social and emotional development of children. It is absolutely vital. It is not just a concern of rich countries, it is a concern of all countries; it is a global concern. There is nobody really tasked with that. There are bits—UNESCO, UNICEF, WHO—there are bits and pieces all over the place, but lack of co-ordination.

Q224 Lord Geddes: What is your answer?

Professor Sir Michael Marmot: I have been struggling with this a great deal, and it is one of the things my Commission is wrestling with, and I see an issue that is quite similar to issues of governance within a country. The question is what is the role of the Minister of Health, in this country the Secretary of State for Health, if you argue that the key drivers of health lie outside the healthcare system? The levers which the Secretary of State for Health can reach are all within the healthcare system, so those are the ones for which he tends to reach, but the main drivers are elsewhere. It seems to me (and I think it gets back to your question about WHO) that the Minister of Health, the Secretary of State for Health, has a key role, because nobody cares as much about health as she or he ought to be doing. Nobody has the added capacity to look at the drivers for health other than those that tend to lie within the sphere of influence of the Ministry of Health. The Minister of Health has a key role as an advocate, as an analyst, in monitoring how well things are happening and measuring health status and, more importantly, the distribution of health, health inequities within countries; so the role of the Minister of Health, I think, is vital, a leadership role, and I think that is the role that WHO ought to be playing here. I think WHO ought to be playing a leadership role among other international government organisations looking at the key drivers that affect health globally because of their concern particularly in low-income and middle-income countries. That is very difficult. I work in a university. We talk about cross-disciplinary work, and getting people to talk outside their own academic department is extraordinarily difficult. Everybody

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tries it and everybody finds it very difficult. I have been advising, in one way or another, across government in this country for a long time. We talk about cross-department working. It is extraordinarily difficult. People pay lip-service to it, but it is really very difficult. Since my Commission got started, we have been to ILO, we have been to World Bank, we have been to UN DESA to talk to people about how they might link up, and everybody says, "Yeah, great idea", and then, when I get out of the room, they go back to business as usual, so it is extraordinarily difficult. But, to come back to your original concern, what would the role of the British Government be? The British Government has a very respected voice, certainly in WHO and, I presume, in other inter-governmental organisations, but it is a highly respected voice in WHO. It could play a very powerful role in trying to bolster, push, encourage a WHO leadership role among the various actors in the healthcare system but, more broadly, among the various actors whose core business is to effect the key drivers of health and health equity.

Q225 Chairman: That was a very full and helpful answer, but would any of the other three like to come in?

Professor Ferguson: I would agree whole-heartedly but would voice maybe a slight cynicism. The WHO annual budget is about 1.65 billion US dollars per year, of which about one-third is core budget, which can be applied to both administration and horizontal programmes. Most of the rest is earmarked for vertical programmes by Member States such as our own. We, the Japanese, the Germans and, of course, the United States are big donors to WHO and, increasingly, the Chinese, but overall it is a tiny budget to do any significant amount of global development. Even if you took the sum across all the UN agencies, we are talking about a tiny budget. If you compare it with what the Bill and Melinda Gates Foundation has to spend, then the people who are actually going to determine what is spent on the ground and, because they are not having to filter the money to governments, have much greater ability to implement things on the ground are going to be those NGOs, and influencing those NGOs to have a broader health perspective, I think, is where, to some extent, WHO but also governments have a role. To be fair, I think the Gates Foundation is moving in that direction already. Even from the outset they identified population concerns, women's health, women's education as key determinants. They have not invested as much in that and they are internally getting rather siloed at the moment, just because of the difficulty of spending money fast enough, but if you take a market approach, and follow where the money is, then influencing Gates and the other NGOs

is where the focus should be, given they collectively spend as much as all the UN agencies on developing per year.

Professor Johnson: I want to return to this issue of education, training and human resources. If one takes the view, which I do, that primary healthcare and health systems are important for the long-term sustainability of these programmes and the developing world, then you have to have a strong education infrastructure. That goes right through from primary education, through secondary education, through tertiary education. Education is absolutely at the root of human development, in the kind of things that we have been talking about. If people have education, so employment follows, so greater prosperity follows, child development improves, nations improve their overall wealth. It is extraordinarily important, as is women's education along the lines that have been described, but you must then invest in those education programmes. You cannot educate five-year olds without teachers and you cannot have teachers without tertiary education and, indeed, universities. You cannot have doctors and nurses without a sustainable infrastructure in the education sector. One thing I have recently engaged with is a Wellcome Trust scheme, which is trying to develop a programme of improved infrastructure for research in an African context and trying to get greater interaction between UK universities and African universities. It is pushing the African universities to take the leadership role in building that kind of infrastructure. That seems to me an extraordinarily important place to invest if you are going to start from the kind of grassroots that you describe, which will alter the parameters which ultimately affect health. We cannot continue in a situation where those human resources do not exist and we are always trying to take people from outside in. When people get trained up, as Professor Mclean has described, they often migrate out again. That is a key area for investment, but with encouragement of leadership from developing countries.

Chairman: Lord Desai, we have covered some of your points on European Centre for Disease Control. You might also want to pick up some of the other regional ones as well, I am not sure.

Lord Desai: In the structure, where does the European Centre for Disease Control fit in? Is it an extra leg that we could do without? Or is it a very helpful thing to have?

Q226 Chairman: The witness is smiling here. I am puzzled by this. Go ahead anyway, Professor Ferguson.

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Professor Ferguson: I do not think it is relevant on the global health scene in terms of what we have talked about; its remit is entirely within the European Union. It should be compared with WHO Regional Office for Europe. Actually the Regional Office for Europe for WHO is mostly looking east towards Russia and the less developed Eastern European countries rather than the European Union. ECDC has a small budget at the moment, and a very limited influence. We could have an entirely separate meeting about ECDC. I think it does some things well, in terms of co-ordinating information and meetings, and in other ways it is achieving very little, overall the European Union does not have much of a role in health anyhow by statute, and what activity exists is also fragmented. I deal with bioterrorism at both ECDC and something called DG SANCO, the Directorate-General of Health, which actually has a much larger budget but almost no political remit within the European Union. So I would to some extent leave ECDC to one side, because neither of those organisations is significantly contributing to what we are talking about with respect to WHO.

Chairman: I want to bring in Professor Mclean and Professor Johnson on this because they are both looking with some interest on this. Lord Desai, did you want to pursue this?

Q227 Lord Desai: No, but I want to ask a supplementary without forgetting the first question. Would it help us, as a committee, not to think about developed countries at all, just parcel them out, and only worry about effectiveness in combining policies in poor countries?

Professor Johnson: Developed countries, since they have control over quite a substantial amount of resources, are very important in the way they impact on global health. The responses of developed countries with respect to key issues—for example, a flu pandemic—is clearly critical as that is a very big and sudden global health problem. But, if you are concerned about where the major burdens of disease lie in infectious diseases, then you are talking primarily about the developing countries, although infectious diseases remain a really significant cause of morbidity and mortality in the UK, just at lower rates.

Professor Mclean: I do not think you should leave the developed countries out, because the way we behave has such an impact on what happens. For example, the way that we hire nurses from developing countries has an enormous impact in developing countries, and I think these issues that we were talking about, about co-ordinating roles and a role in education, are just very, very important. We know that we have to stop hiring nurses from overseas. I do not think we have stopped yet, we know we need to,

but there are other things we need to learn about education. Setting up yet another MSc in London is not what we need.

Q228 Chairman: Setting up what?

Professor Ferguson: Setting up yet another Master's degree course in London in order to---

Professor Sir Michael Marmot: In Oxford!

Professor Mclean: It would be fine if it was in Oxford. Setting up yet more postgraduate training here is just not what is wanted by the people who are trying to establish in-country healthcare.

Chairman: But you are dealing with a slightly different thing. The issue of the ECDC, I think, is next.

Q229 Lord Desai: Yes. We have this thing about ECDC. Perhaps we should ignore ECDC altogether and really concentrate on the impact of disease on the poor countries. Developed countries appear as suppliers of advice, money, and so on, and sometimes the takers-away of resources.

Professor Johnson: Absolutely.

Chairman: I know Lord Avebury wants to come in on this.

Q230 Lord Avebury: I am a bit puzzled, because in the announcement of ECDC's Mission by Commissioner Kiprianou, he said that it was to co-ordinate all activities regarding risk assessment, surveillance, detection and investigation. He then went on to describe how its goal was to co-ordinate existing networks on communicable disease. That implies a global role, but you said it was purely European.

Professor Johnson: My understanding is that the role of ECDC is to co-ordinate the activities in the European Union. Therefore, they have a role in working with Member States, as I understand it, to bring together surveillance data, to work with Member States on the number of policies in relation to the control of infectious diseases but, primarily, round the EU setting. Of course, they must also be responsible if there were an outbreak. If pandemic flu started somewhere in the EU, then of course they would have a very important role in control and, I think, in liaising with WHO, and so on. I think it is a little unfair to dismiss ECDC in any sense when it is a very new organisation. It is just building up its capacity and beginning to develop its teeth, to be fair. I think perhaps a better analogy might be with the US CDC, where the US CDC has a very important role in infectious disease surveillance and control and the development of policies within the United States and, obviously, interfaces with the WHO but is entirely independent thereof. The analogy is obviously not complete, because there are so many Member States

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in the EU. It is parallel but not within the WHO family in quite the same way.

Professor Ferguson: I would agree. ECDC would like to model itself on the CDC, but the CDC has an executive function.

Q231 Chairman: Can you remind me what CDC stands for?

Professor Ferguson: CDC is the Centres for Disease Control, but the Centres for Disease Control have a budget which is roughly 30 to 40 times that of ECDC. Most importantly, they have an executive function. They retain a lot of the US public health service, which has a statutory responsibility and authority to deal with public health, which supersedes that, indeed, of states within the United States. ECDC, by its formation, has absolutely no power to do anything at all. It can only co-ordinate. I think it has done quite a good job in some areas, but I would say the two organisations are only similar in name really, perhaps aspiration.

Q232 Chairman: Professor Marmot.

Professor Sir Michael Marmot: It relates to Lord Desai's supplementary. If I interpret the questions of this Committee as being about intergovernmental organisations where communicable disease is an example, the question is: should we ignore the developed countries? If we look at the global burden of disease—Professor Ferguson pointed to the global burden of disease—for every region of the world outside Sub-Saharan Africa, the poorest of the low-income countries, non-communicable disease makes a bigger contribution to loss of disability-adjusted-life-years than does communicable disease. If we are worried about global health and global health inequities, we cannot focus only on communicable disease, we must focus on non-communicable disease as well. My concern the whole of my research life, and the concern of my Commission, is with health inequity, or, putting it positively, health equity. Should we ignore the developed countries? Life expectancy for men in the most deprived part of Glasgow is 52. The average for men in India is 62. You have got worse health in the most deprived part of Glasgow than in India. I would argue that, if our focus is on health inequity, then the global health agenda and the domestic health agenda come together. We actually have to be concerned as to how these health inequities arise and how we can deal with them.

Chairman: I want to move on, I think, to the investment and international use of funds. Lord Avebury, you had an interest in this.

Lord Avebury: I think we have covered a lot of that.

Chairman: You are right: we have covered a lot of it. I wondered if you wanted to talk about the intergovernmental organisations or the voluntary funds. But, if you are happy with what we have had, that is fine.

Lord Avebury: I would like to ask another question.

Chairman: It is the balance of investment between surveillance, prevention and treatment that I was thinking of particularly.

Lord Avebury: Before we come on to that question, I want to ask: at Question Time today we were dealing with the UNICEF report on the state of the world's children, particularly the very poor records in the West African region as regards progress on the reduction of infant and child mortality. I was wondering whether, considering that there is a huge variation in this figure between one region and another and the West African region is miles behind any of the rest of the world, what funds should DFID be allocating to international organisations to correct that imbalance? Is that the task of the WHO to look at the Millennium Development Goals and to remove these disparities? It touches on what Professor Sir Michael Marmot has just said about inequities in health. Here is a gross inequity in health; it is an order of magnitude between some of the states in West Africa and the developed countries of Europe in terms of child mortality.

Chairman: This is the issue of distribution within regions, is it not?

Q233 Lord Avebury: Is that something that the WHO should be addressing. And where should we put our money if we want to make a difference?

Professor Sir Michael Marmot: Once again, we have thought about and grappled with this issue on the Commission on Social Determinants of Health, and one of the things we will put to WHO is that WHO should take a leadership role with other organisations. The revolution in child survival came from Jim Grant, not from WHO. It came from UNICEF, not from WHO. One does not want to see turf warfare here, but it is very important to realise that there is more than one agency that is likely to have interest in this. If UNESCO's interest is in education for all and UNICEF is interested in child survival and WHO is interested in child health, you have got to bring them together. I personally do not have a big issue with who has the leadership role. What I do think, though, with current issues about UN reform on the table, we hear so much about the Security Council of the UN and so little about ECOSOC. I would have thought ECOSOC would have been more important than the Security Council, much more important. In fact, there would probably be less need for the Security Council if we had got economic and social development right. So,

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ECOSOC really ought to be where we are putting our emphasis and ECOSOC could then help these organisations get together. WHO could well play the leadership role in child survival, but when I heard a minister of health from West Africa point to the problem of rising infant and child mortality in her country and say, “Our solution is to empower the private healthcare sector”, my blood ran cold. She not once mentioned anything about education for girls, the fact that all over West Africa, in fact globally, girls are enrolled in school to a much lower extent than boys. It is just an issue of social justice to get this right, and that must be a key driver of child survival.

Q234 Lord Avebury: Is it entirely a question of the leadership role? Or is it just a matter of money? These are the statistics that we read from UNICEF, and they, as you say, have a primary interest in the reduction of infant and child mortality. The World Health Organisation does not have the money to fund the delivery systems that would be necessary?

Professor Sir Michael Marmot: Absolutely; no.

Professor Johnson: It is not their role.

Professor Sir Michael Marmot: That is why they could play the leadership role. They are not going to deliver the services themselves.

Q235 Chairman: Can I intervene here? One of the things I wanted a clear answer to here, because it is one of the important issues, is the balance of spending between surveillance, prevention and treatment, because that, it seems to me, would be a core part that we need to understand about the spending issue. Do not let me take away from any other answer you want to give there, but that I want an answer to, because it is one of the things that keeps coming up.

Professor Johnson: Could I take the issue in relation to HIV/AIDS programmes? There has been huge investment in treatment for HIV in the last few years, but actually that has not gone hand in hand with investment in prevention. It is not just investment in prevention, it is the attempt to try and integrate prevention and treatment services. Arguably, we have a long way to go in this country too in integrating prevention and treatment services. HIV is a life-long condition. We are treating a lot of people in this country; we are treating a lot of people in Africa. If they remain infectious, they will go on transmitting the infection, so life-long management of HIV, particularly as people live longer, also has to involve prevention services in a clinical setting. It also requires that we have very strong and continuing prevention programmes at the national level, through widespread advertising and education programmes in schools, and so on, which have to be sustained, just like vaccination programmes. You

have to sustain them and refresh them if you are going to go on through time to achieve that. I think a lot of agencies now would see that we have got a mismatch between investment in treatment and prevention, which often happens. Once a treatment hoves into sight, the prevention agenda gets forgotten. While we may be seeing globally a relatively stable prevalence of HIV, that is because people are dying so you are maintaining a number of new cases. On the surveillance front, the surveillance systems vary enormously between countries and the sophistication varies enormously between diseases. The Foresight programme on infectious diseases, on which I was a member of the expert group, emphasised the need for improved surveillance programmes and systems which harness new technologies to improve surveillance. These things are critical to understanding the future transmission dynamics of these infections.

Q236 Chairman: Do you want to come in on this, Professor Ferguson?

Professor Ferguson: Coming back to child healthcare, we know how to reduce childhood mortality. I would actually be more direct and say that, quite often it is a failure of governments in the countries concerned. They are largely simply failed states and it is very difficult to operate in that backdrop. Coming to detection, I think one needs to distinguish between routine surveillance for endemic diseases where the goals of surveillance, are really to monitor treatment programmes, monitor trends in incidence and prevalence and take corrective action if the trends are in the wrong direction or at least to understand the trends. Then the newer sense, post-SARS particularly, of surveillance being outbreak detection, and response. I think a lot has been done on outbreak detection and response, particularly for acute respiratory diseases, even in some very challenging settings, with limited infrastructure such as rural Indonesia or Cambodia, where we are picking up single cases and certainly clusters of cases in a relative short timescale. I am quite positive here—I think the moves are in the right direction—and we are also putting in generic capacity; there is a degree of capacity—building going in on the ground on that. There are questions from individual countries about what they get out of such systems, but CDC, in particular, has put a lot of money into it. Where I would agree with the others is on monitoring of burden of disease. In particular, to monitor disease prevalence and incidence through time. Those systems are much more patchy. They are also more expensive quite often, because you are not just looking for an early warning, and it is particularly easy just to get a signal; you are having to do quantitative, representative monitoring of the

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whole population in a setting where, as we have just commented, there is no infrastructure and primary healthcare to actually do what we would normally do in this country to monitor. It means it is a very challenging issue.

Q237 Lord Hannay of Chiswick: I would like to come back to this question which we have been circling round about WHO, horizontal, vertical, and so on. All the answers we have had from you seem to indicate that, first of all, you think the WHO does play a very valuable role in co-ordination in so far as it has authority to do so now and, secondly, that it is really the best place to do that with your remark about ECOSOC. I have to say, having been to rather a lot of ECOSOC meetings, that I would not share your enthusiasm. The trouble about ECOSOC is that it is in a worse position than WHO: it has no resources at all. It actually has no budget or money. It strikes me that in terms of the WHO, if it were to have a wider remit, a co-ordinating remit, it probably will not be very effective at it if it does not have also some more money, though not, I hasten to say, oodles more money, drawing it away from other financial centres. But, am I right in thinking that, as far as co-ordination is concerned, as far as striking a balance between healthcare systems and individual diseases, and so on, really it has to be the World Health Organisation which provides the forum in which you can try and get a balancing-off of these items? In which case, should one not be saying that the WHO needs a wider, more fully supported remit of a co-ordinating kind than it already has now and that, if it is to be taken seriously, it almost certainly needs some more money as well? Or have I got that completely wrong?

Professor Sir Michael Marmot: If I may, I would say you have it completely right. Its co-ordinating role at the moment, I would say, is more potential than actual, but it has real status. If you did not have WHO, you would have nobody else. Bill and Melinda Gates—it is wonderful that a philanthropist wants to use his money to improve global health. But WHO has real status in the system, and people love to criticise it; but, if we did not have it, we would need to start again and develop it and then people would criticise it all over again. I think we cannot do without WHO. We ought to support it, build it up, try and fix the creaking problems, give it an expanded role model. So, I would endorse that completely.

Professor Ferguson: It is difficult to underestimate. I have experienced it just once in South East Asia. How dominant is WHO? It is the first point of call of most developing countries' ministries of health if they have any crisis whatsoever, particularly an infectious disease crisis. They will call on the WHO local office and then on Geneva, and WHO has status because it

is perceived as being representative. Frankly, while such organisations waste money, WHO needs ten times the budget, then they really could actually do something, they could actually start implementing programmes and have real clout. The problem WHO has at the moment is just too limited resources to actually implement programmes on the ground.

Chairman: I want to move on to health and non-health intergovernmental organisations. Baroness Whitaker?

Q238 Baroness Whitaker: We have touched on the social determinants of world health. In fact, I was just wondering if WHO did not show some joined-upness in setting up your Commission already. What I would like to know is what is the picture of co-ordination between health and non-health IGOs? You have mentioned education, of course, poverty itself, but there is also trade, migration, there are a lot of other things which affect healthy habitat too. I know that UNICEF has quite a unified programme, which they call “wellbeing” and which encompasses quite a lot of what you call “child development”. Can you tell us, first of all, are there people from other IGOs on your Commission apart from distinguished independents? Is it UN-representative, as it were? And are there some other co-ordinating entities? Or ought there to be? Is that one of the creaking problems?

Professor Sir Michael Marmot: This is such an important issue. The only representative of another organisation on the Commission is from UN-HABITAT. Anna Tibaijuka is a member of the Commission. All the other commissioners are independent. For example, Ricardo Lagos, the former President of Chile, who is a Commissioner, has been very much involved in UN reforms; he was on the committee looking at UN reforms, so although he does not represent another UN organisation, he certainly has been close to UN activity. The issue of co-ordination, I would say, is not working well. I described before going in and out of offices of other members of the UN family and getting a very warm reception, but then I go back and talk to people at the secretariat level and say, “I have met the Director-General of ILO, he is very keen on our agenda, he wants to work with us. Can you make some link?”, and it does not happen. I go to the World Bank and I get the same very positive reception, and then I report back to the colleagues at WHO and say that World Bank in their new health strategy recognises explicitly that their lending in the non-health sector has a huge impact on health and that they need to monitor the health impact of what they do, and I put it to World Bank, “You need WHO to help you do that.” They say, “Yes, absolutely right.” I go back to WHO and say, “There

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is a real opportunity here for you to play a key role”, and it does not get picked up. I think it is a vital issue, the co-ordination issue. I am not sure I know how to do it.

Baroness Whitaker: That was my next question!

Q239 Lord Geddes: Why does it not get picked up? Is it lethargy? Are they frightened?

Professor Sir Michael Marmot: I think there is a lot of human nature in these organisations! I think it is why a Professor of Medicine has difficulty talking with a Professor of Anthropology in the university. People understand their own turf. In setting up the Commission on the Social Determinants of Health I did not realise at the time what a bold move J W Lee had taken, because as I now have seen it play out, everybody within the organisation, by and large, is involved in vertical disease control programmes and they were quite threatened initially, saying, “We do not know what all this is about. We do tuberculosis control, we do malaria, we do smoking, we do HIV/AIDS, we do cancer, diabetes.” What has happened now, and it is very positive, is a group of these people from the different disease control areas, say, “We cannot do our work properly unless we take these issues on board”, and we have actually, in a rather subversive way, I think, got people involved in these different programmes at WHO talking to each other and recognising that the issues we are talking about—to do with human settlements, with employment conditions, with education—help them do their work in tuberculosis control better, in safe pregnancy, in violence, and so on. The next step, in a sense, is to institutionalise that within the organisation and to get the forum right (and I am naive but that is why I was thinking of ECOSOC) to make it easier to talk across organisations, and there is nothing like money to give an incentive. If there were money to get these organisations to talk to each other, they would talk to each other.

Q240 Baroness Whitaker: That is one thing we can consider, of course, but everybody always recommends more funding. We shall be talking to WHO, and I quite see that it is not your job to reform the whole of WHO. But are there any mechanisms, any institutional measures which you think should be adopted to improve this, because it seems to me this is a really important weakness?

Professor Sir Michael Marmot: I think Dr Chan is very receptive to this. Once the organisation accepts that health equity is a core value for the organisation (and she is very receptive to this idea that it is a core value), then you cannot achieve health equity without taking action across the whole terrain that I have been laying out, and that means that, for her organisation to deliver on that core value, it has to function in a

different way. There are mechanisms that she can set up. For example, there is a cluster devoted to evidence for policy and information. It seems to me easily feasible to set up a cross-cluster activity, as we have been doing with these key people who are working in different vertical programmes. We have got a priority Public Health Conditions group that meets. I went to meet with them to encourage what they are doing. So we have actually set up a potential mechanism which she could support easily and make it part of the way the organisation functions. It would mean bringing in some extra expertise, so when people say “We do not know about education”, bring in some people who do know about education, and they would help you to interface with the other relevant organisations.

Chairman: Before I bring you in, Professor Mclean, Lord Desai, you wanted to come in.

Lord Desai: I just wanted to try out an idea. When governments or NGOs want to give money, they probably find that a vertical programme is much more directly effective, they can see it can actually fight disease. Forget about clean water, development, education; it is very hard to raise money for that. Or, they may think, you are not getting the bang for the buck: “We actually put this money in to fight disease and you are telling me you have started a primary school.” So it is partly a matter of showing from previous example that education of mothers, for example, is effective, but beyond that I think it would be difficult for horizontal programmes to command respect. That may be a conceptual difficulty rather than an administrative difficulty.

Q241 Chairman: Would you like to respond, because I suspect this might be an area of your interest too, Professor Mclean?

Professor Mclean: I was very taken with Baroness Whitaker’s question about, apart from giving money to WHO, how could one change it. Partly I am interested for personal reasons. My life plan, when I was in my twenties, was that I would train myself up as an epidemiologist and then go and work at the World Health Organisation, because it seemed like such an amazing organisation. Then, fortunately for me, my PhD supervisor said, “Perhaps you had better spend a summer there first.” So I did, and it was like swimming through treacle. I do not know if you have been there. I am sure that at moments of emergency it all gets pretty exciting, but it is not an energetic place. I think that is a very interesting question, especially if one had some clout, because you might be thinking about putting in some more money. What could you do so that there are some little moments of energy? I think perhaps there are things one could do. One could think about sending people in for a while, bringing them out again, sending in

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people to do specific things, not necessarily vertical things. So I think that is a really fascinating idea. I do not understand why international civil service has to be like that.

Professor Ferguson: I think some of that is happening now. Part of a recent criticism of WHO is that it is almost entirely staffed by CDC people, and a few HPA people, and they are drawing hugely on the expertise of short-term people, particularly on programmes they want to get moving quickly. The downside of that is there has been a degree of resentment between long-time, arguably less competent, staffers within the core organisation and the new brought—in people, and also that they lose that expertise when people leave. They gain quick expertise in priority areas and then it is not sustained within the organisation. I think a lot of the institution's inertia is about the constitution of the organisation, it being governed by the World Health Assembly formally and the same inertia exists with all UN organisations in trying to achieve major change. I think also the quality of some of the people they get has not always been what it needed to be. I have seen different areas, say on the avian flu side, where a lot of money and expertise and effort has gone in and it has been a priority and it has actually been quite fast-moving as an organisation.

Q242 Chairman: There is a very big issue around this. I want to move on, though. I will do this fairly briefly, because to some extent you have covered it, but it is an area between intergovernmental organisations to which I think we have to pay a bit more attention. It is this one between those which monitor human health and those which monitor animal health. I wonder if you could say a word about that.

Professor Ferguson: Diplomatically?

Q243 Chairman: Not too diplomatically!

Professor Ferguson: My interactions with OIE I have found intensely frustrating, FAO is a little better, but they really do have different perspectives on health. I think WHO, for all of its faults, is principally targeted on trying to improve the health of humanity. OIE is nominally targeted on that, but it is not entirely evidence-based and a lot of the infrastructure of international regulations on animal health has been developed, over a very long period of time and, I think, act in a largely negative way in some cases. You have a certain list of designated diseases—foot-and-mouth disease being one, avian influenza being another—which, should a country which is “free of that disease” discover the disease on its territory, a whole set of very damaging economic consequences fall on that country. This is because OIE designates disease-free areas and areas with disease and they are

not allowed to trade with each other. Many people (and I am not unique in saying this) have said this is, in essence, a way round WTO rules, to maintain protectionism in agriculture. Some countries in the world can afford to control some animal diseases like foot-and-mouth disease, other countries cannot afford to control the disease. In fact, foot-and-mouth disease is not a very important animal disease; it is not a highly lethal disease; we create it as a disease of importance. The relevance of this to human diseases has been sharply shown in avian influenza crises, that countries have been slow to report outbreaks and, indeed, avian influenza activity in countries has been detected via human cases rather than by ministries of agriculture in those countries reporting outbreaks. I will not give a list of those countries because I work with them, but in many cases I have talked to people in ministries of health who have been aware of agriculture outbreaks, who say their ministry of agriculture is aware of the outbreak and they have sat on the data for two or three months before reporting it to OIE because of economic concerns. It is fundamentally amiss. There are some efforts now to change this. I was reading an editorial, written by the new director of OIE, commenting on these issues, saying that in the future countries should not use the international animal health regulations as an indirect method for inhibiting free trade, but at the moment the economic consequences are such that it is very deleterious to accurate surveillance for animal diseases.

Chairman: Unless any of the three of you would like to come in on that, I am happy to move on. Lord Jay, the drugs issue. This again is about whether people are operating in their own closed areas or whether they are crossing boundaries, but perhaps we need to clarify the drug issue.

Lord Jay of Ewelme: Thank you. I should have declared an interest earlier on as Chairman of the Trustees of the medical aid NGO Merlin. That is going to be an interest Lord Geddes would disapprove of! Anyway, there we are.

Lord Geddes: I do not disapprove of it!

Q244 Lord Jay of Ewelme: I mean the organisation. Just a question on drugs. I think better and better drugs exist, but I am certainly struck, in travelling to some pretty difficult bits of the world, that they very often do not get to where they are wanted at the time they are wanted: or, if they do get there, they are then cut off and then more are needed. I suppose the question is; whose responsibility is it to try to overcome that problem? Is it international organisations? Is it WHO, is it WTO and the TRIPS organisation? Is it national governments? Is it the drug companies themselves? Can we make more use, or could more use be made, of commercial

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distribution systems within countries? I think Coca-Cola are developing a system of distributing drugs. Can more be done in that way? I am just interested in your thoughts on that in the face of what Professor Ferguson was saying about the success, as I understood it, in getting schistosomiasis drugs through to people who needed them. Maybe there are some lessons to be learned from that?

Professor Ferguson: Yes, totally.

Professor Sir Michael Marmot: Could I start by saying something that I should have said in answer to Baroness Whitaker as well. Again, we are toying with the idea of an equity gauge to look at all policies as they affect health equity. If you take the argument that health of the population is basic and we should not pursue policies that are detrimental to the health of the population and the further argument that health equity should be a fundamental value, then we should look at all policies with an equity gauge. If we then come to WTO and intellectual property, we should look at it with a health equity gauge, both the agreements that we reach under WTO generally, and in relation to pharmaceuticals and intellectual property. What impact do they have on health equity? You do not have to be a genius to look at the impact they are having on health equity, which is extremely adverse. The self-serving arguments about how global health will benefit by restrictive practices do not hold water, and if we said that we wanted the issue of health equity to be on all WTO agreements, not just those that apply to drugs but that apply to everything, that is in a way saying we want to look at how fair WTO agreements are. I think we ought to apply it specifically to pharmaceuticals, and then the other side of it is that, if you can get the drugs into the countries at affordable prices, if you have got a horizontally-developed healthcare system, you can get them to people.

Chairman: The International Health Regulations. Lord Geddes?

Q245 Lord Geddes: I am hoping to get through this rather quickly. Could we have your comments, please, on the International Health Regulations, on which we have heard a considerable amount of scepticism. In your opinion, are they useful? And, even if they are or are not, are they enforceable?

Professor Ferguson: I think they are useful because they state a country's responsibilities and what countries expect of the WHO, which was implicit before but not fully stated, and so from that point of view I do you think they are valuable. They give countries an obligation to report certain diseases, i.e. building on the SARS, experience and expectations of WHO. As to whether they are enforceable, then if you tell me an international law regulation or treaty which is enforceable fundamentally, I would be glad

to hear it. Particularly at a UN level rather than necessarily an EU level, there are not the mechanisms in place for enforcement but I think, (again, China learnt this lesson in SARS) being a good global citizen is the implicit enforcement mechanism. Countries have signed up and WHO is already starting to do naming and shaming exercises when countries start to slide back on their responsibilities. So I would be actually quite positive about the international health regulations.

Q246 Lord Geddes: Is that view held across the board?

Professor Mclean: They are better than what we had before.

Q247 Lord Geddes: That does not say an awful lot!

Professor Mclean: No.

Q248 Chairman: I pick up from what some of you are saying that you feel there have been changes in the WHO which mean that it is working more effectively—I am jumping back a bit—than it was before, because you actually seem to have been less critical of the WHO now than it was previously. Is that right? Do you think the WHO is getting better?

Professor Johnson: It is a difficult question to answer in the absolute. I think in some of the areas that you have highlighted, particularly the response to things like SARS, the point that Neil has made is important. The fact that WHO is seen as the body that is respected and is seen probably to deal a fair hand, I think that is very important too. The recent efforts, for example, around flu pandemic plans is one internationally that WHO has had a very important role in. I would certainly support the view that this is an agency which needs to have that leadership role internationally, but all the problems that have been described pertain, such as funding. There are obviously a lot of different political interests in how WHO operates. One issue is that there is quite a high staff turnover, because people come in with relatively short-term secondments and there is a lot of reliance on consultants coming in for relatively short periods. This has the advantage that you bring new blood into the organisation, but, on the other hand, you have got quite rapid throughput of staff from a large number of Member States. Broadly, some of these new efforts in infectious diseases, I think, have borne fruit. I know relatively little about the new regulations, but they are new and, as understand it, Member States are still trying to explore how best they be interpreted, and I suspect that will be an ongoing process for some time to come.

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Q249 Baroness Whitaker: A quick question. Of course the new regulations are an enormous advance in their reach from the previous ones, but as for the premium they put on surveillance systems, obviously many countries just have not the capacity to implement those properly. Is it not possible that, because of the existence of the regulations and their mandatory obligations, countries might get more funding from the developed world to improve their surveillance systems? You do not necessarily know the answer to that, but would that be a desirable outcome?

Professor Johnson: There is no doubt that across the piece people are recognising the need for investing and strengthening surveillance systems, and that has been said by a whole range of organisations. FORESIGHT said it loudly, WHO said it presumably also partly through the regulations and, I suppose regulations do always provide a sense of imperatives which may allow money to follow, but I think there are a number of other bodies trying to strengthen that area in addition.

Q250 Lord Hannay of Chiswick: Following up this line of thought, it must, surely, be fairly evident that a lot of very weak countries are going to find it very difficult to grapple with these new regulations but that it is in our interests as a developed country that they should succeed in grappling, not just for their good but for our good too. In which case we and other developed countries ought to be giving them more help to do it, not saying we doubt whether these regulations were enforceable, which I am sure they are not in many weakly administrative bodies, but (and this is what Baroness Whitaker, I think, was saying) giving them more assistance to actually implement regulations which it is in our interests they should implement.

Professor Ferguson: The US has been doing this to quite a significant degree, particularly in the avian flu area.

Q251 Lord Hannay of Chiswick: Have you?

Professor Ferguson: I honestly do not know the answer to that, but the US, through WHO and bilaterally with countries on the ground, has given probably in excess of \$100 million, maybe quite a lot in excess of that. That has involved, to be fair to them, quite good programmes of building up surveillance systems, data systems and lab capacity on the ground. It has been quite productive and WHO has co-ordinated much of the effort. Some of the issues have been thrown into sharp relief by the Indonesian crisis and in some ways that has accelerated the increase in local capacity for lab diagnosis as well. But as regards monitoring the burden of disease more generally, I think hugely more work needs to be done there.

Q252 Chairman: It has been said that the International Health Regulations cannot be enforced in a literal sense and therefore you are looking for a way for WHO, or individual governments like CDC in the US, or whatever, to do it. I think that is what I am struggling with, I do not know about my colleagues, but it is very hard to see how you can best help. If individual nations just give that sort of help on a one-to-one basis, if you like, do you do it through the WHO, do you do it through regional structures? What do you do? How do you do it?

Professor Ferguson: WHO, via their website, in the documents they produce, represent a huge body of knowledge about how you actually do a lot of basic health-related activities, particularly in the developing world. They act as a library of knowledge for practitioners on the ground and I think with the IHR, their protocols on how you implement surveillance systems, what should you do, should not be underestimated in how they will have influence. People really do just follow the guidelines WHO issue.

Q253 Chairman: And governments can do that individually, even though in many countries you are talking about governments which are not very effective, to put it mildly.

Professor Ferguson: In Sub-Saharan Africa, a lot of activity is just trying to follow WHO guidelines, from the people on the ground to the ministries of health. The grey area is countries like Indonesia, Thailand, Vietnam, China, where they do not just follow, they have more capacity than just to follow guidelines, but even for those countries on needs to realise that IHR would not have got through without Chinese support and China was the country most criticised in SARS. I think the lessons have been learned there as well.

Q254 Chairman: I am sorry; did you want to come in?

Professor Johnson: I was going to say, on surveillance and investment in surveillance, that this is an issue of Global Stewardship, to take a phrase from the Nuffield Working Party on Public Health Ethics of which I was a member. Investment in these areas in developing countries is extraordinarily important for identifying new and emerging infections and being able to deal with the public health consequences. It is also a form of enlightened self-interest, because, as you identified in your original questions, infectious diseases move very rapidly round the world because of the social, economic and other circumstances in which we currently live. There is a massive amount of population-mixing which allows problems to emerge quite rapidly. So there is, a responsibility for investment in these areas and working with WHO in that capacity.

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Chairman: Anyone else on this before I move on to bioterrorism?

Q255 Lord Hannay of Chiswick: Would I be right in thinking that it is not really sensible to think of bioterrorism as a separate subject in its own right, because in fact the impact on world health, international security issues, and so on, of a major bioterrorist action would not be particularly different from an outbreak of a highly infectious new disease, like SARS or avian flu, that had crossed the line, and so on. Therefore, basically we should not be putting the two things into completely separate boxes, we should be looking at them as similarly catastrophic events against which we are probably not very well prepared but which developed countries are infinitely better prepared than developing ones. I am not talking about the security aspects of stopping people using biological weapons, I am talking about what happens if they do use them like, for example, ensuring that there are enough drugs to deal with a situation positioned in particular places where they can be available quickly, that there is some machinery that links up the WHO with organisations that are involved in security, like the Security Council and so on, if it came to closing off a particular part of the world, or whatever it is, in a controlled fashion rather than a completely uncontrolled and anarchic fashion. These are all issues that could just as well arise from SARS or avian flu crossing the line as they could from one of Osama bin Laden's merry men getting hold of something very nasty and releasing it somewhere.

Professor Johnson: I think the concerns about bioterrorism probably have strengthened our health protection function in this country. I think it has been one of the drivers for improving the health protection structure. The Health Protection Agency has been significantly strengthened over the last decade and taken on a broader range of activities. So, I think I agree with your point that the same mechanisms will be put into place, and to some extent the same protection functions would be put in place by government, as would be the case if there was a threat of avian flu, and with concerns about H5N1 in poultry flocks recently in the UK. Those same sort of mechanisms are put in place to protect the health of the public. So, yes, I think it is important to think of the two going hand in hand and not requiring entirely separate infrastructures for the management of the protection of the population. The Ministry of Defence issues are entirely different, but the human containment issues would use the same infrastructure, as I understand it.

Q256 Lord Hannay of Chiswick: Following on from that then, has the WHO got a handle on this sort of thing? Are the huge range of developing countries even remotely capable of operating any of these necessary disciplines and prophylactic measures and goodness knows what else? Or are we, again, living in a world in which we are all preparing ourselves for the worst, probably quite effectively, but we are forgetting about the rest of the world which has got no defences at all?

Professor Ferguson: One has only to look at the threat assessments to see the catastrophic scenarios of an infectious disease release are actually very unlikely. The only real candidate is smallpox but we were more concerned about that a few years ago. The developed world is much more prepared than the developing world for smallpox. All the other potential candidate agents are non-infectious. Without doubt, the developed world is, again, much more prepared than the developing world here as well but those agents do not pose quite the same cross-border risks you were perhaps implying. In my own honest opinion, having worked in this area for quite a while now, the threat is very minor. The capability of potential people who might use biological agents is very limited at the current time. That is not to say it should be completely dismissed, because that capability will grow significantly, but at the moment I would agree with what Ann said. It is actually a lesson the US learned in the last few years in terms of their investment in this area. It is much more cost-effective to invest in dual capability response measures which can be used against acute natural occurrences as well as deliberately introduced agents than very specific counter measures against particular pathogens which may or may not be used. Specific counter measures are very expensive to develop and you do not get very good value for money for the size of the investment. The Bio-shield initial investment in the States was not terribly productive for such a large amount of money. The second generation of that initiative post—H5N1 avian flu has been much broader in its scope and arguably better invested. In terms of WHO, there are a few discussions of these things, but the general consensus there, if I was to be a little bit cynical, is that most people, I think, view it as a threat which has been invented in the States and propagated in the Anglophone world and it is really not a serious public health threat. They may be being a little narrow-sighted in that, but I think the perspective is that there has been such a distortion of spending in the United States on this issue that they will focus on what they are doing and let the US invest.

Q257 Lord Hannay of Chiswick: If you are agreeing with the analysis that there is not a huge difference between how you handle SARS and this, then WHO

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should not have to ask themselves too many questions about how real the threat from bioterrorism is?

Professor Ferguson: I feel, and others feel, the real threat in bioterrorism is not in the human health side, it is much more likely to be deliberately introduced animal pathogens targeting developed countries. That is easy to do and has economic impact.

Q258 Chairman: I was going to ask you about that, because my understanding is that the problem for anybody choosing to do this, be it a state or a non-state organisation, is actually weaponising it, making it something you can transport. But some of the work that has been done by some of the countries that were looking at it, and they were actually developing countries, if you look at Hans Blix's report on Iraq, it was things like wheat germs, so it was targeting crops. Is that not right?

Professor Ferguson: If you take the foot-and-mouth virus—and the United States Homeland Security are very concerned about this—it is very easy to transport, you can deliberately cause an outbreak which has no human health consequences but has a very significant economic impact. I would agree, again, that some of the plant pathogens are a risk as well.

Q259 Chairman: The answer, in a sense, is still this issue of having a really good detection, identification and monitoring programme which applies whether it comes about from natural or unnatural sources. Is that right?

Professor Mclean: And a contingency plan and practice.

Q260 Chairman: You need both or separately?

Professor Mclean: I agree with the point that the two would be the same.

Q261 Chairman: Right.

Professor Ferguson: The US has a slightly different perspective. They agree that you want multi-use strategies, particularly response and contingency plans. But the forensic aspect of investigation, of identifying culprits and responding is very important to them as well, and talking to people in the Home Office that is also a concern here and does lead to some differences in how to go about doing things.

Q262 Chairman: But not the essential—

Professor Ferguson: Not in terms of the human response, but in terms of how you maybe investigate.

Q263 Chairman: So it may be a security response rather than if you like—

Professor Ferguson: It is a broader response because it involves the security apparatus as well.

Chairman: Any other questions?

Baroness Whitaker: Could I be really messy and jump back.

Chairman: Please jump back for a few more moments.

Q264 Baroness Whitaker: This very potent idea of health equity: in respect of patent medicines, what happens if the WTO is not prepared to adopt the idea of the primacy of health equity? What if it only wants to enable trade and for manufacturers to make a lot of money? How does the WHO on this co-ordinated committee sell health equity as a criterion for patent law to the WTO?

Professor Sir Michael Marmot: The civil society organisations who have been co-operating with my Commission from the beginning say: "You give us the ammunition, we will run with it."

Q265 Baroness Whitaker: They will make a fuss?

Professor Sir Michael Marmot: They will make a fuss.

Baroness Whitaker: Which has actually happened to some extent.

Lord Desai: I think there is a conflict there, because somebody could argue that trade encourages development, which improves health, and so it is not always clear that some of the NGOs who do not like free trade are necessarily on the side of development.

Chairman: If you can answer this in one minute, you will do rather better than the rest of us put together, but have a shot at it.

Q266 Lord Hannay of Chiswick: Surely it is another aspect of the environmental issue with trade, which is exactly the same thing?

Professor Sir Michael Marmot: I can answer it easily by saying we are not against trade. We do not buy the argument. We are not against globalisation.

Q267 Chairman: It is not an either/or you mean?

Professor Sir Michael Marmot: Globalisation is a force for good, the problem is the way it is operated; and trade is a force good, the issue is the way it is operated. That is why we would want to have the idea of an equity gauge in the context of agreements about trade. Similarly, tariff reduction. Tariff reduction, if it promotes trade, is potentially a force for good, but where it is a main source of government revenue for poor countries, there have got to be transitional arrangements. So we are not against trade, we are not against the markets, we are not against any of those things. Some NGOs that we have talked to are against those things, but we are not. We are in favour of operating in a way that is fair and just and our criterion is health equity.

3 March 2008

Professor Sir Michael Marmot, Professor Anne Johnson,
Professor Angela McLean and Professor Neil Ferguson

Chairman: Thank you very much indeed. We are very grateful. You have given very full and very helpful answers. If you feel there are other issues or things we

have not touched on, or if there is anything you want to elaborate on, as I have indicated, please contact the Clerk. Meanwhile, thank you very much indeed.

MONDAY 10 MARCH 2008

Present	Avebury, L Desai, L Eccles of Moulton, B Falkner of Margravine, B Flather, B Geddes, L	Hannay of Chiswick, L Howarth of Newport, L Soley, L (Chairman) Steinberg, L Whitaker, B
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Memorandum by Royal College of General Practitioners

1. The College welcomes the opportunity to comment on the Intergovernmental Organisations Ad Hoc Committee inquiry into Intergovernmental Action to Control the Spread of Communicable Diseases.
2. The Royal College of General Practitioners is the largest membership organisation in the United Kingdom solely for GPs. It aims to encourage and maintain the highest standards of general medical practice and to act as the “voice” of GPs on issues concerned with education, training, research, and clinical standards. Founded in 1952, the RCGP has over 33,000 members who are committed to improving patient care, developing their own skills and promoting general practice as a discipline.
3. Whilst recognising that “no country is an island” when considering infectious disease, the intergovernmental structures for tackling them have little day-to-day impact on the working lives of GPs. Consequently, many of the questions raised, whilst fully valid for exploration, are not those which the college feels competent to give evidence upon, particularly with regard to intergovernmental structures.
4. The college would, however, wish to see the problem of communicable diseases raised as a priority on a national and international stage. We would also like to draw attention to other pressing issues related to world health: supplying clean water; providing adequate food and sanitation; supplying preventative medicine, including immunization programmes; lifestyle challenges, such as smoking, alcohol, sexually transmitted diseases and obesity.¹

REDUCING HEALTH INEQUALITIES

5. The college would like to highlight the fact that GPs have a duty within their ethical code, as laid down by the General Medical Council, to provide care in the best interests of patients and the public health, regardless of their socio-economic status. This is particularly relevant to this inquiry because allowing equitable access to healthcare is vital to our efforts to control the spread of communicable diseases.
6. Reducing health inequalities and improving patient safety are national priorities that have international counterparts. We suggest that proportionate study is given to the major public health problems and that resources are realistic for preventive work in disadvantaged communities. It is more important than ever to enhance the self esteem of vulnerable families, to take simple steps to intercept transmissible disease and not have our attention monopolised by borderline technological advances that benefit a fortunate few.²

INTERGOVERNMENTAL COLLABORATION

7. To tackle the issue of communicable diseases effectively, a joined-up approach is necessary on a national and international level. A recent RCGP response to a Department of Health consultation on Pandemic Flu documents³ argued the case for government departments, principally the Department of Health and the Cabinet Office, to work in close collaboration to respond to a pandemic influenza epidemic. A national framework must be brought into existence to encompass all the departments involved. A joined-up approach is also necessary on an international level, both within the EU and elsewhere. The consequences of an influenza epidemic will be exacerbated by global interconnectedness.⁴

¹ RCGP response to the Department of Health Consultation: Health is Global: Proposals for a UK Government-wide Strategy, May 2007

² RCGP response to the DH Consultation: Health is Global

³ RCGP response to the Department of Health Consultation: Pandemic Flu Discussion Documents, May 2007.

⁴ The Royal Society, Report of a Royal Society/Academy of Medical Sciences symposium on pandemic influenza held on 27 November 2007

PUBLIC ENGAGEMENT

8. Public engagement is critical if measures to tackle communicable diseases are successful. This will depend on the extent to which governments and/or healthcare systems are able to engender the trust and confidence of the populations they serve. Any policies in place to respond to the problem of communicable diseases must be patient-centred and developed from the perspective of the patient, particularly those with complex and interrelated health problems e.g. those with positive HIV status suffering from additional infections, such as pneumonia.

POLICY FORMULATION

9. Policy decisions must be based on advice from a wide spectrum of scientific disciplines. It is, for example, not sufficient for governments to rely exclusively on the advice of virologists or modellers. Medical historians and behavioural scientists could provide valuable insights and ensure that appropriate lessons are adaptively learned from past experiences.⁵ To illustrate this point we can use the example of planning for an influenza epidemic. From the GPs perspective, the following expert disciplines will need to be incorporated:

- Operations research, using modelling and algorithms to determine the most efficient ways to act
- Queuing theory, for example to evaluate probable waiting times and numbers waiting
- Logistics, for managing the supply chain

Intergovernmental organisations must take account of these varied disciplines and consider how skills can be utilised from a number of sectors. They also need to consider how leadership expertise can be drawn from multiple sectors, including the military and media as well as business and academia in order to support objectives for panic minimisation, assessment of economic impact, scenario-based decision-making and optimisation of telecommunications resilience. Academies could potentially play a greater leadership role in the future.⁶

10. Planning on an intergovernmental level must take account of the vast disparities which exist between countries in terms of food supply, utilities, transport infrastructure, availability of essential medicines, support for the healthcare workforce and access to specialist advice. The increasing prominence of Africa in the spread of influenza is a great concern, at an international as well as national level, given the weakness of infrastructure and reporting systems in some African countries.⁷

11. It must be recognised that there is variation between healthcare systems in individual countries, some of which have greater capacity than others to deliver healthcare services to their populations. Furthermore, different types of healthcare systems may affect our ability to implement policies to control communicable diseases. It may, for example, be more difficult to implement policies in a country whose health system is based on privatisation and/or outsourcing because private companies will have a specific contract as opposed to the potentially open-remit of public sector organisations.⁸

THE IMPORTANCE OF PRIMARY CARE AND THE ROLE OF THE GP

12. It is essential that individual countries have effective primary health care systems in order to implement policies successfully. In the UK, frontline primary care accounts for 90% of the contacts with the NHS. In the case of a pandemic, it will be the GP's role to assess those patients at particular risk or who are developing complications and to provide urgent care for non-pandemic problems which may be exacerbated by the pandemic, in particular by the increased difficulty in admitting non-pandemic patients to hospital.⁹

RESEARCH AND ETHICAL CONSIDERATIONS

13. All action to control the spread of communicable diseases should be carried out within an ethical framework. Research into the prevention of communicable diseases should not be driven by commercial interests. Furthermore, the process of using modelling when planning for a pandemic must take account of additional variables when setting parameters.¹⁰ These should include the greater frequency of co-morbidities in the elderly when comparing with children to select target populations for intervention, and the impact of population density on behavioural change.

⁵ RCGP response to the DH Consultation: Pandemic Flu Discussion Documents

⁶ The Royal Society, Report, 27 November 2007

⁷ The Royal Society, Report, 27 November 2007

⁸ RCGP response to the DH Consultation: Pandemic Flu Discussion Documents

⁹ The Royal Society, Report, 27 November 2007

¹⁰ The Royal Society, Report, 27 November 2007

OTHER POINTS

14. The RCGP feels that our educational and primary care expertise should be shared with our counterparts abroad. Those delivering health education and those delivering health care need to be adequately trained and supported. The opportunity to influence the continuing professional development of health care clinicians can be seized as we consider practice quality and re-accreditation here in the UK.¹¹

15. The college believes that GPs are better able to prepare for the consequences of a new pandemic rather than try to prevent it.

16. With reference to Issue 12, there is some concern that GPs will be blamed for over-prescribing anti-biotics and thus contributing to the increased microbial resistance to them. There is arguably pressure on GPs to “play safe” and give antibiotics to those who might not require them. For example, a GP may face recrimination for missing an emerging pneumonia in a toddler but also face criticism for treating an infant’s sore throat with amoxicillin.

17. I acknowledge the contributions of Dr Simon Stockley towards the above comments.

6 February 2008

Memorandum by The Royal College of Pathologists

Q1: A recent report on Communicable Diseases by the UK Department of Health stated that “post-war optimism that their conquest was near has proved dramatically unfounded”. What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis?

A: The situation varies in different countries. Some diseases are much less common where the benefits of public health (water, sewerage, nutrition, housing, environment), vaccination and antibiotics have been realised. Poverty often equates with lack of public health benefit, and is a major influence on infectious disease.

Substantial progress has been made in some areas, such as the eradication of Small pox. Some of the others like Malaria and TB have proven to be far more difficult to eradicate than previously thought. In many cases evidence about how to reduce the burden is available but there is lack of action e.g. poor diagnosis and treatment of Malaria.

There are increased risks from: new diseases e.g. SARS; travel, lifestyle, war, breakdown of infrastructure; medical advances can create new ecological niches e.g. immunosuppression, polypharmacy; antimicrobial resistance. Lack of infrastructure also means that when the developing world is faced with new challenges it is less able to cope (HIV, drug resistant TB).

Q2: What reliable data exist regarding the numbers of people infected globally with the four diseases¹² on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?

A: WHO and HPA will have figures. Surveillance mechanisms could be improved in rural areas in developing countries, but confirmation of diagnosis will also depend on laboratory diagnostic facilities being available.

Malaria will continue to be a problem but hopefully the use of ACT, insecticide impregnated nets and spraying of insecticides will reduce cases.

Despite development of drug resistance and increase of TB in HIV/AIDS patients, improvement in detection of smear positive TB cases and DOTS will hopefully result in reduced transmission of infection.

Similarly the availability of relatively low cost ART to increasing numbers of HIV patients, especially in Africa provides some hope given the size of the population. However diagnostic facilities to support the use of ARTs and follow disease progression are generally lacking. The HIV epidemic in India continues to pose a major threat. Recent reliable surveillance data suggests that this epidemic is declining slowly through the sustained commitment of the national government and inter-governmental organisations like WHO and charitable organisations.

Avian influenza H₅N₁ currently does not appear to transmit very readily either to or between humans.

Changes in incidence and pattern are affected by population growth, shifts from rural to urban living without adequate infrastructure, and cultural issues.

¹¹ RCGP response to the DH Consultation: Health is Global

¹² HIV/AIDS, Tuberculosis, Malaria and Avian Influenza.

Q3: What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? And what improvements might be made?

A: WHO and demographic health surveys internationally. HPA will be able to give information on UK and European surveillance systems. It is impossible to say if they are adequate for all situations e.g. detection of cases in rural areas poorly served by healthcare facilities; for some diseases spread is likely to be more rapid in urban areas with high person-to-person contact. Providing accurate data about public health in developing countries continues to be a major challenge.

Q4: Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years?.

A: Political stability and conflict are major factors that affect spread of diseases, and undermine progress made. They need to be included in any model (not underestimating the difficulty). Travel, migration, drug resistance, and success of control programmes will influence spread and pattern.

Q5: What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?

A: The four diseases are most prevalent in the developing world. The major blockages are: poverty; poor public health; insufficient diagnostic facilities and ineffective use of laboratory services; political instability; poor governance; educational and cultural issues.

BETTER MANAGEMENT SYSTEMS AND SUPERVISION TO ENSURE POLICIES ARE IMPLEMENTED PROPERLY

Better diagnostics—the UK has enormous expertise in this area, but there is little support for “time out” for doctors or scientists to spend time abroad—either those in training or established in their careers (despite the recommendations in the Crisp report).

BETTER CO-ORDINATION BETWEEN INTERESTED PARTIES AND IMPROVED LIAISON

Outside the political solutions to these underlying problems the availability of medication, education and research should improve the situation.

Most government health services now recognise that TB control must go beyond DOTS, but the broader Stop TB strategy is not yet fully operational in most countries. Although the funds available for TB control have increased enormously since 2002, reaching US\$ 2 billion in 2007, interventions on the scale required by the Global Plan to stop TB would cost an extra US\$ 1.1 billion in 2007.

IN HIV there are many people involved with no clear strategy/plan given the complexity of the disease. Strong vertical programmes, like HIV, risk diverting resources away from other priority areas like TB and Malaria.

Q6: What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?

A: The Royal College of Pathologists promotes excellence in the practice of pathology and is responsible for maintaining standards of practice through training, assessments, examinations and professional development.

Members of the College, both medical and scientists, are experts in the diagnosis and management of disease, including infectious disease. They provide a spectrum of laboratory and clinical services which varies from specialty to specialty. Many laboratory services, microbiology, virology, haematology, chemical pathology for example are critically important in the diagnosis, treatment and control of many communicable diseases including Malaria, TB, HIV, and Avian Influenza.

The RCPATH has an international committee co-chaired by a Vice President of the College. This committee aims to further the aims of the College in other parts of the world in a context sensitive manner, and members of this committee have contributed to this paper. Many international members of the College are frequently leaders in medical microbiology and virology in their countries and have considerable influence in the detection and control of the four communicable diseases.

We believe the Academy of Medical Royal Colleges could enhance its co-ordinating role for College International activities. Also we believe that UK quality assurance in diagnostics (such as through CPA (UK) Ltd) could be helpful in relevant context specific ways.

Members of the RCPATH are frequently the first to detect infections with the four diseases and alert other clinicians and public authorities in the UK, contributing to surveillance via HPA and others.

RCPATH liaises with Department of Health, academic institutions, professional and scientific organisations in the UK, CPA (UK) Ltd, and other Royal Colleges.

Q7: What are the main non-health causes (e.g. global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient “joined-up” thinking in approaching the problem?

A: Poverty and weak management systems are very important. Lifestyle—HIV; global warming and population movement—Malaria; international travel—all 4. No, there is not sufficient joined up thinking (viz. Crisp report and lack of NHS support for overseas placements)—but this also needs to be complemented by joined up activities in overseas governments (e.g. between ministries of health, education, finance, agriculture, water, etc.).

The lack of laboratory diagnostic facilities to enable accurate diagnosis is important—they underpin effective treatment, control and surveillance. There needs to be better support for simple good quality diagnostics.

Q8: Cases of Tuberculosis fell progressively in the UK until the mid-1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of Tuberculosis infections in Britain? And how could intergovernmental action help to reverse the trend?

A: The rise in TB in the UK is largely due to migration from countries of high prevalence, and drug resistance is also a threat.

Intergovernmental action should: make efforts to reduce TB in the countries from where the migrants originate; address underlying reasons for migration be it political, economic or social or AIDS/HIV related; work to reduce stigma, thereby promoting better care-seeking.

Q9: Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions—e.g. HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?

A: See earlier comments. However HIV is driving the TB epidemic in Africa. MDR TB is the main challenge in Russia and Western Europe; XDR TB in Africa and in high HIV settings is another emerging threat. There is failure to detect smear-negative cases (especially in HIV and paediatric cases) and improvements in laboratory diagnosis are required.

Q10: To what extent do you believe that the 2004 Stockholm Convention limiting the use of DDT against Malaria-carrying mosquitoes has been a factor of increases in the spread of the disease? Has any risk analysis been carried out comparing the relative dangers to human health posed by DDT and Malaria?

A: There is some evidence that reduction in use of DDT has resulted in increase in Malaria. There is also now more interest in vector control (see Gates investment for work based at Liverpool School of Tropical Medicine).

Q11: What intergovernmental action is planned or in hand for early detection of the transmission of Avian Flu from birds to humans and of human-to-human transmission in potential source countries? Is this proving sufficiently effective to prevent an Influenza pandemic? What more could be done?

A: WHO is the main organisation for human (globally), HPA major role UK. Will however depend on infrastructure and arrangements in various countries.

Q12: To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?

A: The rise in Falciparum Malaria and the associated morbidity and mortality has been attributed to increasing drug resistance to antimalarials and the resistance of mosquitoes to insecticides. This is being addressed with aggressive ACT combination therapy together with the use of long lasting insecticide impregnated nets and DDT spraying. There is however evidence that ACTs are not being used effectively; also use of ACT has not been linked to the need for a confirmed diagnosis of Malaria. National policies in malarious areas are in a state of flux—leadership from WHO is ambiguous on some topics e.g. Malaria and anaemia diagnosis.

The increase in MDR TB has contributed to increasing TB in certain parts of the world, though overall the majority of the strains remain sensitive to standard ATT.

Primary resistance to ART is not thought to have contributed significantly to the HIV epidemic but lack of laboratory support to detect resistance is lacking, so problem may be under-estimated.

Q13: In a number of countries, including the UK, there is a problem with hospital-acquired infections. What intergovernmental sharing of knowledge is taking place to help bring this problem under control?

A: There is very little formal intergovernmental sharing of knowledge of HCAI. The scale of HCAI both in terms of morbidity and mortality is not known in many countries, plus definitions will differ making comparisons difficult. HCAI is influenced by many factors including configuration of services and staffing levels. With increasing international travel and health tourism, there are many opportunities for spread of HCAI. Many developing countries either do not have (or only have) rudimentary surveillance systems.

Q14: Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?

A: The issue of intellectual property rights is a sensitive issue in the area of AI—regarding the development of a vaccine as well as for newer drugs. An intergovernmental body has been created to discuss this, the last meeting was held in Singapore last year. Also issues around patents on medicines for Malaria and HIV.

Q15: What interchange exists between States in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?

A: WHO has extensive Guidelines on all four diseases, though for some the evidence base is not robust. The challenge at country level is translating paper into action. That is where the difficulty arises in developing countries whose resources and capabilities are already overstretched and/or weak.

16: The International Health Regulations 2005 are intended to provide a global framework for the rapid identification and containment of public health emergencies. How effective do you consider this response system to be? Do improvements need to be made?

A: It is better than previous arrangements and will be the mechanism of response to a Pandemic in the future. There will be improvements to be made.

Q17: What intergovernmental planning has been undertaken to cope with the impact of an outbreak of infectious disease caused by deliberate release of micro-organisms into the environment? Is there adequate liaison between the various agencies involved, including intelligence, law enforcement and health care professionals? How could action by intergovernmental bodies help further?

A: HPA has worked on this and liaised with NHS and others.

Q18: *Though our remit is focused specifically on known infectious diseases, we would be interested to know how you view the global threat from new or previously unrecognised ones and from the transmission of infections from animals to humans.*

A: Many of the issues mentioned in Question 1 are relevant.

There is a lack of appreciation of relationships between diagnostics, clinical management of infected patients (including use of antimicrobials), healthcare associated infection, health protection and health promotion—all services currently provided by UK Medical Microbiology Departments working with others. The current UK preoccupation with “tests” being done as cheaply as possible threatens this valuable integration of knowledge. UK could provide expertise in providing evidence about cost effectiveness and clinical effectiveness.

Q19: *What resources (subscriptions, staff, training, medicines etc) does the UK Government commit to intergovernmental bodies to help in the fight against the four diseases listed?*

A: Global fund with direct government support through SWAPs disease. Specific international research programmes.

Q20: *Do you wish to provide any other relevant information in addition to what you have said in answer to the above?*

A: No.

February 2008

Memorandum by the Royal College of Physicians

1. The Royal College of Physicians (RCP) plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in the United Kingdom and overseas with education, training and support throughout their careers. As an independent body representing over 20,000 Fellows and Members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare.

2. The RCP has a number of specialties with an interest in this issue, and our evidence reflects their views. The following responses are based on opinion among a number of key specialties with an interest in this issue, including from our Joint Specialty Committee (JSC) on Genito-urinary Medicine, and our JSC on Infection and Tropical Medicine.

Q1. *A recent report on Communicable Diseases by the UK Department of Health stated that “post-war optimism that their conquest was near has proved dramatically unfounded”. What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis?*

3. Global population increases and the vastly increased movement of populations, such as through the increase in travel globally, increasing numbers of refugees and economic migrants, can all impact on the spread of disease. Although the world-wide level of infectious diseases has remained similar, there are some specific increases/decreases in certain disease areas, and with increased drug resistance and new emerging infections. In the context of tuberculosis, plans to increase the number of patients who are successfully diagnosed with tuberculosis have had only minor success. It is the opinion of some of our colleagues working in this area that the burden of tuberculosis is approximately stable, but the problems associated with drug resistant disease are increasing and provide an increased threat to the UK. The burden of disease could be considered a crisis. Other new infectious diseases continue to emerge and assessing their relative impact in advance is difficult.

SEXUAL HEALTH

4. It is a pertinent and useful example therefore to consider sexually transmitted infections including HIV in the UK. In 2005 the Health Select Committee described the “sexual health crisis”, and the government swiftly responded within the White Paper “Choosing Health” to highlight sexual health as a priority. This was backed with the announcement by the Secretary of State for health that there would be “targeted” funding to achieve improvements in services to improve access, to shorten the time to diagnosis and treatment, and to prime innovative outreach services to increase the diagnosis of HIV and other infections.

5. This approach was extremely well received by specialists and at the time the RCP convened a working party on sexual health, with a multidisciplinary group with representatives from different colleges, the BMA and the HPA. At the time that Choosing Health was launched, particularly around the funding announcement, our working party felt its work in making the case had been achieved, and agreed to disband itself. This was, however, alongside the warning from the working party that as the money earmarked by government to achieve public health improvement was not ring-fenced, there needed to be close scrutiny of how that money was effectively delivered to provider services.
6. Assurances were given by the Department of Health that this would be achieved by performance management through strategic health authorities, for example for PCTs achieving reductions in access time to genitourinary medicine services and implementation of the national Chlamydia screening programme. RCP and speciality associations (such as BASHH) continued to monitor this, and along with the independent advisory group on sexual health have since sadly documented the failure of the mechanism for delivering funding targeted at public health through primary care trusts. The financial problems in the NHS in 2006–07 have resulted in numerous examples of where money targeted by government to improve sexual health of the population was used to make up the deficits. Multiple examples of PCTs failing to implement Chlamydia screening have also been documented. Indeed, when this issue was raised with the Department of Health, speciality societies were advised to “keep up the pressure on PCTs’.
7. These concerns about the lack of delivery were so strongly felt at the highest level that a national support team for sexual health was created to try to assist PCTs with their plans and implementation.
8. There are a number of lessons that can be learnt from this with regards to other aspects of the public health control of communicable diseases. Certainly it is clear that the PCTs, even when given targets which are included in the NHS top 6 targets, cannot be automatically relied upon to deliver those resources to enable services to meet public health targets because of the priority given to dealing with the short term financial problems within the NHS. Whether this scenario would also apply to pandemic flu or MDRTB is conjecture, but this does illustrate the great dilemma for public health improvements which may require investment for a longer period and in the main are not supporting acute services.
9. Despite the limitations on resources, specialists across all disciplines in sexual health services have achieved improvements in access targets by modernisation. However, the sustainability of this is now threatened by the implementation of Payment by Results (PbR) and other new systems of funding without appropriate communication. Furthermore, if the management of HIV and other services are to be funded through such a PbR route then there must be a reality check regarding the importance of public health in commissioning bodies. In the experience of some of our colleagues, this has been lacking and there appear to be great concerns regarding the impact of privatisation on public health.

Q2. What reliable data exist regarding the numbers of people infected globally with the four diseases¹³ on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?

10. Factual data regarding numbers of people infected globally should be provided from this consultation by the WHO. There is recent published data on HIV infection and the burden of HIV disease worldwide has been adjusted downwards, but this still leaves very large numbers of people involved with no room for complacency. Figures for tuberculosis suggest the disease is constant since tuberculosis is essentially a disease of man. More robust data on patterns of transmission, duration of infection and better isolation procedures could be used to decrease disease. In terms of tuberculosis, approximately one third of the world’s population (1.6 billion people) is estimated to be infected with the organism and therefore it is unlikely that there will be a major decrease in disease numbers in the medium term. However, tuberculosis reactivation is associated with poverty and it is clear that the major decline in this disease in the UK was associated with improved social and economic conditions rather than with drug discovery or vaccination. This concept is pivotal in the understanding of tuberculosis. Multi- and now extensively-drug resistant (MDR/XDR-TB) have emerged and are on the increase.

11. Reliable data in the UK come from CDSC (part of the HPA), particularly with HIV and TB. The WHO has reasonable data on TB and malaria and UNAIDS produces data on the global HIV problem. In addition, EuroSurveillance provides information on a variety of communicable diseases of public health import. One of the most important issues is the link between HIV and TB; a lot of the new cases of TB in the UK are linked to HIV infection. These are often related to immigrants and many can be related to the terrible situation in Zimbabwe, forcing people to flee that country.

¹³ HIV/AIDS, Tuberculosis, Malaria and Avian Influenza.

Q3. What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? And what improvements might be made?

12. UK surveillance of communicable diseases is considered to be very good, among the best globally. The current systems are good but threats to the HPA budget may impact on this. However, if there is an increasing trend to use private suppliers of diagnostics, some of the established notification systems may be threatened.

Q4. Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years?.

13. Those who are involved in such programmes may predict decreases in incidence but to date success had been limited and it is hard to be optimistic about the future. In particular, the worldwide incidence of tuberculosis and malaria are unlikely to change. In terms of pandemic flu, a need for an extremely rapid response at the country of origin in the face of the emergence of a new strain requires prior agreement from a great number of countries to divert significant resources to a resource poor nation, and there is no good evidence that this is likely to occur.

14. If the conflicts around the world continue, particularly in Africa, there will be increasing numbers of HIV and TB-infected people. Perhaps more important numerically in the next 10 years is the epidemic of HIV in Asia, particularly in India and China. If HIV increases, so will TB. Malaria is likely to increase as a problem because of global warming so that some regions previously free of malaria may become endemic again. It is also possible that some transmission may occur in southern Europe.

Q5. What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?

15. The principle blockade to achieving progress in the prevention of control tuberculosis, malaria and HIV is economic and social deprivation. In the short term, in tuberculosis there is a major issue with a very prolonged duration of drug therapy required, which is for a minimum of 6 months, and could be tackled by new drug regimens. Better diagnostics for tuberculosis are also urgently required.

16. Another block to progress on these important 4 diseases is the relative lack of infection specialists in the UK compared to Europe and the USA. Reducing risk to travellers needs better education of the public and infection specialists can raise awareness. Communicable diseases presenting to UK hospitals may be missed if there are inadequate numbers of physicians with expertise in infectious diseases. Better education of clinical staff will help. Intergovernmental involvement in the promotion of training and education in infection can help, as can continued provision of funding for research. New vaccines will be required, as will new antimicrobials.

SEXUAL HEALTH

17. From the perspective of our colleagues working in GUM, it is clear that the major block to improvement in STI rates in the UK was not government, which provided leadership and strategy at the highest level, nor clinicians and managers in provider services, but was in commissioning bodies where competing priorities meant that public health investment, even when targeted, lost out to addressing the financial deficits, which necessitated making savings.

18. Our JSC on Genito-urinary Medicine calls for the reintroduction of ring-fenced money to ensure that primary care trusts are not able to divert funding away from national strategic health priorities.

19. This issue is particularly pertinent as only a few weeks ago the European Union has taken forward a call for action to increase the uptake of HIV testing to reduce late presentation of individuals with AIDS. To implement greater testing in the UK requires investment by primary care trusts but will then, if successful, lead to increased numbers of individuals diagnosed with HIV who will require antiretroviral treatment. In the absence of a national tariff for the management of outpatients, it would be up to commissioners in different areas to find different solutions for a problem that must be nationally equitable and accessible to achieve the expected economic and public health benefits of improved management and fewer transmissions of HIV. This equally applies to problems associated with this infection such as MDRTB and co-infection with hepatitis. We trust that in preparing changes in the way in which these services are funded that the Department of Health will ensure that clinical priorities and public health are paramount and guides the mechanism of funding rather than the converse.

Q6. What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?

20. The RCP interacts with specialist societies such as the British Infection Society and the Royal Society of Tropical Medicine & Hygiene which are involved in disseminating research findings, developing local guidelines and international protocols for the management of influenza, tuberculosis and malaria. However, these organisations do not have a front line role in dealing with diseases that are largely based internationally.

21. The RCP is closely involved with infectious diseases training and professional standards through its Medical Specialties committees and through joint working with the RCPATH, and Medical Microbiology in particular. It is also allied closely with the Medical Research Council and the Wellcome Trust, both of which fund important research in this area.

Q7. *What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient "joined-up" thinking in approaching the problem?*

22. Tuberculosis, as discussed previously, is closely linked to poverty and social crowding. Influenza is affected by lifestyle, social crowding, sharing space with animal reservoirs and international travel. Malaria is predominantly related to lifestyle and changes in land use, and HIV is related to lifestyle and poverty.

23. Global warming is also important for communicable diseases in 2 main ways. Firstly, there is a higher risk of increasing the breeding sites for vectors of disease, such as mosquitos, so that disease transmission is facilitated. Secondly, because of increased flooding and increased regions of drought, there will be a rise in the number of waterborne diseases such as cholera.

24. Increased travel by UK residents increased their risk of acquiring infections abroad (including HIV) and bringing these diseases back to the UK. They potentially increase the reservoir of infection in the UK. More importantly, the unrest in the world will increase the pressure on the UK from refugees and economic migrants who may bring infections with them. Providing proper health care, and research into the health needs of migrants, is one way that intergovernmental agencies can help. Things are not as "joined up" as they should be—for example, the work of the Home Office in moving asylum seekers around the country disrupts their health care in detrimental ways, interrupting treatment regimens for serious conditions like TB and HIV.

Q8. *Cases of Tuberculosis fell progressively in the UK until the mid-1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of Tuberculosis infections in Britain? And how could intergovernmental action help to reverse the trend?*

25. Action to alleviate poverty would have a major effect on all these diseases but cannot be undertaken by a single government alone and requires commitment at levels far greater than are currently considered. The main factors driving the rise in tuberculosis in the UK are migration and poverty with relatively little contribution from HIV. The restriction of access of migrants, refugees and asylum seekers to health services both the primary and secondary care which is currently ongoing is conducive to the spread of tuberculosis in the community. This approach is not ethical and significant financial savings to the NHS cannot be made by preventing refugees and asylum seekers accessing healthcare, but the health detriment is significant. This trend could and should be reversed if there is a serious intention to combat the rise of TB; such people should be encouraged to have health checks independently from immigration procedures. The prospect of financing this by appropriate charging of outpatient and primary care use by those who should pay (eg US visitors & others with whom there is no reciprocal health care arrangement) needs investigation. This requires governmental rather than intergovernmental action.

26. The increase in TB cases is largely related to increases in immigration from countries with high TB prevalences but is also linked to the increased numbers of people with HIV in the UK. At the same time, the expertise to diagnose and manage TB is limited with too few specialists in infection so that often patients are managed by those with less knowledge and experience. Laboratories need to be strengthened so that they have the resources to use new methods of rapid diagnostics and rapid assessment of drug resistance in TB isolates. Intergovernmental cooperation in providing better screening for TB in asylum seekers and new immigrants will help, as will raising the awareness in general practice about the presenting features of TB. Although the dispersion of asylum seekers in the UK may make sense from a Home Office perspective, this should not be

pursued for those in the middle of treatment programmes for TB. Having to move home or city during a treatment course will lead to poor adherence to the treatment programme, will lead to risk of disease relapse and possibly increase the risk of drug resistance evolving.

Q9. Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions—eg HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?

27. There are many reasons why tuberculosis appears to be on the increase. Firstly, approximately 50% of patients with the disease are not diagnosed. The gold standard for worldwide diagnosis is microscopy, which has 50% of the sensitivity of culture which is the standard used in more affluent countries despite the fact that there are tests available which are both cheap and culture based. (N. Engl. J. Med. 2006; 355:1539-50). Secondly, the crowding of people together in poor urban centres increases transmission of tuberculosis generally. Thirdly, there is a major interplay between tuberculosis and HIV. HIV increases the rate of reactivation of tuberculosis and conversely tuberculosis drives the HIV genome to replicate.

28. Intergovernmental action could be used to support the development of appropriate diagnostics and new short course regimens for treatment. It could provide funds for such diagnostics and for laboratories in resource poor environments to be properly equipped such as to protect the workers from the diseases in which they encounter. In addition there could be action to improve healthcare facility design reduce nosocomial transmission of disease in outpatient and inpatient settings which would have a broad range of benefits. Reducing disease transmission is also a priority in prisons which tend to be run by governments.

29. Most of the failure of TB treatment is due to the fact that the resources are not available in many countries to provide the supervision of therapy that is needed. Directly observed anti-TB therapy is the ideal but is rarely realised, even in developed countries. Treatment courses take at least 6 months and this can be difficult for the patient without encouragement and support. There can also be problems in maintaining adequate supplies of TB medication for patients in some settings.

30. In addition, HIV affects the way that TB presents and may lead to delayed diagnosis so that the infected individual may have longer to infect others before receiving treatment. Many countries do not have the resources to culture specimens for TB so both under- and over-treatment occur. Very few places do adequate surveillance of drug resistance. Resistant TB is an increasingly recognised issue. In addition to risks to the individual patient in not being cured, the risk of infecting others increases with inadequate therapy. Also, second line treatment for resistant TB is considerably more expensive than standard treatments. Intergovernmental efforts to improve diagnostics in high prevalence areas would help, as would research in to better diagnostics. There should also be encouragement to produce better drugs for TB that act more quickly and could, therefore, shorten treatment times.

Q10. To what extent do you believe that the 2004 Stockholm Convention limiting the use of DDT against Malaria-carrying mosquitoes has been a factor of increases in the spread of the disease? Has any risk analysis been carried out comparing the relative dangers to human health posed by DDT and Malaria?

31. Although the DDT ban will have had some effect, there are more fundamental issues to do with resources that governments use to combat mosquitoes and other insect vectors of diseases.

Q11. What intergovernmental action is planned or in hand for early detection of the transmission of Avian Flu from birds to humans and of human-to-human transmission in potential source countries? Is this proving sufficiently effective to prevent an Influenza pandemic? What more could be done?

32. There is certainly a (probably realistic) assumption that intergovernmental efforts to prevent spread of flu at source are unlikely to work since a great deal of effort is being put into pandemic flu planning, such as the DH Expert Panel and HPA. It is vitally important that universal sharing of data, which has been a problem in certain areas (see section 16) and reciprocal agreements for highly effective treatment campaigns at sites of emergence for pandemic should be supported at an intergovernmental level.

33. The preparation for and response to avian “flu has been very good, particularly in the UK. The problem is that vigilance will have to be maintained over long time periods.

Q12. *To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?*

34. Antimicrobial resistance is a particular problem in TB, but less so in HIV. The adopting of ACT (artemisinin combination therapy) for malaria by the WHO should help to reduce the threats from drug-resistant malaria. However, good surveillance of drug resistance in all of these diseases needs to be maintained.

Q13. *In a number of countries, including the UK, there is a problem with hospital-acquired infections. What intergovernmental sharing of knowledge is taking place to help bring this problem under control?*

35. There is wide recognition of the problem of healthcare-associated infections (HCAI) and there is now increased public awareness about it. Unfortunately, the reduction in hospital beds in the UK, plus failure to manage many patients outside hospital, increases pressures so that bed occupancy is far too high. This increases the risk of HCAI, as does the increasing number of frail, elderly people in hospital who do not have sufficient defences against infection. Surveillance is improving but there needs to be more work with hospitals, community trusts and the HPA to help to reduce the problem. The RCP has a HCAI committee chaired by Professor Jonathan Friedland.

Q14. *Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?*

36. There are considerable issues in the area of diagnostics in which many new tests are based on patented molecular approaches which will almost certainly be too expensive for the parts of the world where they are most needed. A shareware approach should be encouraged. Intergovernmental action to suspend patent issues for resource-poor countries (possibly compensating companies) should be considered. Support for the purchasing of equipment by affluent country health systems could be directly linked providing similar equipment at reduced prices for poorer countries (see also section 16).

Q15. *What interchange exists between States in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?*

37. Education of the public is essential and this needs to be in the context of health programmes which can provide necessary diagnosis and treatment. In some areas of the world there are conflicts between religious messages (ie superstition) and the knowledge base which need to be addressed. Worldwide provision of internet-based learning opportunities for those in healthcare are required. Support for education would benefit from intergovernmental co-operation.

38. Interchange between the United States and the UK is largely via academic links, with many UK specialists attending international meetings in the United States and elsewhere. Most of these meetings are research based but some are knowledge based and related to clinical issues. The changes in training of UK doctors (through MMC) has made it difficult for exchange of clinical trainees to occur. This was very useful and many UK specialists had time training in the US in the past. In addition, the restrictions placed on foreign doctors coming to the UK also affects US trainees who may want to experience NHS practice. Dealing with outbreaks is probably done fairly well with international epidemiological links.

Q16. *The International Health Regulations 2005 are intended to provide a global framework for the rapid identification and containment of public health emergencies. How effective do you consider this response system to be? Do improvements need to be made?*

39. There are limitations to the IHR which depend on the will of international governments to implement the agreed actions. This was recently clearly demonstrated in the sharing of flu specimens from Indonesia, where there were concerns that these would be used in vaccines which would only be available for rich countries, and the citizens of the country supplying specimens would not benefit. One issue is that IHR does not explicitly cover biological specimens. If IHR is to work so there is need for high quality infrastructure, communication systems and labs. There also should be complementary legislation on animal diseases since this is from where new pathogens may emerge.

Q17. *What intergovernmental planning has been undertaken to cope with the impact of an outbreak of infectious disease caused by deliberate release of micro-organisms into the environment? Is there adequate liaison between the various agencies involved, including intelligence, law enforcement and health care professionals? How could action by intergovernmental bodies help further?*

40. Each region has an infectious diseases physician designated as a smallpox diagnostic expert and to whom authorities would turn in the event of a deliberate release of a pathogen. The HPA also has plans in place.

41. However, it is the feeling of some colleagues that vast amounts of money have been spent on bioterrorism quite out of proportion on the likely damage that this can cause. Any terrorist is likely to find it easier to use radioactive or chemical weapons than biological ones and this should not therefore be a priority area.

Q18. *Though our remit is focused specifically on known infectious diseases, we would be interested to know how you view the global threat from new or previously unrecognised ones and from the transmission of infections from animals to humans.*

42. It is inevitable there will be continued emergence of new infectious diseases and in transmission of diseases from the animal population to the human population for the foreseeable future and therefore surveillance needs to be generic and not too disease specific for the recognition of new outbreaks.

43. The threat of emerging infections, such as SARS, is ever-present and the government needs to maintain readiness. There needs to be a network of good diagnostic laboratories able to respond rapidly to new diseases and the surveillance system needs to be in place. The weakness is in the number of clinicians trained in clinical infection so there is a risk that new infections or odd presentations of known infections may be recognised late. In addition, the pace of NHS work and the reduction in beds may mean that some people are discharged with new infections so rapidly that the new problem is not diagnosed. There is also a paucity of isolation beds in the UK and very few isolation facilities in Emergency Departments in NHS hospitals.

Q19. *What resources (subscriptions, staff, training, medicines etc) does the UK Government commit to intergovernmental bodies to help in the fight against the four diseases listed?*

44. The UK needs to strengthen clinical infection services in the NHS; currently infectious diseases physicians are rarely employed outside of teaching hospitals. There should be an increase in emphasis on training on infectious diseases in the UK medical school curricula and in postgraduate medical training. There should also be more emphasis on providing help to developing countries where these four diseases are highly prevalent so that appropriate research, clinical trials and clinical management can be pioneered. Funding for basic science and applied clinical science in these areas needs to be a priority.

Q20. *Do you wish to provide any other relevant information in addition to what you have said in answer to the above?*

45. The UK is at the forefront on international health and infectious disease (ID) research internationally and this research base needs to be protected. Increased numbers of academic ID and epidemiology physicians and scientists are required. The UK has very few ID doctors per head of population (compared to the US, Scandinavia etc) and expansion of training and an increase in consultant numbers is urgently required.

18 January 2008

Examination of Witnesses

Witnesses: DR CHRISTOPHER CONLON, representing the Royal College of Physicians, DR MAUREEN BAKER, representing the Royal College of General Practitioners, DR HELEN WILLIAMS, Co-Chair of the International Committee and DR IMELDA BATES, Co-Chair of the International Committee, Royal College of Pathologists, examined.

Q268 Chairman: Good afternoon. Welcome to this session of the Intergovernmental Organisations Select Committee. Can I tell you, first of all, that this session is being web cast and recorded. You will see a transcript of your comments so that you can correct any factual or other matters; that will be sent to you. Please feel free to answer any of the questions that are asked. A question may be asked to one specific person, but if someone else has something useful to say, please indicate and I will bring you in. Having said that, you do not need to answer every single question if you do not wish to do so. Also, I would want to encourage you if, after this session, you feel that there are other things that were not said that should have been said or anything you want to clarify, not to hesitate to write in with comments to that effect; that is very helpful to us. Finally, can I tell you what is the difficult part of this Committee. We are actually focusing on intergovernmental organisations and their effectiveness and the ability of the British Government to use intergovernmental organisations effectively. It is quite a complex area and that means that we have to have knowledge of the medical side, but we do not need to have the detail of the medical side unless it is particularly relevant to that. So it is quite a delicate balancing act, but you will understand if we focus on the intergovernmental organisations at times. We are not expecting you to be experts on intergovernmental organisations; if you do not know an answer, then please do not hesitate to say so. We understand that you are essentially people with a medical background. Can I start by asking each of you to introduce yourselves?

Dr Conlon: I am Chris Conlon; I am representing the Royal College of Physicians. I am an infectious diseases physician and general physician in Oxford.

Dr Baker: I am Maureen Baker. I am Honorary Secretary of the Royal College of GPs

Dr Williams: I am Helen Williams. I am Vice President of the Royal College of Pathologists and I am also a consultant medical microbiologist in Norwich. I also co-chair the International Committee at the Royal College of Pathologists.

Dr Bates: I am Imelda Bates. I co-chair the International Committee at the Royal College of Pathologists with Helen. I am a clinical tropical haematologist and I work at the Liverpool School of Tropical Medicine.

Q269 Chairman: We have heard already that there is a view that the intergovernmental organisations are quite fragmented and there is a question of how effective they are at controlling the spread of

infectious diseases. We are not quite sure, in other words, if the intergovernmental architecture, as it has been called, is quite as it should be or whether it is overlapping and confused by too many groups being involved and so on. Do you have a view about that? And, if so, can you tell us what it is?

Dr Bates: To be honest, the only intergovernmental organisation that I have had anything to do with really is WHO, and occasionally a bit with UNAIDS and FAO a bit, where they interact, but it is mostly with WHO. We do not see much of the other intergovernmental organisations.

Q270 Chairman: How effective do you find the WHO to be?

Dr Bates: In some areas reasonably effective. It depends whether you are talking about headquarters or the regional offices. Some of them function well and some of them seem to act very autonomously, separate from headquarters. WHO headquarters have some departments which function very well and some which do not function well at all, particularly in the area of not using evidence-based information to develop policy.

Q271 Chairman: What you are saying we have heard before, so you are not alone in saying this. Can you perhaps help us by giving some examples of where you think it is not working as well as it could?

Dr Bates: I can give you two examples. One is that WHO are very vertical in their approach. For instance, in communicable disease programmes one of the common factors is anaemia; and, when I wanted to talk to anyone in WHO on anaemia, I had to go round eight different departments and get them all together to talk across the table about anaemia. Another example is blood transfusion, where the policies are not very evidence-based. There is evidence there but there seems to be a party line which is not necessarily based on updated evidence and there do not seem to be appropriate expertise groups brought together to advise about what should be policy updates.

Q272 Chairman: Do you see this is a problem of the central organisation of WHO?

Dr Bates: Yes.

Q273 Chairman: It is essentially a problem of the centre.

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Dr Bates: I think so, and yet some departments work well and they have recently introduced a system of recommendations as to how you produce evidence-based guidelines, which seems to be percolating through WHO, and which is a really good move forward. However, I do not think that has reached all the departments. I do not know whether it is something to do with the structure of WHO or whether it is just to do with individuals running different areas.

Q274 Lord Geddes: Dr Bates, you used the expression just now “party line”; what do you mean by that?

Dr Bates: If you do not get a very good group of experts bringing all different perspectives together, what you tend to get is a polarised view. A lot of the documentation and people’s views are fixed down one line that may have been stated long ago. What you need is new blood coming in and a sort of panel of experts who can bring different perspectives instead of just a biased view.

Q275 Lord Geddes: Can I switch just slightly but still on WHO. You said you had experience of the Centre, but you did mention the Regional Offices as well. Do you have any experience of the Regional Offices as well?

Dr Bates: I have some experience of AFRO, which is the African Regional Office. I think the other Regional Offices, from what I hear, seem to work very well with the Central Offices, but AFRO seems to be much more autonomous somehow. Whenever you go to Headquarters in Geneva and talk to them about something, it does not necessarily percolate down to AFRO and vice versa.

Q276 Lord Geddes: With other parts of the world do you think that does percolate down?

Dr Bates: I do not have personal experience of other parts of the world, but from what I hear from colleagues it does seem to.

Q277 Lord Geddes: I wonder if our other experts have any experience on this?

Dr Conlon: My experience is purely from Africa as well, in the field of HIV. As Imelda has said, there is often a disconnect between what is happening in Geneva and what is happening on the ground and even on the ground the Regional Office is often quite far away from where the field work may be going on and where programmes are being implemented. I think I have the same view as Imelda has—that there appears to be much more politicisation of the Geneva headquarters and party lines—a methodology in doing things—not necessarily the best but what is

told to them is carried on. It is quite hard to translate that bureaucratic view to hands-on in the field.

Q278 Chairman: So it is more a failure of the Centre than of the Regions?

Dr Conlon: I think it is a bit of both. There has to be feedback from the Regions but I think the Centre probably should be responsible for making sure that happens. It is quite hard for the Regions sometimes to report back if they are not invited to do so. I do not have any first hand of the mechanisms by which that happens.

Q279 Lord Geddes: Coming back to the Royal College of Pathologists, in your evidence you used a very interesting expression, that “leadership from the WHO is ambiguous”. What do you mean by “ambiguous”.

Dr Bates: Some of the policies do not necessarily join up. For instance, for malaria WHO was very strong in advocating for combination therapy when chloroquine resistance became very prevalent, but they did not link that onto the need for a diagnosis for malaria. So, although the combination anti-malarials are much more expensive than chloroquine, they were still persisting with the policy that says that all fevers should be treated as malaria and yet, on the other hand, also saying that these more expensive drugs should be focused on those who really have malaria. We know in some countries that 90 per cent of fevers are not due to malaria, so there is 90 per cent over-diagnosis of malaria. Where there really is no evidence, they need to say, “Look, we actually don’t know, but we need to generate more information”. It is ambiguous in that, where it is not clear what you should do, it is somehow not made that explicit.

Q280 Lord Geddes: Do you get the impression that they are frightened of admitting that they do not know?

Dr Bates: I do think in some areas yes, but I also think that their role is to find the gaps and to commission people to generate the evidence. In some instances I have seen people from the WHO themselves generating and managing projects. They are not academics, they are not researchers; that is not what they should be doing. They should be generating policy from evidence; where there is no evidence they should ask expert researchers to generate evidence for them.

Dr Baker: The point I would like to make is that, from the point of view of the perspective of British GPs, intergovernmental organisations by and large are pretty invisible really. Certainly from the perspective of the Royal College of GPs I suppose, being a professional body of primary care physicians in the United Kingdom, you could consider that is

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fairly surprising. For very many communicable diseases, GPs and primary care teams are in the first line of seeing and treating people, yet it is as if we do not exist. Is there a role for such organisations to come to bodies such as ours and say, "What do GPs need in the event of this condition or that condition?" but those sorts of discussions never happen. I am just throwing this up to you in that I do not know if that is the experience in primary care in other countries, but I think it would be reasonable to say that that is what it feels like for British GPs.

Q281 Chairman: What would happen if you went to them and said, "We would like you to look at this"?

Dr Baker: I do not suppose there is any reason why we cannot, although because we are a generalist body and we comment and participate in so many fields, we tend to be busy enough dealing with people who come to us rather than to create an area of activity for ourselves.

Q282 Lord Hannay of Chiswick: I want to follow up on the same point. Do you not think that it is likely that an organisation like the World Health Organisation feels that it has to put most of its effort into developing countries which have very inadequate health programmes and that probably developed countries are perhaps not such a high priority because they are better able to look after themselves? On the other hand, the question Lord Soley asked is surely a very reasonable one. If you and your organisation are generating very valuable material from your own experience and your own practice, would it not be a good thing if you were to share that with organisations, whether they are at the European or world level, whether they come looking for it or not?

Dr Baker: I suppose it is a question of what comes first. I totally accept your point about developing countries and the priority; I would not argue with that at all. I think what we would consider is that we have been around as a professional body for GPs and primary care physicians longer than any other and, therefore, I would consider that we probably do have expertise and networks that would be of value. To what extent it would be our responsibility to say to whom is our expertise valuable and go out and push it and to what extent it is our responsibility to actively respond to requests should be debated.

Q283 Lord Avebury: Are GPs not also members of an international body of general practitioners? And do you not have links with other primary care medical organisations? Would it not be more appropriate for the international organisation that represents primary care to be the interface with the WHO?

Dr Baker: The only international body that comes anywhere meeting that description is a body called WONCA. It actually stands for something like World Organisation of National Councils of Family Medicine; I do not know how the acronym arrived. WONCA is an organisation that very much relates to the development of research and education in primary care, so the type of organisation you describe does not really exist.

Chairman: I think perhaps we need to move.

Q284 Lord Hannay of Chiswick: We have had a pretty persistent message in the evidence we have taken so far that there is some tension between what you could call vertical health initiatives, initiatives to eradicate specific diseases (HIV/AIDS, malaria, TB or whatever it is). The evidence suggests that they are not very sustainable if they are not properly embedded with well-resourced and functioning healthcare systems, which of course are lacking in many parts of the world. I wonder if you could comment on this tension. We are not suggesting that it would make sense to immediately abolish all the specific programmes and put all the money on healthcare or anything silly like that. But do you think that the balance is about right or not right? If it is not right, how can it be shifted? Is it a question of robbing Peter to pay Paul? Or can the imbalance side of the equation be pushed up without pulling down the other? Perhaps, just as a last point, you could comment on criticism that the word "eradication" comes in rather too often in the publicity material, for instance on malaria. I saw a quite powerful article last week suggesting that it was really quite silly that you could very possibly reduce malaria incidence by 80 or 90 per cent but you were not going to eradicate it in the foreseeable future. Perhaps you could comment on that eradication point as you go along as well, commenting on the balance between public health systems and disease specific initiatives.

Dr Bates: I came back from Nigeria where we were trying to do exactly this, which is to integrate across programmes in the field and it is very difficult. Some of the vertical programmes, particularly HIV, are very strong and very focused on HIV activities; there is huge potential in those vertical programmes for strengthening health systems across the board for horizontal delivery of essential packages of care, but nobody is making the donors do it. Essentially the vertical programmes are mostly donor-run or donor-funded and they run in countries where the ministries of health are not very strong. If the ministries were strong, they could make those donors integrate key activities across other programmes, but they do not. It is difficult because the donors have funding for specific activities which are very tunnelled on their individual disease.

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Dr Conlon: I would agree with that. From my experience of working in Zambia, which was HIV-related again but in practice you cannot separate different diseases because they interact. HIV and TB is a very good example, and Imelda has already referred to the fact that many people come into hospital with fever in the tropics and they call it malaria but actually they have HIV or TB or something else. Part of the problem is that, because of the infrastructure in the health system, it is not uncommon for a disease to raise money among NGO donors or to be a focus for governmental donation, and, although there is a lot of money put into that, it neglects whatever else is going on in the next ward or the next patient. The other problem, I think, in terms of a ministries of health in developing countries is that the Minister of Health is often a transient being, more so than in the UK, so that causes a problem in trying to focus on strengthening the underlying health service to meet the demands that are more horizontal.

Chairman: I think we are all slightly shaken by the idea that ministers move faster in other countries than they do here!

Q285 Lord Howarth of Newport: Would you actually go so far as to say that vertical programmes can, albeit inadvertently, damage wider health services?

Dr Bates: Yes, absolutely.

Dr Conlon: A good example is people putting a lot of money into HIV and then sucking doctors out of the clinics to work for the HIV programmes and not running the malaria programme or the child nutrition programme or whatever. That can be damaging in that respect.

Q286 Lord Steinberg: Would that not militate very much against a lot of large private charity organisations giving money when they see the problems?

Dr Conlon: Yes, it is easy to think you can fix something but, as Lord Hannay said, you cannot eradicate these things. You need to manage them so you need a portfolio of management and not a single-disease thing. You have to educate the donors as much as the ministries.

Q287 Chairman: How would you try to get this balance right between the vertical and horizontal?

Dr Conlon: I think part of it is trying to get education at a much lower level organised first, so people understand what the processes are both in terms of secondary and tertiary education, because it is very easy for the young doctors in the tropics to be seduced by the big money for a disease and to go into that sort of programme and see that as their way to

make their career and survive in difficult circumstances. A lot of it is to do with making people aware of the interaction between diseases and health.

Q288 Chairman: There must be a problem in Nigeria because of their health system being partly regional?

Dr Bates: Their system is challenging to say the least, because within each state they have three separate health tiers as well. It is challenging, but it offers opportunities because, if you can deal with the local government, they have the money. If you want to release money for communities you can, so long as it fits with policy. You have to go to the top but, so long as it fits with policy, you can then go to the local government, who have money and who can deliver things on the ground.

Q289 Lord Geddes: Lest you think I have an axe to grind, I am neither for nor against the WHO. But is this not where the Country Offices of WHO could come into play?

Dr Bates: I think the Country Offices in WHO do not have a very high profile. Whenever you go to them, they always refer you back to the ministry. They will not work separately from the ministry, so it really means you have to get to the ministry rather than the WHO.

Q290 Lord Geddes: The point of my question was actually the reverse of that. If the in-country offices were somehow enhanced, would that help?

Dr Bates: I think you would have to do more than boost it. They sit on the fence, and they would have to sometimes stand up and be counted if you want to push for vertical programmes to integrate more horizontally.

Q291 Baroness Whitaker: What you have just been saying is very clearly reflected in the GPs' paper—Dr Baker's paper—about a holistic approach to the problems in disadvantaged communities. But there is a consensus generally over all your written evidence that poverty is one of the major influences of the spread of disease and that non-health factors—globalisation, urbanisation—are key. Of course these are primarily dealt with, not by the WHO but by other IGOs. Do you come across, in your WHO or other international contacts, other IGOs? Do you have a sense that WHO brings in the World Trade Organisation or the UN Development Programme at all? What is your feel for the non-health reasons for disease?

Dr Conlon: I think they are often pretty separate really.

Q292 Baroness Whitaker: Not what they are but how they are being managed.

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Dr Conlon: I do not get the impression from my experience that somebody in the WHO would say, "Let's go and find out what the UNDP is doing or UNAIDS is doing". They would be on almost parallel—sometimes convergent but not always—tracks.

Q293 Baroness Whitaker: Would you say duplicating?

Dr Conlon: Not necessarily duplicating but I think not necessarily focusing on what the problem is.

Q294 Baroness Whitaker: Would you say there is more scope for integration and coordination?

Dr Conlon: There is certainly more scope for integration but the question is how you would manage the integration and who would have the upper hand in managing it.

Q295 Chairman: It is the coordination rather than the integration, if I understand what you are saying.

Dr Conlon: Yes, integration of effort but coordination of services.

Lord Hannay of Chiswick: I should just warn that the word coordination is a dirty word in the UN family. It means that organisations join together, spend two days saying what each is doing and go away and go on doing it. I think it is actually a very real challenge to integrate more the way that health and other programmes are involved and I think that, if our report just talked about coordination, a lot of people will laugh bitterly and say, "We've tried that fifty times before".

Chairman: That is a very helpful reminder from Lord Hannay, who spent many years at the United Nations.

Q296 Baroness Whitaker: Just to continue, do you have any thoughts about how this might be better managed? We do not expect it of you, but if you do have anything to say we would be very receptive.

Dr Conlon: I wish I could solve it.

Q297 Chairman: Dr Bates, did you want to come in here?

Dr Bates: No, I do not have any dealings with other organisations apart from WHO.

Q298 Baroness Whitaker: Would you welcome that?

Dr Bates: Yes, because on a community level in developing countries in Africa we deal with pro-poor issues all the time and you see things like town planning, environmental issues, agriculture and education. All these different areas bring to bear on improving health.

Q299 Baroness Whitaker: So you would see the need for more input.

Dr Bates: There is a need but it is really difficult to do.

Q300 Baroness Whitaker: Is there any work being done either in poor countries or for that matter in richer countries on who does not catch an infectious disease? Obviously poverty and malnutrition makes a huge difference, but even in rich countries there are plenty of people who do not get flu, measles or colds; there were the Kenyan prostitutes who did not get AIDS. Are people looking at this?

Dr Conlon: There is a whole building in Oxford looking at this!

Q301 Baroness Whitaker: Is it being fed into the international scene?

Dr Conlon: Yes it is, and it will form part of the basis for some of the vaccine development that is going on now, looking at people who are clearly exposed but immune for whatever reason. They are looking at the genetic basis of that to try to unravel what in their genes allows them to be immune to that pathogen and then try to unravel that further to make a vaccine. Certainly that approach is going on quite a lot.

Q302 Baroness Whitaker: Would you say that would be productive?

Dr Conlon: I think for something like malaria, for example, there is a bit of hope in that. HIV is a long way off; TB vaccines may get better because of that. It is an approach, because clearly a lot of people are exposed and do not get infected. Most people walking around in Africa are not ill with malaria or TB or HIV, and some of that is genetic.

Q303 Baroness Whitaker: Does WHO take an interest in this too?

Dr Conlon: I am sure it takes an interest but it would not be funding that sort of thing. It might eventually develop policy in terms of whether this vaccine should be used in the field and promoted by WHO; it would be in that guise.

Q304 Baroness Whitaker: They do not have an interest in genetic research.

Dr Conlon: WHO would not have an interest, no; it would not be their remit.

Q305 Lord Howarth of Newport: I am encouraged by what Dr Bates was saying to ask you all whether you think we would be right to stress in our report that different organisations working in the same countries and the same regions really do need to develop integrated approaches to deal with such issues as lack of clean water, lack of sanitation, lack

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of education, poverty, inequality, violence, corruption, lack of administrative capacity, all these conditions which must have the most powerful bearing on health within these countries. Should we stress this in our report?

Dr Williams: I would certainly support that.

Q306 Chairman: You are agreeing?

Dr Conlon: Part of it is also to do with how you implement governance in the different countries.

Q307 Baroness Eccles of Moulton: We have heard an awful lot about top-down, but surely if it is going to be enduring and accepted it really has to be more bottom-up, does it not?

Dr Bates: I think it has to be both. I think bottom-up will not move if it is not coming as a directive from on top and it has to be joined up all the way from top to bottom. I do agree that on the ground in the villages people are doing these things all the time as an integrated thing. It is not really formalised. At ministry level it is really difficult to get the ministry of education to talk to the ministry of finance to talk to the ministry of health. It is really hard and yet when you get down to grass roots level it is clear how that should work and how it should be done. These village communities do a lot of this for themselves.

Q308 Lord Desai: I just want to ask the counter to what Baroness Whitaker and Lord Howarth said. We know these things should be integrated—town planning and clean water and such matters. But, when people give money, they want to give money for malaria or for HIV. They do not want to mess about with town planning. Is the problem not that donors want to see the impact of their dollar and they do not believe in these diffused, perhaps true, theories? They just want to get an immediate reaction and that prevents integration.

Dr Bates: Yes, it does prevent integration. One of the ways of making vertical programmes integrate more would be to have, as their measures of success, not how many people have swallowed anti-retroviral tablets but how much they have managed to strengthen the health systems for other diseases apart from HIV, for instance. That just does not happen because for the donors it is not clean enough, it is too messy around the edges for the donors.

Q309 Baroness Flather: You have actually made the point that I was going to ask you about. You said that you want to strengthen the central system so that all these things can be looked at. When we had DFID officials here, they said that there had been a great improvement through DFID aid projects to strengthen health systems—I suppose they mean the administration—in Nigeria. I am involved in the

NGO world as well and I do not get that same feeling from them. In fact, when I said that, I got quite a big laugh around the table. I just wanted to know how you felt. The second question is about fevers. Coming from India, we always had fevers which had no particular cause—or at least a particular cause was not diagnosed. All you did was take some analgesics, drink a lot of fluids and rest, and in two or three days the fever was gone. You did not actually rush to take serious medication of any particular kind and I wanted to know if that is still happening. Is that still the case that people get fevers because they live in this kind of environment?

Dr Bates: DFID are one of the only organisations which are very far thinking; they have pro-poor indicators on their programmes and programmes are not disease specific. They are very much about strengthening systems. They are going back into Nigeria with a big governance programme. DFID are very unusual in that respect. They have even put calls out for cross-agricultural environment and health projects. DFID is a very good example of the sort of innovative thinking that you can have around building systems and structures. They have done it in Nigeria. Nigeria is a big country, so the impact is small. But the systems strengthening can work.

Q310 Baroness Flather: You think there is an impact?

Dr Bates: Yes, I think there is. In terms of fever, about 60 per cent of people in Africa do not access normal health care at all. If we are just focusing on health facilities, we are missing more than half the population. Those people in the villages, if they get a fever, they will do as you say; they will wait a bit and then they will go to buy some herbs or something cheap and only as a very last resort would they pay for transport and have all the aggravation that comes with trying to access healthcare.

Q311 Baroness Flather: Is that late then?

Dr Bates: Yes, and then they come late.

Q312 Baroness Flather: They will not have ordinary analgesics like paracetamol.

Dr Bates: They would but that is further down the line.

Q313 Baroness Flather: Is that not at the early stage?

Dr Bates: The first thing they do is local herbs and local treatments, which they will buy themselves from the market. Then they might go to the traditional healer before accessing healthcare.

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Q314 Baroness Flather: Could that be damaging?

Dr Bates: Most of these fevers, as you say, are probably just viral infections and they settle on their own. However, if it is not a viral infection, if it is something that is going to get worse with time, then the fact that they present late means that in the end their health suffers, they have to pay more for their healthcare and they are getting into this deepening cycle of poverty.

Q315 Baroness Falkner of Margravine: Dr Conlon, I thought you were going to say something about governance and structures but you left that behind and moved on. My question relates to Lady Eccles's question also about bottom-up versus top-down. I should declare a past interest. I ran an HIV/AIDS charity across several African countries, so I know very well what you are talking about and have great sympathy with what you are saying. Do you find that, when you say that you are working for the health ministry, it becomes very difficult but then out in the rural areas at community level you get much better feedback and much better ability to do things? Is that affected by the level of governance structures in different countries? In other words, the stronger the governance structure, the easier it is to incorporate programmes and take programmes forward; the weaker a governance structure, the more difficult it becomes because of gate-keeping and also donor funds being much more predicated on keeping control of the situation. Is that your experience?

Dr Conlon: I think that is right, yes. Clearly, if it is very centralised, then nothing gets out to the rural areas and that is a problem in itself. But, if there is a good structure that allows decisions to be made and decisions to be looked at when they are made, that is helpful but that is not very common. One of the problems is that people might make decisions based on all sorts of things which are not evidence-based; they may be based on things to do with whatever finances come in through their ministry at the time or what their job prospects may be. As I said earlier, you need to start educating people about responsibility for decision making and the use of governance.

Q316 Baroness Falkner of Margravine: You mean educate the public servants?

Dr Conlon: Yes, but at an early stage so that you can get this more broadspread.

Q317 Lord Avebury: You place great emphasis on the need for better diagnostics and laboratory facilities in a lot of countries, and we heard earlier from Dr Bates about the particular case of malaria, where she said that there is a 90 per cent over-diagnosis because of lack of these facilities. Would you say that IGOs should be investing more in this

area and, if so, how would they make the necessary choices in their investment programme?

Dr Williams: To take a specific example, if you look at drug-resistant TB—either multi-drug resistant or extensively drug-resistant TB—the whole future of that programme depends on having a developed capacity for not only diagnosing TB but diagnosing drug-resistant TB. The whole issue of diagnostics extends beyond the individual patient and the appropriate use of drugs in that patient. It is also using drugs in people who perhaps do not need them, so you have exposure and development of resistance. It also influences any infection control activity that you might want to implement as well, which again reflects back on the TB. It also absolutely helps you with knowing what your prevalence of a disease is and your impact of any interventions. It is fundamental, actually, to developing the control programmes for these diseases.

Q318 Lord Avebury: Which IGOs are investing in multi-drug resistant TB? Or are none of them doing so?

Dr Williams: There is the WHO report which names 400 organisations and countries that are engaged in putting that programme through, but it stresses the essential nature of developing diagnostic capacity.

Q319 Lord Avebury: Are you saying it is not so much a question of lack of investment but a lack of coordination between these 400 organisations?

Dr Williams: I think it is a lack of investment too in diagnostics, because diagnostics also requires expertise and infrastructure. It is very easy for us to say that you need diagnostics but, if you have unreliable power supplies or you do not have the equipment that allows you to make a diagnosis, then it is quite difficult.

Q320 Chairman: So it would not be enough, for example, to say, “We will set up a diagnostic centre in a particular area” unless there was an underpinning for it?

Dr Williams: Yes, you would need an appropriate infrastructure, including the expertise that understands how to use the diagnostic tests, so you can actually do it properly and interpret it properly.

Q321 Lord Avebury: Do you think it is possible to identify the countries or centres where the proper infrastructure does exist?

Dr Bates: I think we are talking about two separate things. One is about the actual technology and, if you want to impact on health, you have to get simple technology out to the communities because most people cannot travel to a centre where you have good diagnostics. There has to be much more investment in

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developing technologies that are field-friendly and also in the systems that support that. One of the problems in the past has been that people put those simple diagnostics in the villages and they just leave people to get on with it. There is no quality monitoring or no training, so the diagnostics should not go in without the whole capacity of system strengthening on top of it. There is no investment in any of those. Diagnostics is now becoming a major bottleneck in delivering these disease control programmes in many countries now because it has been so neglected.

Q322 Lord Desai: Is this where the Regional Offices of WHO could have a role, the basic R&D of diagnostics could be done there? Once they have found some simple technique, then that could be disseminated to new countries. Is that kind of division of labour possible?

Dr Bates: The actual development of the technology could happen here or anywhere, but the field-testing in a real life situation could be facilitated by WHO Offices. They should not do the R&D themselves; that is not what their remit is.

Q323 Baroness Eccles of Moulton: I think we are mainly talking about Africa because that is where your general knowledge lies. But I was just trying to get a feel while you were talking about the distribution of population, because there is a general global movement of people out of the country into the city and we know some of the pretty awful health consequences of that. There has been a lot of mention of villages, so we have an idea of the village and the market and the herbal remedies and all that. But what I was really wanting to try to get a feel for is the local traditional access to the first line of cure which you described earlier on that is available in the city, and maybe a little bit more general information about what is happening, if there is a big population shift and the effects that is having.

Dr Bates: We have done some research on urban poor and how they access health care. In the rural villages at least the structure is clear: you go to the village heads, they have a town crier, you can mobilise the community. Once they get into the town it is much more difficult. They are not a discreet population; they have lost their family social support networks; they are often poorer than they were in the village because they have no land. The way you deliver healthcare to them in the cities has to be reorganised. Certainly there is some evidence now that malaria mosquitoes which previously would only breed in nice clean water are now beginning to breed in dirty water. If we now get malaria hitting the towns as hard as it has hit the villages, we are going to be in big trouble.

Q324 Baroness Whitaker: There is some scepticism in your evidence about the effectiveness of the new International Health Regulations, but I imagine you would agree they are an advance on the previous ones. Could you say what you think they ought to be doing and how should their problems be better coped with if they are not doing it and who ought to be doing it among the organisations?

Dr Conlon: Who ought to do it is a difficult question. What we might be addressing is to do with cooperation rather than coordination, so that if new pathogens arise those pathogens are made available for study, that there is easy movement of investigative teams internationally to look at outbreaks to try to determine what is going on and to look at how you would deal with the movement of populations with infections. I think all those things are do-able, but who coordinates them?

Q325 Baroness Whitaker: You say “teams”; you are not then thinking of a requirement on each national government to have this surveillance system but expertise moving around?

Dr Conlon: In an ideal world you would say that each country would have a surveillance system but that is not possible. So what you would like to have is a bit like they do in the States with outbreaks within the states, where they have Outbreak Investigation Teams that can move and help local investigators to deal with outbreaks and to allow that to happen internationally. I can see the International Health Regulations helping that quite a bit.

Q326 Baroness Whitaker: Do you think the WHO would be capable, as presently constituted, of organising that?

Dr Conlon: Could they do it? Possibly. I am never quite clear what the WHO sees as its remit both in terms of devising policy or doing things in the field. I do not see the WHO initiating research; I see them implementing successful research with enough guidance for them to do that. I would be doubtful whether they would necessarily coordinate investigations into things other than saying that there is a problem in such and such a country, can we send a team from the UK or the US.

Q327 Baroness Whitaker: Under whose auspices might a team with really good diagnostic equipment go into a country?

Dr Conlon: I think it would be under the auspices of the WHO but whether it would be organised by the WHO would be a different matter.

Q328 Lord Howarth of Newport: I would like to pursue with you a little further the issue of the balance between treatment and prevention. We have

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already covered a certain amount of the ground this afternoon, but the Royal College of Pathologists draws attention in its evidence to “a lack of appreciation of relationships between diagnostics clinical management of sick patients (including use of antimicrobials), health protection and health promotion”. Would you be kind enough to expand a little bit on your thoughts there?

Dr Williams: It goes back a little to what I was saying around the use of diagnostics—that, unless you reasonably accurately diagnose what someone has, then you risk using precious drugs and precious resources wrongly and treating people inappropriately. You also risk—which is clearly a major issue with HIV, TB and malaria—inducing resistance in the organisms; resistance is a problem for all of those diseases. It also helps you with those where you have infection prevention measures you want to implement. Unless you have a reasonably accurate diagnosis, those infection control measures can be very burdensome and, if you try to impose them all the time without making a diagnosis, people can lose their enthusiasm for actually observing them if they are not there. There is also the issue of assessing the burden of disease that you are trying to deal with and how effective your interventions are. That is where diagnostics come into both balancing up with your treatment and your prevention because they influence both of those.

Q329 *Lord Howarth of Newport:* The Hippocratic ethos tells you that you must treat patients who are suffering. But would you prefer to see more investment through international governmental organisations going into prevention in the first place as opposed to treatment? Would that mean, for example, more investment in ensuring that developing countries were aware of research and evidence, more awareness of proven good practice in other parts of the world and also have more trained staff and a better capacity to retain their own trained staff? These are all things which would help to build up capacity and effectiveness. Would you rather see money going into prevention and building up the infrastructure that you have been talking about before, if we had to make the choice between that or treatment programmes.

Dr Williams: I would rather not have to make the choice. What I would like to do is actually to see a programme that perhaps pays adequate attention to that aspect of it, so that as time evolves you would not actually be doing that awful thing of saying “I’m not going to treat people”—because that is clearly an awful thing—but actually build your programme so that you do start to improve the diagnostics, you do start to improve the direction of your interventions so they are more appropriate.

Dr Baker: It is obviously very important to provide access to treatment for people who are ill and who are suffering, but of course in the process of treating and providing treatment there is money to be made. In the process of prevention and in the strategies that are used in a number of areas for prevention, there is not the same profit motif necessarily at the end of that.

Q330 *Lord Howarth of Newport:* Not treatment?

Dr Baker: The sort of things you have been talking about around non-health measures—the way in which you build, town planning, public health approaches—I would just flag up, is there necessarily the same lobbying and interest and bringing people to take forward those programmes in the same way as there can be for major pharmaceutical programmes?

Q331 *Chairman:* It seems to me that it is the non-governmental organisations which want to target their money onto vertical treatment because they say they want to do something about malaria or they want to do something about AIDS. The WHO would need to be the body that looks at the horizontal bit for general health improvement. Is that developing or is it happening like that by chance? Because so much money—the Bill and Melinda Gates Foundation, for example—is going into the treatment of disease and the WHO is concentrating more on the infrastructure. Is that happening or is it not happening or is anybody thinking about that?

Dr Conlon: I do not think it is as straightforward as that. The WHO has a remit to my mind in terms of looking at how they would implement policy to do things but may not actually implement them themselves; they would try to get NGOs and government organisations to do that. I think some NGOs are very good at doing the horizontal bit, things like Save the Children and Oxfam; others are much more disease-focused. I do not personally get the impression that that sort of thing is coordinated in any way by WHO. I may be too negative but I think you are putting much more faith in WHO organising things than I would.

Q332 *Baroness Eccles of Moulton:* We have heard certain evidence which has indicated to us that emergent infections tend to come from animals—though not always—and that some come from the domestic animal source but the majority of emergent infections come from the wild. It is a question of early detection and then moving into how to deal with preventing spread and remedies et cetera. Our impression is that the organisations, particularly the intergovernmental organisations that are dealing with human health and the organisations that are

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dealing with animal health, simply do not share knowledge and assist each other in preventing or dealing with these nasty infections either before they reach the human victims or when they have actually become a human infection.

Dr Conlon: I think you are right. If you look at veterinary services in a lot of the countries there are problems with how they are organised and how many people there are on the ground. Most countries that I have come across in the tropics have medical schools of some sort but very few have vet schools. Again the expertise, if it is available, tends to go to commercial farming rather than husbandry or surveillance of animal diseases. It is a real problem. If you think about most of the epidemics over the last few years that have derived from animals, it has usually been the human disease that has pointed to the problem in a retrospective analysis, finding the animal source. The caveat to that would be in South America, where they are much better at finding yellow fever in monkeys through surveillance and warning about human yellow fever, but that is a pretty isolated example of that I think.

Q333 *Baroness Eccles of Moulton:* The lack of integration or exchange of information between the organisations is quite serious and maybe effort should be made to try to make that better. Do you have any ideas about how this could be done?

Dr Conlon: I would go back to the infrastructure in terms of how people are educated and what they are educated for and how you resource veterinary schools or interest in infectious pathogen research in countries and, of course, exchange of expertise between the west and the south, if you like.

Q334 *Baroness Eccles of Moulton:* Could the responsibility for this lie largely with the World Health Organisation? Or could one, as it were, point the finger at other organisations and say that they should be getting on with doing something about it?

Dr Conlon: Again I think it would be helpful for other organisations to be involved rather than just WHO.

Q335 *Chairman:* Dr Bates, would you agree with that?

Dr Bates: Yes, I think so. We started talking about having sentinel sites and monitoring in places where it is possible these diseases would emerge. That means really rural Africa—because that is where a lot of these diseases come from—and it will require the zoonoses people, the human to animal interface, to be much stronger. How you actually achieve that on the ground is difficult. WHO is not an implementer

and is not a researcher; they just should take evidence and build it into policy and then advise how this policy should be implemented. The guidance could come from them but actually what you need on the ground are the ministries of health and agriculture to join together.

Q336 *Baroness Eccles of Moulton:* Once again?

Dr Bates: Yes.

Dr Conlon: Even in this country, if you look at some of the vet science, it is a lot better than some of the medical science in terms of some pathogen research. But we do not go to the same meetings, we do not come across each other easily and that is magnified ten-fold in Africa or in South East Asia.

Q337 *Baroness Eccles of Moulton:* What about in the United States? Are they better at it than we are?

Dr Conlon: I do not think so, no. I think it is much more disintegrated in the States because of the federal system and because of private practice. This is one of the things you mentioned about urban-versus-rural health, and when you start throwing private practice in for both vet medicine and human medicine there is another complication to add in in terms of surveillance.

Q338 *Baroness Eccles of Moulton:* I think you did actually have something to add to the conversation about urban-versus-rural?

Dr Conlon: Just that, at least in rural areas, you can sort of work out what is happening. But, once you get to a large city where there is a lot of health-seeking behaviour and you may go from one private practitioner to somewhere else to a state hospital with no communication between them, there are many more opportunities to pass diseases on in urban areas, so the whole thing becomes much more complicated.

Q339 *Chairman:* Coming on to the issue of flu detection, which I think the Royal College of Physicians raised, it was your argument that we should divert more funds to the developing nations because you actually thought that intergovernmental organisations could not solve the problem of flu pandemic in a developing nation. Can you tell us a little more about what you mean by that?

Dr Conlon: I think there are two aspects. One is, as we have just been talking about, trying to identify things happening, emerging from animals to humans—that is clearly what has happened with avian flu—so that you are able to pinpoint when that is happening at an earlier stage. Then you can put in control measures more quickly locally. Strengthening local vet services

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would have allowed people to have got onto the poultry culling and other control measures in South East Asia more quickly. That is one issue. The other issue, of course, is to do with the fact that once humans get a disease it is pretty hard for any organisation to stop it moving. I think that is particularly true with flu. You can be incubating flu but not be symptomatic; there is so much travel going on it is pretty hard to see how intergovernmental organisations are going to stop that, unless you have very draconian measures during a declared pandemic to stop travel, but by that stage it is too late anyway because it is pandemic.

Q340 Chairman: So it is essentially identifying it and stopping it at source?

Dr Conlon: Yes. A good example, although it is a much less contagious disease in terms of zoonoses, is the ebola virus that has been happening in Uganda recently. It is contagious locally with poor infection control but by getting in there, finding the disease and controlling it locally—which is what has happened—it is less likely to spread beyond that, but you cannot do that without having the infrastructure locally.

Q341 Baroness Falkner of Margravine: I would just like to pick up the point you made about having travel restrictions against citizens. As I understand it, the United States does. The Disease Control Center at Atlanta can, in fact, issue a travel ban against individuals?

Dr Conlon: Yes, and it was clearly circumvented by a lawyer with TB without any clear repercussions last year.

Q342 Baroness Falkner of Margravine: Yes, that is the case I am thinking of. The State does have the power.

Dr Conlon: Yes, but that is for one individual with a known, declared disease. When you start to talk about large populations who are incubating a disease, it is very hard to stop people travelling because you think they might have something.

Q343 Baroness Falkner of Margravine: Would you recommend, in the case of people who are beyond the incubation period, that there should be rules to prevent them from travelling?

Dr Conlon: I think that, if somebody is actively ill with a contagious disease which is a public threat, then yes, I do. You can do that but I think it is very hard to implement because of the incubation period. In a pandemic flu setting, if somebody has a high fever, is coughing and looks terrible, you can stop them getting the airplane, but the guy behind him

who has the same infection but is not symptomatic, how do you stop him? That is where I think the intergovernmental organisations would have a hard time stopping a pandemic.

Q344 Baroness Whitaker: There might be an area where an intergovernmental organisation could come in. I have been reading an article in *The Economist* about something called the Global Viral Forecasting Initiative, which is a chap in America who wants to spot the virus which is going to jump from the animal to the human species. I am not competent to know whether this is feasible, but he has a great programme for that. Is that the kind of thing, do you think, that WHO could reasonably commission research in? Is that the sort of thing they should be looking at because it is not just human, it is looking at the actual virus; it is virus hunting rather like butterfly hunting, as it were?

Dr Conlon: I think the concept of WHO initiating research is just wrong; they do not do it to any degree that is helpful. If research has been done, more commonly initiated by Research Council money or Wellcome Trust money or something like that, then that research can be made more useable and made more applicable to the local scene.

Q345 Baroness Whitaker: They could facilitate the transmission of knowledge about such a programme; they could not initiate such a programme?

Dr Conlon: They could but they do not; that is not how they are designed to work.

Q346 Lord Hannay of Chiswick: Is the question not more where the powers lie to impose restrictions on travelling, whether they rely exclusively with 192 independent governments or whether they lie partly with intergovernmental organisations like the WHO and behind it other UN organisations like the Security Council? These are not totally impossible concepts but they are very difficult concepts. Surely what we are talking about is not so much organising research about how to do this—although that would be necessary but not done by these intergovernmental organisations—but whether or not there should be powers to do this and, if so, how should they be exercised in relation to the powers that governments do have to quarantine situations. Do we need world quarantine guidelines, arrangements or what have you?

Dr Conlon: There are guidelines for travelling with TB, but the WHO has no powers to implement them, so they can only advise either governments or regions how to do that. I am not an expert on international

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law, so I would not know how it is actually effected, but the WHO would have no power to do anything; they can only recommend things.

Q347 Lord Hannay of Chiswick: Unless they were given it?

Dr Conlon: Yes, but I cannot see that happening; maybe I am wrong.

Q348 Lord Geddes: Both Dr Conlon and Dr Bates have advertised very strongly that it is not up to WHO to instigate research, is that right?

Dr Bates: I think they can identify the question but they should not do it; they should then commission academic institutions to do the research.

Q349 Lord Geddes: I think your two views are slightly at odds because I thought I heard that they should not instigate research, but actually what you are saying is that they should instigate the research and get somebody else to do it.

Dr Bates: What they need to do is to say, “We have a policy for malaria but we do not have any evidence around this bit of treatment, so we need evidence”; and they can then commission some research to fill that gap. They would not know the exact research questions to ask.

Q350 Lord Geddes: Would you go along with that?

Dr Conlon: I think they are not actually sufficiently academic to even commission research in the way I think you are interpreting Imelda’s comments. I think what they should say is, “There is a problem and we would like research done in this area; it would be nice if somebody did that”, but the WHO very rarely is going to commission basic science or basic clinical research. They might look at operational research as to how it is employed in the field; that is how I would see it.

Q351 Baroness Eccles of Moulton: This, then, comes to the question of funding. You can only commission if you can pay. I thought commissioning meant you could actually say, “Do this and what’s it going to cost?” and get people to tender. Can they actually do that?

Dr Bates: The WHO do not have any money but what they can do is lever money from other organisations.

Q352 Baroness Eccles of Moulton: So they turn the idea out and hope somebody picks it up?

Dr Bates: Yes.

Q353 Chairman: Do they approach organisations or countries or whatever?

Dr Bates: Sometimes but mostly not, in my experience.

Q354 Chairman: They just put the idea out there most of the time and hope somebody responds. Is that your experience is it?

Dr Bates: Yes.

Q355 Lord Desai: I would have thought that other people are also picking up and throwing out ideas; WHO is not the only one. It must be a very collective effort.

Dr Bates: In practice the way it works is that WHO themselves do not know where the evidence gaps are because they may not be academic enough to see the holes in the policy. What tends to happen is that other organisations proactively go to WHO and say, “Look, your policy does not add up; you need some more evidence around this area”. Sometimes it is picked up and sometimes it is not, and sometimes they will pick it up but there is no funding.

Q356 Lord Desai: If you want money to do research that you have identified, does it help to say, “WHO supports us”?

Dr Bates: Absolutely. If you can go with WHO to a funding agency you stand a much better chance of getting money.

Q357 Chairman: Moving onto bioterrorism, I think the Royal College of Physicians were rather dubious about the problem of spreading pathogens by artificial means. Can you say a little more about why that is? I would also like to know whether, when you talk about pathogens, you are talking about the human variety or indeed the variety that applies to crops.

Dr Conlon: The argument is based on human pathogens, and I think most of us would think that biological warfare in that sense is pretty inefficient and, therefore, is unlikely to be a major player in a terrorism event. If you were going to cause terror, it is much better to have dirty radiation rather than smallpox or something that is not that easily transmissible. I think the argument we put forward is that quite a lot of effort went into this a few years ago, a lot of us got vaccinated, there is a lot of money going into education about smallpox and seminars on bioterrorism, whereas in fact MRSA and CDiff and things like that were getting less attention at the time and are much more of a problem.

Q358 Chairman: What about wheat germ, foot and mouth, and things of that nature? Do you take a similar view?

Dr Conlon: I take a pretty similar view. They are all pretty inefficient ways of terrorising countries.

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Q359 Chairman: That is, presumably, because of the problem of weaponising these things and transporting them, as opposed to chemicals or radiation, which is so much easier to transport?

Dr Conlon: Yes, and disseminate.

Q360 Chairman: Am I also right in saying that, presumably, the mechanisms you have in place to identify and then deal with an outbreak of a normally occurring pathogen would not in any event be different from what you would have from one that was spread by unnatural causes, if you like, by a state or a non-state player. Is that right?

Dr Conlon: Yes.

Q361 Chairman: Would the rest of you agree with that?

Dr Baker: I think at this stage I would like to say that the work that has gone on in the UK on pandemic planning is a very good model for dealing with a major outbreak of communicable disease regardless of how it arises. It makes much more sense probably to model on something that is reasonably likely to happen at some point but to be able to draw upon that work in the event that the next major outbreak is not pandemic flu but something unknown. That would seem to be a good use of the resource and the energy that has gone into pandemic planning. It is a good thing to do from the point of view of that level of preparedness, but it should also serve as a model for dealing with very many other possibilities that could arise.

Dr Williams: Could I just add to that and say that the detection of any disease, whether it is bioterrorism or a naturally occurring one, depends entirely on having a good infrastructure, which is about having alert clinicians when patients present, it is about having good diagnostics available, people thinking outside of the normal things when something is abnormal and having good surveillance systems and good communication systems in place to actually deal with it. In this country we do have quite a reasonable surveillance and alert system.

Chairman: I have heard a number of quite good things said about the system here.

Q362 Lord Hannay of Chiswick: I want to follow this up a little bit further, because this is not the first time that witnesses have said that there is not a real distinction between a bioterrorism event and the outbreak of a communicable disease of an unknown nature which comes suddenly upon the world and threatens to spread very rapidly. Do you think, therefore, that it would be helpful if governments stopped dealing with these two things in two separate kinds of categories and admitted that they were phenomena of a very similar kind which would need

very similar responses and, therefore, got away from an argument about whether or not bioterrorism was terribly likely to happen? That seems to me slightly dodgy territory because, although you are probably right that at the moment it is a very inefficient way to take terrorist action, I doubt any of us could put our hand on our heart and say that it would still be as inefficient in 30 years' time. If it is true that there is not a real distinction between these two things, would it not be much better if they were addressed internationally as a kind of single group rather than as two different groups?

Dr Conlon: I think that is the point that Dr Bates was making. I have sat through smallpox scenario planning meetings and I have sat through a lot of pandemic flu planning meetings; they are exactly the same. One is much more likely than the other but the planning is the same, the infrastructure you need is the same; you have to make sure that you have the infrastructure in place that works and you can recognise that. That involves clinicians and laboratory scientists being aware of the possibilities. There is no difference particularly other than saying that, if it is a new virus and you do not have a vaccine for it, it is slightly trickier than a virus you do have a vaccine for, which is the only argument for vaccinating against smallpox possibly.

Q363 Lord Hannay of Chiswick: Presumably, the countries which are most vulnerable to this sort of thing are developing countries because they have very little capacity either to spot the thing in the first place or to take action thereafter. They might respond more readily if it was not said that what they were doing was guarding themselves against bioterrorism—which they probably think is a completely zero threat to them—but that they were guarding against an unknown infectious disease, which they probably realise could be a very real threat to them. If their responses and defences are the same, it seems to me to be unhelpful basically to put two different labels on it.

Dr Conlon: The SARS outbreak a few years ago and the current avian flu situation have focused people much better on what the problems are and have actually made people get away from bioterrorism. These are new diseases, what new infrastructures do we need for these, how are we going to deal with this internationally? I think things have got better from that point of view.

Q364 Lord Desai: Just to add a comment, if you call it bioterrorism you get more money assigned to it. Your evidence from the Royal College of Physicians draws attention to the fact that migration is possibly

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one of the major factors in spreading infectious diseases. Can the WHO do something constructive about that, perhaps instruct governments to screen immigrants or whatever?

Dr Conlon: Again I do not think the WHO can do that. I think there can be guidance as to what may be useful as screening tests for certain diseases but there are not many that there easy screenings for. Tuberculosis is the one that is characteristically talked about, but I commonly see people with TB who have been screened at Heathrow or somewhere else, who were genuinely negative on the screening but are still carrying the disease a couple of years later. I think there are ways to screen people, and it may depend on how acute the problem is, but it is hard.

Q365 *Lord Desai:* Does it make a difference whether you screen on boarding the plane or upon landing?

Dr Conlon: It depends on the disease.

Q366 *Chairman:* Are there any particular things you would like to draw our attention to which could help on this because clearly world travel is one of the factors in spreading disease. Are there any ways of dealing with that that you can think of that are not before us?

Dr Conlon: Going back to what we have been talking about all afternoon to some extent, if you increase infrastructure, diagnostic treatment and abilities in other countries, it reduces disease burden and therefore reduces the amount of disease travelling.

Chairman: Unless you have anything else to add, that completes our session today. Thank you very much; you have been very helpful. If you do have any other ideas or thoughts about this session when you have read the evidence, or before then if you like, please send them in. Thank you very much for your attendance today.

MONDAY 17 MARCH 2008

Present	Avebury, L Desai, L Eccles of Moulton, B Geddes, L Hannay of Chiswick, L	Howarth of Newport, L Jay of Ewelme, L Soley, L (Chairman) Steinberg, L Whitaker, B
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Memorandum by UNAIDS

Issue 1: A recent report on Communicable Diseases by the UK Department of Health stated that “post-war optimism that their conquest was near has proved dramatically unfounded”. What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis?

1. While there has certainly been progress in responding to AIDS in recent years, the HIV pandemic remains the most serious of all infectious disease challenges today, and will clearly be with us for generations to come. It should also be noted that AIDS actually drives other deadly infectious disease such as Tuberculosis and XDR TB: this poses economic and security threats that go beyond national boundaries.
2. Some 33 million people worldwide are currently estimated to be living with HIV, two thirds of them in sub-Saharan Africa. To sustain progress already made, it will be important to accelerate (and diversify) efforts to prevent new infections and ensure that the provision of HIV treatment can be maintained over the longer term. It is critically important to understand the dynamics of the impact of AIDS as well as of HIV transmission, stemming from the fact that HIV—unlike other diseases—is concentrated in the productive adult population.
3. There is still no vaccine or cure for HIV. Its initially asymptomatic nature means that people living with HIV may remain unaware of their status for years. These facts, along with the stigma that still surrounds HIV, the taboos around the principal means of transmission (sexual relations, sharing needles for injecting drugs), and the extent to which socio-economic inequalities influence the spread of the epidemic and intensify its impact, pose exceptional challenges for both HIV treatment and prevention.
4. Since the discovery of combination anti-retroviral therapies (ART) in the late 1990s, most people requiring HIV treatment in developed countries are now able to access life-lengthening drugs. Thanks to an increase in international funding for AIDS since the turn of the century (the Global Fund to fight AIDS, TB and Malaria and the US PEPFAR programme have played a major role here), and a growing commitment from national governments of some of the most affected countries, around one third of people who need ART in low and middle income countries can now obtain it. Residents of developed countries whose conditions become resistant to first line drugs can switch to new regimens. Relatively few residents of developing countries currently have this opportunity, though it is encouraging to see countries such as India initiate efforts to provide second line treatments free of charge. To make progress on treatment, it will be vital to keep investing in the development of new drugs, and to ensure that they are affordable and available to all who require them. One of the principal challenges facing us today is not just to scale up access to HIV prevention, treatment, care and support, but to sustain it.
5. The most important cause of illness and death among people living with HIV, even among those on antiretroviral therapy, is tuberculosis. This interaction with HIV, combined with under-investment in health systems, inadequate research into new drugs and diagnostics, and complex socio-economic factors has reversed many of the gains made in TB control since the advent of effective treatment in the 1950s, resulting in the development and spread of drug resistant strains of TB and millions of avoidable deaths.

Issue 2: What reliable data exist regarding the numbers of people infected globally with the four diseases on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?

1. Data on HIV and AIDS is some of the most accurate and up-to-date for any health issue. There are more HIV epidemics than there are countries in the world, and tremendous differences in the ways they are evolving. Overall, HIV prevalence is stabilizing. The causes of its spread are multiple and complex: biological, social, and economic.

2. The “AIDS epidemic update” reports on the latest developments in the global AIDS epidemic and has been published annually since 1998. The 2007 edition provides the most recent estimates of the epidemic’s scope and human toll and explores new trends in the epidemic’s evolution. This is a joint UNAIDS and WHO report. It includes estimates produced by the UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance, based on methods and parameters that are informed by the UNAIDS Reference Group on HIV/AIDS Estimates, Modeling and Projections. These estimates are also based on work by country analysts in a series of 11 regional HIV estimates workshops conducted in 2007 by UNAIDS and WHO. The process and methodology used by UNAIDS and WHO were reviewed and endorsed by an International Consultation on AIDS Epidemiological Estimates convened jointly by the UNAIDS Secretariat and WHO on 14–15 November 2007 in Geneva.

3. According to the 2007 AIDS EpiUpdate, 33.2 million people were living with HIV in 2007. Every day, over 6,800 persons become infected with HIV and over 5,700 persons die from AIDS. Nonetheless, the current epidemiologic assessment is encouraging in that it indicates that the global prevalence of HIV infection (percentage of persons infected with HIV) remains steady, even though the global number of persons living with HIV is increasing. There are four reasons for this: (1) the ongoing accumulation of new infections with longer survival times, measured over a continuously growing general population; (2) localised reductions in prevalence in specific countries accompanied by changes in behaviour; (3) a reduction in HIV-associated deaths, partly attributable to the recent scaling up of treatment access; (4) a reduction in the number of annual new HIV infections globally. Examination of global and regional trends suggests the pandemic has formed two broad patterns: generalized epidemics sustained in the general populations of many sub-Saharan African countries, especially in the southern part of the continent; and epidemics in the rest of the world that are primarily concentrated among populations most at risk, such as men who have sex with men, injecting drug users, sex workers and their sexual partners.

4. The burden of tuberculosis occurring in people living with HIV and national responses to the interaction between the epidemics of TB and HIV have been reported annually since 2005 in the WHO Global Tuberculosis Report which collates data from around 200 countries and territories. Efforts are currently under way to collect additional global data on the impact of TB on people living with HIV through the UNGASS indicators and global reporting of HIV care and treatment.

Issue 3: What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? And what improvements might be made?

1. Detection of an outbreak of an asymptomatic blood borne infection like HIV is difficult if not impossible. The typically asymptomatic nature of HIV infection and the inability to screen contacts or individuals exposed to the virus, limits the potential to detect outbreaks.¹ It is therefore recommended that countries develop appropriate surveillance systems to track the behaviors that expose individuals to the risk of HIV transmission, as well as to track HIV prevalence in different populations. Many countries have adequate surveillance systems; in other countries these systems need to be improved or expanded. Important investments should be made in data collection and analysis, to guide prevention programming and to assess the impact of the AIDS response. Also, the importance of HIV/TB and the need to work closely with TB programmes to build lab networks/efforts to improve drug resistance surveillance for X/MDR among people living with HIV who are more likely to develop TB.

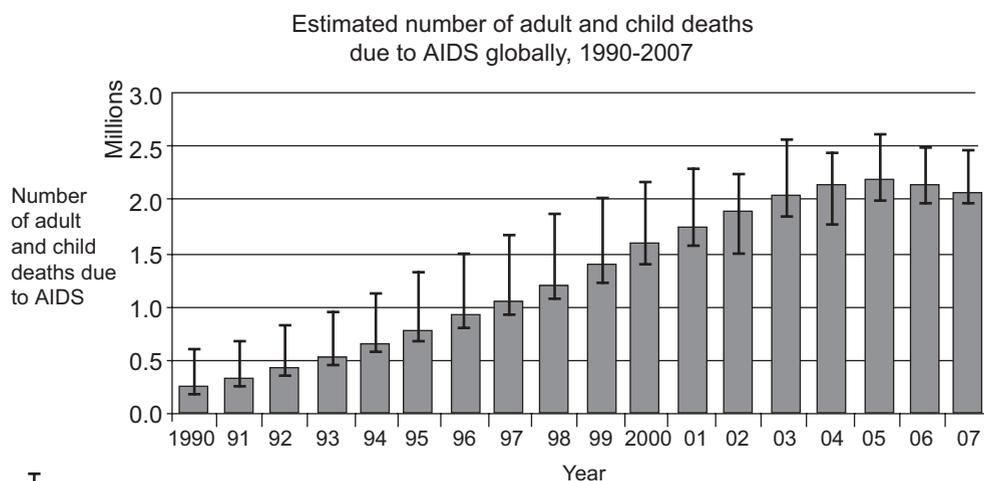
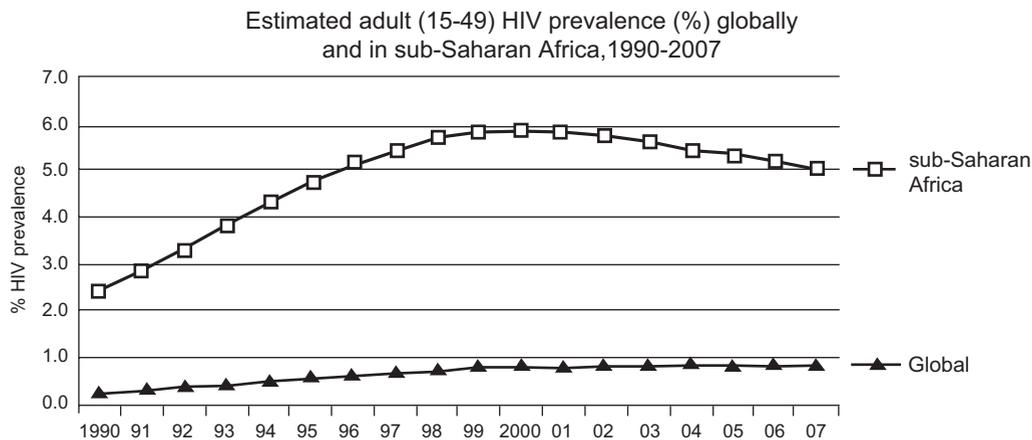
¹ Detection of such an outbreak would require large scale blood screening and regular (serial) blood tests for a selected population of individuals. Occasionally, outbreaks of blood borne pathogens can be detected in closed populations (prisons and hepatitis B or C), but usually these types of investigations require the presence of and detection of one symptomatic individual, confirmed through laboratory tests as an incident case, and then subsequent case findings through large scale contact tracing and screening programs.

Issue 4: *Given the continuance of current and planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years?*

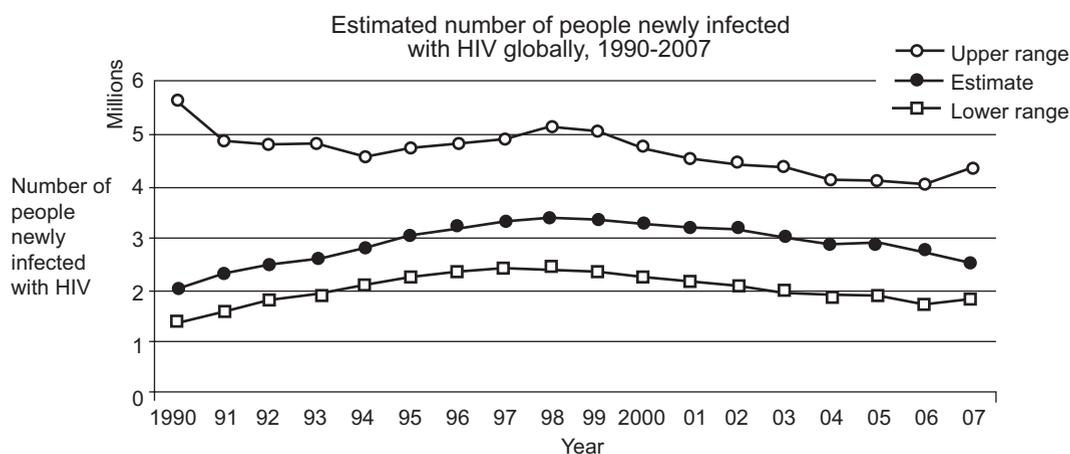
1. Global HIV prevalence—the percentage of the world’s adult population living with HIV—has been estimated to be level since 2001 (Figure 1). Downward trends in HIV prevalence are occurring in a number of countries, where prevention efforts aimed at reducing new HIV infections since 2000 and 2001 are showing results. In most of sub-Saharan Africa, national HIV prevalence has either stabilized or is showing signs of a decline (Figure 1). Cote d’Ivoire, Kenya and Zimbabwe have all seen declines in national prevalence, continuing earlier trends. In South-East Asia, the epidemics in Cambodia, Myanmar and Thailand all show declines in HIV prevalence. The estimated number of deaths due to AIDS in 2007 was 2.1 million (1.9–2.4 million) worldwide (Figure 2), of which 76% occurred in sub-Saharan Africa. Declines in the past two years are partly attributable to the scaling up of antiretroviral treatment services.

2. AIDS remains a leading cause of mortality worldwide and the primary cause of death in sub-Saharan Africa. HIV incidence (the number of new HIV infections in a population per year) is the key parameter that prevention efforts aim to reduce, since newly infected persons contribute to the total number of persons living with HIV; they will progress to disease and death over time; and are a potential source of further transmission. Global HIV incidence likely peaked in the late 1990s (Figure 3) at over three million new infections per year, and was estimated to be 2.5 million [1.8–4.1 million] new infections in 2007 of which over two thirds (68%) occurred in sub-Saharan Africa. This reduction in HIV incidence likely reflects natural trends in the epidemic as well as the result of prevention programmes resulting in behavioral change in different contexts.

3. The Future: It is difficult to predict the course of incident infections for the next 10 years, although a conservative assessment can be based on the 2007 estimate of 2.5 million (1.8–4.1 million) new infections per year. This could however evolve as a result of epidemic dynamics as well as be influenced by effective prevention responses. Mortality in the near future is expected to remain stable or even perhaps fall if there is success in increasing access to ART to the millions that need it.



⌋ This bar indicates the range around the estimate.



Issue 5: *What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?*

1. At the September 2005 World Summit, heads of state committed to a massive scaling up of HIV prevention, treatment and care by 2010, as a mid-way point towards achieving the Millennium Development Goals (MDGs). A UNAIDS-supported review of individual countries' progress on scaling up access identified six major challenges. The Joint Programme is working to address each of these, with a particular focus on providing technical support at country level:

- (a) **Setting national priorities:** Countries face difficulties in developing credible evidence-based and costed plans that reflect national priorities and local realities. This is partly due to lack of understanding of what is actually driving the epidemic and the absence of baseline data, in particular for most-at-risk populations. Moreover, current funding is often insufficiently targeted towards national priorities.
- (b) **Predictable, adequate and sustainable financing:** Funding for AIDS falls well short of what is needed—despite a remarkable increase from less than US\$500 million just over a decade ago to some US\$10 billion today. One third of that money currently comes from low and middle income countries a positive trend in terms of ensuring sustainability of financing. But they will not achieve this on their own—particularly in the short term. For example, given that for every one person who starts taking ART, another four become infected with HIV, providing treatment is going to remain an expensive challenge for years to come.
- (c) **Strengthening human resources and systems:** Lack of human resources and limited institutional capacity, partly due to internal and external migration and under-investment in health systems, seriously impede provision of HIV prevention, treatment, care and support services. This includes inadequate access to reproductive health services. Weak infrastructure also represents a serious bottleneck to effective use of the resources available.
- (d) **Affordable commodities:** The availability of affordable HIV-related commodities, for both prevention and treatment, is a critical issue. Current obstacles include the high price of HIV-related commodities, in particular for second and third line antiretroviral combinations and paediatric treatment; taxes and tariffs; weak forecasting, procurement and distribution systems; and delay in regulatory approval of new products.
- (e) **Stigma, discrimination, gender and human rights:** While stigma and discrimination, gender inequity, and human rights abuses continue to fuel the HIV epidemic, limited action is taken at the country level to address these issues. UNAIDS promotes and supports the development and enforcement of supportive laws and the protection of human rights—including the rights of women and children, people living with HIV and members of vulnerable groups. The empowerment of women and gender equality are essential to both men and women to protect themselves from becoming infected with HIV.

- (f) **Targets and accountability:** Strong monitoring and evaluation is a prerequisite to track progress (or lack thereof) and assure effective oversight and accountability. In many cases, monitoring, evaluation, and reporting capacity is poor, and mechanisms limited.
- (g) **Overall recommendations:**
- Support the development of prioritized, evidence-based, inclusive and sustainable multi-sectoral AIDS plans that “make the money work” and are aligned with national priorities;
 - Ensure sustained multi-year funding: develop and implement a long-term investment programme for AIDS;
 - Achieve cost reductions for HIV commodities—for example through greater flexibility within the World Trade Organisation TRIPS agreement;
 - Address structural factors (such as gender inequality) that influence the epidemic via concrete activities;
 - Enhance aid effectiveness through stronger adherence to Three Ones Principles and the recommendations of the Global Task Team on improving AIDS coordination among multilateral donors and international donors;
 - Invest in country-level monitoring and evaluation, support multi-stakeholder planning and evaluation “Partnership Forums” and encourage joint review mechanisms and act on their findings; and
 - Support closer integration of HIV services with other health programmes including sexual and reproductive health services, to strengthen health systems more widely.

Issue 6: What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organizations do you collaborate? How would you assess the degree of synergy?

1. The UNAIDS Cosponsors and Secretariat work on a wide range of cultural, health, social and economic issues related to HIV. The Joint Programme provides knowledge leadership, policy guidance and technical support, with a particular focus on strengthening national AIDS responses. Due to the links between HIV and tuberculosis, the UNAIDS family works closely with global partners in TB control to strengthen responses to the two epidemics.

2. UNAIDS works through regional structures and through Joint UN Teams on AIDS that are facilitated by Country Coordinators at country level. The Joint Programme is correctly configured but under-resourced to optimally support significant scale-up of responses to AIDS at country level. A Second Independent Evaluation of UNAIDS, to be concluded in 2009, aims to ensure that it is strategically and operationally placed to meet the needs of the community it serves.

3. The UNAIDS Secretariat coordinates efforts of ten Cosponsors based on their comparative advantages as defined in an institutionalized Division of Labour. It fosters the active involvement of civil society including organizations of people living with HIV, faith-based institutions and the private sector. UNAIDS also collaborates with major financial mechanisms, notably the Global Fund to Fight AIDS, TB and Malaria and foundations as the Gates Foundation. Ongoing efforts to better define roles and responsibilities (eg the renegotiation of the Memorandum of Understanding between UNAIDS and the Global Fund) will result in stronger synergies.

4. The joint and co-sponsored nature of UNAIDS has paved the way for heightened UN coordination in health issues beyond HIV and has often been cited in wider UN discussions as an example of UN reform in action.

Issue 7: What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is a sufficient “joined-up” thinking in approaching the problem?

1. The AIDS epidemic is, in part, a by-product of globalisation. The causes of its spread are multiple and complex. So is its impact. Intergovernmental intervention to address these causes and impacts is as important as support to more medical aspects of the epidemic. Action is taking place but there is an urgent need for more systematic and more consistent approaches, and for greater cohesion with health-sector responses.

2. Since the early stages of the epidemic, organizations such as ILO, UNDP, UNFPA; UNESCO, WHO and the World Bank (all now cosponsors of UNAIDS), have highlighted structural factors associated with the spread of HIV. Human rights abuses, income inequality and the low status of women were all identified as “drivers” of the epidemic. The implications for labour, productivity and employment, and for society as a whole, all provoked alarm.
3. It is now well documented, for example, that gender dynamics are particularly influential in the spread of HIV. For example, there is a powerful association between gender based violence and vulnerability to HIV. In South Africa, women with violent partners have been found to be 50% more likely to be HIV infected than other women².
4. People from marginalised or stigmatised populations, including sexual minorities, injection drug users, sex workers, prisoners, migrants, and refugees often struggle for human rights protection and may well find it harder to protect themselves from HIV infection and to access HIV services (including access to male and female condoms), when they need them. Stigma is a major issue for the entire population. Revealing an HIV diagnosis can lead to violence, ostracism and job loss for anyone, making it more difficult for people with HIV to access proper care and to engage consistently in behaviour less likely to put others at risk of infection.
5. In many countries, injecting drug users and sex workers are forced to live clandestinely without access to information and to health care, and may be unnecessarily sent to prisons. Imprisonment has been proved to be ineffective and counterproductive, as access to HIV and TB services are lower than elsewhere in the community, and the risks of infection higher.
6. Education is another important factor. HIV and sex education delivered through school curriculum-based programmes has proved highly effective in reducing sexual risk taking.³ But even simply keeping girls in school longer is now directly associated with lower risk of HIV infection in most of Eastern and Southern Africa, empowering girls and women in their sexual relationships and in escaping poverty⁴.
7. The multilateral system has played a key role in both understanding these complex and changing dynamics and in supporting countries and communities to respond effectively.
8. For example, in 2005, UNICEF, UNAIDS and partners launched “*Unite for Children, Unite against AIDS*” to put children (aged 0–18) more prominently on the global AIDS agenda. The ILO integrates AIDS issues in labour-related policies at all provides guidance for the provision of HIV prevention, treatment, care, and support through the workplace. Other initiatives include support for cash transfers to HIV-affected families. UNFPA supports programmes and youth peer networks (eg Y-PEER, AFRIYAN and others) which both influence programming and reach young people with HIV prevention information, skills and services.
9. There is broad recognition among the international community that poor planning inevitably results in a lack of priority setting and the ineffective use of available financing. Therefore, national HIV/AIDS strategies and action plans that are evidence-informed (addressing the key drivers of the epidemic), prioritised and costed are a prerequisite for successful implementation of national programmes. To support countries in enhancing their national AIDS strategies, UNAIDS set up the AIDS Strategy and Action Plan (ASAP) service in 2006 hosted by the World Bank. The ASAP service is demand-driven and provides a one-stop shop where countries can seek guidance and support to enhance their national AIDS strategies, to translate those strategies into action plans, and build capacity. ASAP has also developed tools that countries can use to promote coordination and harmonisation in strategic planning.
10. Alongside its analytical work on the associations between HIV and a wide range of structural issues⁵, UNDP has pioneered a methodology to examine the relationship between the potential impact of development policies on HIV, and the impact of AIDS on development outcomes.⁶ UNDP has also contributed to research into the links between urbanization, migration, HIV/AIDS and food security⁷ and is currently leading the UNAIDS effort to develop and promote new country-oriented guidance and action strategies on gender, sexual minorities and human rights. Since 2005, the Joint UNDP/UNAIDS/World Bank Programme on Building National Capacity to Integrate HIV in Poverty Reduction Strategy Processes has provided training to 25 countries to better understand the linkages between poverty and vulnerability to HIV infection.

² Dunkle & Jewkes, Lancet

³ c.f. Kirby D, Laris BA, and Rolled L., 2007; and ActionAid International, 2006

⁴ De Walque D. How does the impact of an HIV/AIDS information campaign vary with educational attainment? Evidence from rural Uganda: World Bank Development Research Group; 2006.

⁵ HIV and Migration in Asia Pacific, www.UNDP.org. The UNDP Regional Programme in Asia and the Pacific has recently formulated a programme on HIV and AIDS, Mobility and Human Trafficking.

⁶ UNDP Regional Service Centre, Johannesburg

⁷ Crush, J. et al. “Linking Migration, HIV/AIDS and Urban Food Security in Southern and Eastern Africa”, Regional Network on HIV/AIDS, Livelihoods and Food Security, International Food Policy Research Institute, Southern African Migration Project, June 2006.

11. UNESCO provides the secretariat for the UNAIDS Inter-Agency Task Team (IATT) on Education. Comprising UN agencies, bilateral donors⁸, private foundations and civil society partners, the IATT on Education's actions focus on furthering dialogue, understanding and commitment to the role of education in the HIV and AIDS response; generating and sharing research and experiences; and supporting coordination and partnerships for policy and programmatic action in the area of education and HIV. The UNFPA led IATT on Young People and AIDS will soon release seven Policy Briefs providing evidence-based guidance and operational tools for national partners and UN Country Teams, including specific strategies for interventions with young people delivered through a range of settings.

12. UNODC leads the UN's work on HIV prevention among injecting drug users and for prison settings. The main aim of this work is to improve the access to HIV/TB prevention care and support to injecting drug users, in prison settings and for people vulnerable to human trafficking. The lack of attention provided to these populations by States, the stigma attached to them, inappropriate legal frameworks, and the paucity of resources allocated at national levels mean that needs are still very high. The legal framework in most places in the world forces injecting drug users to live clandestinely without access to information and health care, and often does not allow for the provision of evidence-based means of prevention, such as opioid substitution therapies or needles and syringes. People using drugs and/or sex workers or women are often unnecessarily sent to prison, which has shown to be ineffective, counterproductive and where the access to HIV and TB prevention and care is even lower than in the community: prison management is often poor. In some countries where sexual relations with people of the same sex is criminalized there is no access to condoms, especially in male prisons.

13. UNFPA leads the UN's efforts in the area of HIV and sex work. It promotes a comprehensive, rights-based approach to address inequalities that can drive women into sex work, prevention of HIV in sex work settings, alternative economic opportunities, reduction of stigma and discrimination and strengthen realisation of human rights. As is the case with injecting drug users, programmes reaching sex workers and other marginalised populations are well below actual need.

14. UNAIDS provides a mechanism to coordinate work in these areas. The development of the Three Ones⁹ and the Global Task Team have recently helped strengthen that capacity. But we are still in the very early stages of developing an effective global approach to the structural factors that influence this particular epidemic.

Issue 9: Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions- eg HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?

1. WHO estimates that the global rate of new TB cases has peaked, and in most regions is beginning to fall, albeit too slowly. In Eastern Europe and Africa, case rates have stabilized after rapid increases over more than a decade, due principally to economic/social transition in the former Soviet Union, and due to the HIV epidemic in Africa. The WHO Stop TB Strategy reaches almost two-thirds of estimated global TB cases (compared with less than 10% a decade ago) and global treatment success is now near the target of 85%, so TB is largely curable even in the poorest settings. However, the interaction between TB and HIV, weak health systems and inadequate investment in new ways to diagnose, treat and prevent TB mean that there are still over 1.6 million deaths from TB each year and the threat of drug-resistant TB is rising.

2. The WHO Stop TB Strategy lays out the approaches proven to reach and cure more persons ill with TB, including people living with HIV. The Global Plan to Stop TB, 2006–15 sets out a plan and budget for what the world needs to do to achieve the Millennium Development Goals in 2015, specifically addressing the threats of HIV related TB and drug resistance. However, in 2008 alone there remains about a 50% gap in financing for TB control implementation of over US\$2 billion, for national control efforts and global technical assistance.

3. TB is among the most common causes of illness and death among people living with HIV, despite being preventable and curable. Up to 70% of TB patients are also infected with HIV in the African countries hardest hit by HIV infection. Many opportunities to provide integrated care are being missed because of poor collaboration between TB and HIV programmes. In 2005, only 7% of TB patients were tested for HIV and less than 0.5% of people living with HIV were screened for TB. Recent evidence in Southern Africa has shown

⁸ For the purpose of this request, current members include: Canadian International Development Agency (CIDA), Department for International Development (U.K.) (DFID), Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ), European Commission (EC), Irish Aid, Netherlands Ministry of Foreign Affairs, Norwegian Agency for Development Cooperation (Norad), and the Swedish International Development Cooperation Agency (SIDA). For a full list of IATT members, please visit: <http://www.unesco.org/aids/iatt>.

that the spread of extensively-drug resistant TB (XDR-TB) in hospitals serving as antiretroviral treatment sites can be highly lethal. Policies and field best practice models of integrated TB/HIV care are being applied but need faster scale up and high level commitment to scale up towards universal access to quality TB and HIV prevention, treatment and care. Joint efforts to improve infection control in communities and health facilities would benefit the response to both avian influenza and tuberculosis as they are transmitted in the same way.

4. UNAIDS is working closely with the Stop TB Partnership, WHO and other cosponsors to build joint action on TB and HIV in order to reduce the burden of TB among people living with HIV and accelerate towards universal access to comprehensive TB and HIV prevention, treatment and care.

5. Intergovernmental action is already making a profound difference through commitments, including by the UK Government, technical agencies, academics and civil society organizations, to the Global Plan to Stop TB, 2006–15. Partners are expanding coordination in support of national scale-up proven effective control policies, harmonise approaches and align them with national health sector plans and initiatives, ensure coordinated technical assistance that meets the demands of recipients, and to increase powerful surveillance and urgently needed research. However, awareness of the TB epidemic, its impact and its interaction with HIV is still sorely limited in donor nations and high TB burden countries alike and if raised could spur a much faster more integrated response and broader financial commitments.

Issue 12: To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental actions is taking place in this area?

1. There is no direct evidence that rising levels of drug-resistant TB have affected national or global trends in TB incidence. Nevertheless, overall control of TB, as well as public safety, is at great risk if drug-resistant TB is not prevented, quickly identified and contained. The terrible mortality, morbidity and economic consequences of cleaning up MDR TB should not be underestimated: in the 1980's and 90's New York City spent USD 1 billion on its micro epidemic which had been largely fueled by HIV. There is evidence that drug-resistant TB disproportionately affects people living with HIV, in terms of incidence and mortality rates. Global efforts are focusing on providing effective TB treatment to prevent the emergence and spread of drug-resistant strains; large-scale improvements in laboratory networks worldwide; introduction of new diagnostics and research; surveillance to monitor the emergence and trends of drug-resistant TB locally, regionally and globally; and to expand the treatment of drug-resistant TB. Scale-up of treatment for drug-resistant TB is far behind the estimated projections needed in the Global Plan to Stop TB to reach universal access to treatment for all those detected with drug-resistant TB by 2010.

Issue 14: Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?

1. The cost of anti-retroviral drugs in low and middle income countries is a major issue—particularly as resistance to first line treatment increases. The agreement on Trade related Aspects of Intellectual Property Rights (TRIPS) attempts to balance two objectives: creating incentives for innovation through patents and other measures on the one hand and spreading the benefits of innovation as widely as possible (such as maintaining a sustainable supply of essential medicines) on the other.

2. The debate around the scope and interpretation of the TRIPS flexibilities was settled by the Doha Declaration on the TRIPS Agreement and Public Health⁹ which affirmed that public health considerations can and should shape the extent to which patents on pharmaceuticals are enforced and that flexibilities in the TRIPS Agreement should be used to this end. This was re-enforced by the 30 August 2003 Agreement which allowed developing countries and LDCs with insufficient or no manufacturing capacity to import generic medicines produced under compulsory license. Although more countries have utilized TRIPS flexibilities in recent years, most developing -country WTO members are still in the process of amending their intellectual property legislation to make full use of these flexibilities.

3. However, the unsuccessful conclusion of recent WTO rounds has encouraged several countries to pursue trade liberalisation agendas at a bilateral level. This has resulted in a proliferation of bilateral trading agreements. Based on analysis conducted on some recently concluded bilateral trading agreements, countries appear to be committing themselves to obligations that extend significantly beyond those contained in the TRIPS Agreement and which may prove to be contrary to the objectives contained in the Doha Declaration.

⁹ The Declaration was adopted at the Fourth Session of the WTO Ministerial Conference in Doha, Qatar on 14 November 2001. See WTO document WT/MIN(01)/DEC/W/2.

This development has been noted with concern by several UN agencies and has been the subject of resolutions at the World Health Assembly¹⁰ of the WHO in recent years for instance.

4. Inter-governmental action has yielded some important benefits to date. For example, UNDP's HIV Group provides technical support to countries to analyse TRIPS flexibilities and WTO obligations in order to inform their strategies with regard to access to essential HIV drugs. The WHO's Commission on intellectual property rights, innovation and public health for instance has made important recommendations which are the subject of implementation through the inter-governmental working group on public health innovation and intellectual property. Continued co-operation between developed and developing countries especially regarding the transfer of technology as provided for in Article 66.2 of the TRIPS Agreement should be encouraged and strengthened by WTO member states as well as the relevant international organisations.

Issue 15: What interchange exists between States in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?

1. UNAIDS as a Joint Programme, and through the governance mechanisms of its individual Cosponsors, sets global standards and provides technical collaboration with member states at the global, regional and country levels for diagnosis and treatment and control of HIV. It works with partners at the global, regional and country levels for the diagnosis and treatment of HIV and dealing with outbreaks. While great progress has been made in establishing a global framework for detecting and responding to HIV, increased intergovernmental collaboration and cooperation are needed at the regional and country levels to strengthen surveillance and disease control activities. In the past, the UK seconded experts from academic and public health institutions which greatly helped improve national responses to the different diseases. It is recommended that this continue.

Issue 16: The International Health Regulations 2005 are intended to provide a global framework for the rapid identification and containment of public health emergencies. How effective do you consider this response system to be? Do improvements need to be made?

1. The Regulations make no reference to HIV, which does not fit the criteria for a notifiable public health threat. However, recent experiences with the identified international air travel of passengers with multi-drug resistant TB suggests that the systems that need to be supported to enable countries to fully comply and participate in the aims of the IHR are rudimentary and need committed investments and significant human resources.

21 January 2008

Examination of Witnesses

Witness: MR ELHADJ AMADOU SY, Director of Partnerships and External Relations, UNAIDS, examined via video-link.

Q367 Chairman: Good afternoon, Mr Sy. Can I first of all thank you very much for coming to talk to us. Can I also tell you that the event this afternoon is being recorded and you will have an opportunity to see the transcript of the evidence and make any corrections you think are necessary. We would also like you to feel free to write to the Clerk with any more information after the hearing this afternoon if you think there is anything we have left out or not covered that we should have done. If you are happy with that, I will proceed.

Mr Sy: Yes, thank you.

Q368 Chairman: I would like to start by asking about UNAIDS. My understanding is that this was formed in part because there was fragmentation in

the approach to AIDS, and what we would like to know is whether you think this is the right route to go down in terms of dealing with this specific disease, because it is really very targeted in this way. Is this the best structure? Perhaps in answering that you can touch on the governmental structure of UNAIDS and how effectively that works.

Mr Sy: First of all, thank you for giving us the opportunity to talk with this Committee on behalf of UNAIDS and its Executive Director. We are doing so on behalf of all the Co-sponsoring agencies, but also I may take this opportunity to stress the specific view from the Secretariat of the Joint and Cosponsored Programme. With regard to your question, we believe that AIDS is a multi-dimensional problem which calls for a multi-sectoral

¹⁰ For instance, Resolution WHA57.14 of 22 May 2004 urged Member States to "encourage that bilateral trade agreements take into account the flexibilities contained in the WTO TRIPS Agreement and recognized by the Doha Ministerial Declaration . . ."

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response. We know very well about the health dimension and the health components of HIV, but there are so many other societal and development-related issues that need to be addressed at the same time. What sometimes appears to be like a fragmentation of the response, is what we call a multi-sectoral response to the epidemic. We call on different UN agencies ranging from WHO for the health part to UNDP for the development aspects, down to sector-specific responses such as the one being implemented by UNESCO. ≥ We recognise that we need different entry points to the problem in order to make an impact. We have to promote a broad base: a multi-sectoral response. As far as UNAIDS is concerned we believe that it was a very innovative idea to have a programme such as UNAIDS and we still believe so after ten years. With the results which I hope we can talk about later on in the discussion, it remains the best structure and the best approach both for a coordinated response and to minimise transaction costs at country level for partners.

Q369 Chairman: We have not used this approach to other specific diseases, have we? Do you think it is one that should be used for other specific diseases? Or do you think that AIDS is of a special type?

Mr Sy: We do believe that HIV/AIDS has revealed many socio-economic dysfunctionalities, more than any other disease before. If you look at the different aspects of the response, the amount and the volume of activities that happen outside of the health sector will show how different it is from other diseases. For example, the issue relating to stigma and discrimination—of course, we may find that with some diseases, but the magnitude of it as far as AIDS is concerned is quite unique. There are aspects relating to human rights and gender and gender-based violence are critical; because of the very nature of the epidemic, it is a gender issue par excellence that we would not find in many other diseases. What we have also found is that the way it impacts on the health system is quite unique. If we are in a country, for example, where 33 per cent of the adult population is HIV-positive and between 50 and 70 per cent of all the patients in infectious disease wards have some kind of HIV-related conditions and illnesses, then addressing that particular disease from the health point of view as well as from a societal and economic point of view would be alleviating the impact not only on the health sector but would also have a major impact in terms of even how societies will be kept together; how some of the enterprises will continue to function given the fact that it is the people in the prime of their lives who are becoming HIV-positive; how families can be kept together, given the fact that it is those who are the most productive in society and who should be taking care of the

education of children most affected by AIDS. If we look at this further in the way governments' organise themselves and implement their sectoral approach as well as the development policies, we see the uniqueness of this epidemic that really makes it so different from any other disease we have seen so far, even though we can find many similarities with some of the major infectious diseases such as tuberculosis and malaria, in Africa in particular.

Q370 Lord Geddes: Good afternoon, Mr Sy. In the UNAIDS evidence in Issue 6, Paragraph 4, it says that the structure of UNAIDS "has often been cited . . . as an example of UN reform in action". As I understand it, UNAIDS is not only a vertical programme focusing on the fight against AIDS but also a horizontal programme bringing in a number of other interests, not least development, education, sexual health, et cetera. What puzzles me—and I think puzzles a number of the members of this Committee—is how does all that activity mesh with that of the World Health Organisation, which is the main intergovernmental health body? What is WHO's attitude to you? Does it work well? Are there pluses? Are there minuses?

Mr Sy: We recognise that HIV/AIDS is a health problem and, because of that, WHO has a very important role to play. Our relationship with WHO is strong and healthy for many reasons. Number one, UNAIDS is administered and managed by WHO both because in the nature of the work as well as our geographic proximity here in Geneva. Number two, whatever WHO is doing in relation to HIV/AIDS does not only concern the WHO response to AIDS but it also constitutes the whole UNAIDS response to AIDS as far as the health sector is concerned. When we brought partners together, we agreed on a Division of Labour where each of the Cosponsoring agencies will take a lead role based on their comparative advantage. The biomedical aspect of AIDS issues related to the health system, training and retaining of healthcare workers, these are all WHO-led activities. They lead in these areas not only for their own sake but for the whole UN systems. When we talk about UNAIDS' work on HIV/AIDS and health, what we do is to describe WHO work on that. It is a very healthy relationship that will allow a number of things: better coordination, avoiding the duplication of efforts, and recognising also the lead agencies; and this applies also in the way we structure our programmes as well as the way we use our own resources. We are the only UN programme with what we call a Unified Budget and Workplan where, at the beginning of a biennium we work together with the ten Cosponsoring agencies and agree on what needs to be done to make a difference in the response to AIDS. Based on that agreement we give tasks and leadership to each of the agencies as well as resources

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to do. So the resources are mobilised and a big chunk of what we get from the partners goes to WHO for its HIV/AIDS work within the health sector. If we look at it more broadly, as I said a little bit earlier on, alleviating the impact of AIDS on the health sector is already a contribution to better health but at the same time providing an opportunity for others to look at the broad-based response that each of Cosponsors will lead either from a particular sector or from a societal or development point of view or from a human rights point of view that will allow an enabling environment for a response. We feel there is a false dichotomy between a horizontal or a vertical programme. We are horizontal in the fact that we do contribute to strengthening health systems but also we are very specific in addressing issues that are very important to the response which, as I said before, will range from gender to human rights to socio-economic impact and alleviation of the AIDS epidemic, taking care of orphans and vulnerable children et cetera.

Q371 Lord Geddes: Is there any danger of duplication between what UNAIDS does and what the WHO does?

Mr Sy: What UNAIDS does in the health sector is done by WHO. If I had to describe UNAIDS work in health and AIDS, then I would call on WHO to do that because they are the lead agency in that area and they are the guardians of that particular area of responsibility. They also get resources from UNAIDS and account for it both in terms of money as well as in terms of results. In addition to that we have what we call the Committee of Cosponsoring Agencies, which brings together the Heads of all ten Cosponsoring agencies of UNAIDS to design the programme, monitor its implementation and evaluate the impact. It is an additional platform where complementary activities and better coordination will be discussed to avoid duplication.

Q372 Lord Avebury: In your evidence and in your two replies so far you have described how the ten co-sponsoring agencies each undertake work within their own fields and that you exercise this coordinating role, as you have described it. Who decides the overall budget which applies to all ten co-sponsoring agencies? Or are they each determining the amount of money which they spend on this work on their own initiative and separate from all the others?

Mr Sy: They have to decide how much money the ten Cosponsoring agencies get?

Q373 Lord Avebury: You exercise a coordinating role, you say.

Mr Sy: Yes.

Q374 Lord Avebury: Does that coordinating role extend to advising on the budget for the whole of the AIDS effort devoted by the ten co-sponsoring agencies? Or are each of them responsible for their own budgets and they do not present you with the sum?

Mr Sy: In order to be a Cosponsor of UNAIDS each of the agencies has to have a certain number of requirements in place. Number one, they should each have a dedicated team working on HIV/AIDS; they should each have a dedicated budget from their own resources and work plan on HIV/AIDS. This is the first basis to come together around the table to discuss what needs to be done, what each of the UN agencies are investing from their own resources. Then we evaluate, based on the programme that we want to deliver together with what the gaps are. In the last biennium what we realised was that issues such as strengthening health systems, looking at the biomedical aspects of HIV/AIDS, investing more in monitoring the epidemic in the way that it is going, investing together with our partners at country level on what we call “know your epidemic” and then act on it were priorities, and we allocated a big chunk of the resources. The number one Cosponsor which received most of the resources was WHO and it represented a significant percentage of the overall investment that we made; and if we compare this with all the other Cosponsors, they are getting more than double of each of the other Cosponsors that you could compare with. We look at the next priority, such as under the heading “creating an enabling environment for the AIDS response,” and the issues that relate to that are human rights, to gender as well as governance of the AIDS response. Then we discuss with UNDP, look at the whole contribution and then make an additional contribution to fill the gap. Then there were the three areas in order of priority: UNDP looking at the socio-economic impact and then the mainstreaming of HIV/AIDS into development programmes; the next one was UNICEF for prevention of mother-to-child transmission and orphans and vulnerable children; UNFPA came next, and then the smaller investments were made with organisations like the World Food Programme, UNESCO and UNHCR. Given the specifics of their activities and with regard also to the amount of resources that they were investing in the AIDS programme, to get the final agreement of all of that, we put in place a peer review mechanism where each of the Cosponsoring agencies will be presenting to the group what their priorities are, what is the amount of resources they put in themselves and what the gaps are. Then we compare that within the overall strategic plan for the UN system and agree the

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partition of the resources that we are getting from our Unified Budget and Workplan.

Chairman: That sounds a very complex organisation you have there and quite difficult for you.

Q375 Lord Hannay of Chiswick: I would like to ask you a little bit further about the comment in your evidence that this is an example of UN reform in action. I still find it a little hard to see what the extremely complex arrangements you have just described are. They look slightly more like making the best of a very complicated situation but not something that should be replicated anywhere else. If it was UN reform in action, then one would expect it to be done in a lot of other places, but I think that would probably be—from your own initial answer—not the right thing to do. I wonder if you could just say a little bit more about that. Do you not think that some of the donors find this situation extremely complicated to deal with and not very easy to handle?

Mr Sy: I think we have taken the complexity on ourselves so that countries do not have to deal with it. The whole effort that we are putting in designing the Joint and Cosponsored Programme relies upon a Unified Budget and Workplan, this will result at a country level in simplification and the establishment of one single entry point for a Joint UN team on AIDS for partners at country level. That is the reason why we are saying that UNAIDS is UN reform in action, because instead of having to deal at country level with ten Cosponsoring agencies and the Secretariat, what we have is a Joint UN team on AIDS that is working alongside a number of principles. The number one principle is the principle of harmonisation and simplification for AID effectiveness that is derived from the Paris Declaration. The other one is the principle of delivering as one at a country level. It is a very simple translation at a country level, through a Joint team with one UNAIDS Country Coordinator that is interfacing with all of the partners and calling on the different Cosponsors based on an agreed Unified Budget and Workplan with a division of labour to deliver the programme which is a Joint Co-sponsored programme. Before UN reform was put in motion it was the only programme in the United Nations that could really demonstrate that they were delivering as one at a country level. When the UN country pilots were put in place—I think we have about eight countries where it is being implemented—the preliminary results have shown that it is possible to deliver as one. The example of UNAIDS in countries turned out to be one very specific way of doing it and the feedback that we are receiving also from the partners at a country level is that it has reduced tremendously the transaction costs because instead of dealing with ten they are dealing with one. They know also that there is already a plan, which is not a

UN plan for countries but a UN plan to support a country response that we discussed and agreed on with partners. More importantly, since the creation of the Global Fund, it has also proven itself to be extremely effective because it provides a platform to negotiate a strategic plan for the country that the Global Fund can use also to channel its finances so that it complements all the other efforts.

Chairman: That is a very important area, but we do need to move on. If you get any more thoughts about this I think we would quite like to hear them. It is a very different sort of organisation for one disease. I appreciate you have marked it up as a very different type of disease requiring a different structure, but it does raise this interesting question—if it is a reform of the UN structures, why does it not apply to some of the others? If you have any more thoughts on that, we would like to hear them in due course

Q376 Lord Desai: I would like to ask, first a question about the co-sponsors that you have been describing. You say in your evidence at Issue 7, Paragraphs 10-13 that “there is an urgent need for more systematic and more consistent approaches and for greater cohesion with health-sector responses”. Could you elaborate on this because, in a sense, obviously what you have got is good but you feel it should be better somehow?

Mr Sy: We have realised that there are a number of activities, both in terms of prevention as well as treatment, and treatment is the most obvious part that should be better integrated with the health system. For prevention, let me just mention one which is the most obvious, that is the prevention of mother-to-child transmission that can be better integrated into maternal and child health programmes which already exist. Because of the huge stigma that used to be related to HIV/AIDS and the very little access to testing for women, it was quite a good approach at the beginning, to develop access to voluntary testing and counselling for mothers. Once you get a critical mass now it is really imperative that we get into better integration and we are working together with partners to achieve that. Treatment is thus the most obvious part. Antiretroviral drug have made a lot of difference in the response to AIDS but they have also revealed a lot of weaknesses in the health system in terms of poor diagnosis, in terms of laboratory equipment and testing, in terms of capacity for the health personnel. What HIV also did indirectly, beyond revealing those weaknesses, was to contribute to strengthening our laboratory systems, strengthening our diagnosis and providing big opportunities for training and capacity building for healthcare workers at a different levels. The treatment component will be more and more integrated in both central as well as peripheral health structures, so that integration and coordination is

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really necessary and we are working together with WHO to further strengthen it while maintaining the other aspects of the work that cannot be dealt with within the healthcare setting.

Q377 Lord Desai: You mentioned the Global Fund a while ago and there is also the Gates Foundation in your Memorandum of Understanding with the Global Fund. Is there a need for some further root-and-branch rationalisation of all the various efforts which are being devoted to stop the spread of HIV/AIDS? Do you feel that there are problems with rationalising—things that stand in the way of rationalising—and how would you bring about the coordination of the Global Fund, the Gates Foundation and UNAIDS?

Mr Sy: I am very pleased to report to this Committee that the relationship with the Global Fund is a very good and very beneficial one for partners at country level. I would like just to highlight a number of key elements to illustrate that. We have seen that countries which have benefited from the support of UNAIDS in the design of their proposals of the Global Fund, their success rate for getting a grant increased substantially from 40 per cent—which used to be the success rate of proposals submitted to the Global Fund—and those who benefited from the support of the UN reached a rate up to 70 to 75 per cent which was a good indicator that the collaboration works well if we work where we should and partner together at a country level. When the Global Fund gives grants to countries they apply what they call a performance-based funding which is mainly based on two main issues, one is monitoring and evaluation and the other is quantifiable results within a timeframe. UNAIDS has deployed 65 Monitoring and Evaluation Officers at country level and the majority of their work centres around supporting countries, implementing their Global Fund grant. Thirdly, all ten Co-sponsors, based on their comparative advantage, have provided countries with technical support for great advances of their grant implementation. Those range from training by WHO, to procurement in management systems by the World Bank and UNICEF, to setting up the country coordinating mechanism through governance, through UNDP and the UNAIDS Secretariat and supporting the overall management of the grant and the accounting for it. What we tried to do in the Memorandum of Understanding was to capture the principles of the collaboration and to look also at the different areas of collaboration, which is the strategic, direction and advice we are providing to the Global Fund the technical support to make current grants successful and then monitoring and evaluation. Those areas have been agreed upon and the Global Fund has fully endorsed it. The Memorandum of Understanding will be

finally approved by our board in April and the Global Fund Board in October and will provide a good basis to further strengthen our partnership for the benefit of countries.

Q378 Lord Howarth of Newport: Turning to the governance of UNAIDS, you said just now that coordination was the number one requirement in this field. UNAIDS has a Programme Coordinating Board which, I understand, contains representatives of 22 governments across the world, UNAIDS co-sponsors who also have their own committee and I think five NGOs. This would appear at first glance to be a fairly top heavy Programme Coordinating Board and difficult to manage. Do they manage you? Or do you coordinate them? Is this board an arena in which the coordination that is so badly needed is actually achieved? Or is it an arena in which the different organisations appear, pay lip service to coordination but then go away and continue to do the same things as they were doing before? Or is it, worse, an arena in which they bicker and defend their own interests?

Mr Sy: The configuration of the Programme Coordinating Board of UNAIDS is a very innovative set up in the sense that it provides an opportunity for both so-called recipient countries as well as donor countries to come together and discuss sometimes very difficult issues and provide the Secretariat and Cosponsors guidance. It is extremely useful because beyond the fact of the governance aspect, it is a policy forum that allows our different partners to discuss extremely complex and extremely difficult issues where different perspectives are needed. This kind of agreement at that level will allow us to get very clear guidance from a broad base of partners and then actually take on the implementation of programmes at regional and at country level. It is a very innovative, very effective board. We have seen the recent development in the international health architecture, they get inspiration pretty much from the Programme Coordinating Board. The Global Fund has almost copied the Programme Coordinating Board of UNAIDS because they think it is a very good thing for a public/private partnership, moving programmes forward. Given the fact that we have different partners on the board that will balance the view and the perspective and we are not under pressure of one single constituency or one single group, be it a group of recipients or a group of donors. So it provides a kind of balanced view that allows us to implement programmes in the most effective way. The only challenge we face is that quite often we find the same countries and the same actors in different boards of the UN system, including even in the board of the Global Fund Providing inconsistent messages. Greater consistency in the message and in the position would be quite useful. In

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some instances, unfortunately, we may find ourselves with members of the board providing guidance in a certain direction at the Programme Coordinating Board of UNAIDS and take a different view at the Board of UNDP and the Board of the Global Fund, because sometimes they are different people either coming from health and the others coming from the Ministry of Foreign Affairs, and the coordination is not always very well established. That is the only constraint that we face and, whenever we interact with Board members, we call on them and plead for that consistency and to constantly support us. Apart from that, we think the way the board is structured and the different views it provides will give us quite a well-balanced platform to operate on.

Q379 Lord Howarth of Newport: As you describe it, it sounds an attractive and valuable model, but there are difficulties in achieving strategic follow-through throughout the system. Can I ask you to comment on what was said in a recent report by the United Kingdom's Department for International Development? They said, "UNAIDS's ability to create change is dependent on the willingness and capacity of its co-sponsors, leaving them little room for manoeuvre". Then they went on to say that "current governance mechanisms do not enable UNAIDS to effectively demand accountability from their co-sponsors". What are your reactions to that?

Mr Sy: As I said earlier on, in order to be a Cosponsor of UNAIDS each of the agencies will have to present their own plan, including its own resources that are coming from its own budget before they access the Unified Budget and Workplan that it gets through UNAIDS. What I can say is that every cent that a Cosponsor gets from the Unified Budget and Workplan is accounted for and there is a very strong accountability mechanism. Every year there is a target for an objective that is agreed upon within the Unified Budget and Workplan and is very closely monitored, and only when that target is reached and the first disbursement has been accounted for, then UNAIDS make a second disbursement to the Cosponsor. Where I think the accountability is suffering a little bit is in the investment of the Cosponsors which the UNAIDS Secretariat does not have control over; and if we call, as is in the report, for a stronger accountability mechanism in that the good model that we have within the Unified Budget and Workplan should also reach into the use of the other resources that Cosponsors are investing themselves. There we are in a discussion with the agencies to make sure that it falls within the same framework and the discussion is also going on in our board to strengthen this accountability so that we do not have two measures and then two lines within the Joint Programme, but the one that seems to work

best should be the model that will be including also resources invested by the Cosponsors.

Q380 Lord Howarth of Newport: Are you optimistic that the accountability, the coordination and the follow-through is going to improve?

Mr Sy: Indeed we are optimistic. We are not there yet but I really believe that with the support of the Board and the commitment that the Heads of Agencies will take, consequently to that we may actually win because since what we call the Global Task Team recommendations on coordination a lot of improvements have been achieved, and this should be the extra mile to go and we are quite confident that we will get there. We also have another opportunity really to further explore that and come up with concrete recommendations. We are planning now what we call the Second Evaluation of UNAIDS, and it is looking particularly at the governance aspects and accountability mechanisms between the Secretariat and the Cosponsors. I am quite confident that it will result in recommendations that will have to be enforced for the implementation of the programme.

Q381 Chairman: Before I call in Baroness Eccles, there is a point you might want to give some more thought to. If this governance structure is so good for UNAIDS, why is AIDS so fundamentally different to other diseases that we would not use a similar structure there? One of the things we are constantly told is that this whole area needs more rationalisation within it and you are describing a particular system which you say works well for AIDS. Why would it not work well for Malaria or TB and so on? If you have any thoughts on that, I would like to hear them, because you are actually advertising this model of governance as being a good one and we are being told that there is a need for rationalisation across the board in the way we deal with communicable diseases within intergovernmental organisations.

Mr Sy: I would just re-enforce the point that it is being copied by the Global Fund because it works for Tuberculosis and Malaria and it is a governance structure that the Global Fund also uses, but not exactly. They went a little bit further than we did because they have introduced the private sector in addition to NGOs and representatives of people living with HIV. It really turns out to be the best way to agree on a policy and strategic direction that will also minimise the differences at a country level. For the other communicable diseases, it may be much simpler. The technical intervention and the different things needed to have the environment ready, the training ready, do the procurement and then provide those treatments, and in most of the cases you can treat those conditions. There are many statistics that we can quote, but the most stunning one is that until

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today the vast majority of people living with HIV do not know that they are HIV-positive. Why do they not know? They do not know because in many parts of the world they have absolutely no incentive to know. If you know, then you will lose your job; if you know, you will be kicked out of your home; if you know, then your whole family will be stigmatised against; if you know, you pay sometimes with your own life. We have seen this in many parts of the world, including Southern Africa. When people want to know in most of these instances, either you have barriers like simple infrastructure for testing and diagnosis that are really lacking. Sometimes also, if people want to know, there are all the social barriers that you have to deal with. We are now seeing the specifics of this disease in comparison with the others, with the arrival of the Global Fund and clear funding from bilateral partners, we have excellent testing facilities and we have good treatment centres with laboratories and everything, and in some cases there are fewer patients turning up than were expected. So we have to look at all the other factors and the more advances we make the more we discover how complex the situation is and that is the reason why we are trying to develop this complex answer to this very complex problem. Parts of it are very simple, but as soon as we get into the prevention areas and to the social factors over which the individual do not have any control, that may impact on the epidemic. That is where the complexity is and we need to bring all the partners together to devise what the most effective strategy.

Q382 Baroness Eccles of Moulton: Mr Sy, can I start off by congratulating you on your first-class clear and excellent English, which has made it very easy for us to continue this discussion. I would also say that you have partly answered the questions I was going to pursue by your description of yet another complexity which of course is the psychological aspect of the disease. What I was really wanting to discuss with you was the question of the variety of infrastructure that is provided in the different countries where AIDS is prevalent and how this affects so much the delivery—whether it is through diagnosis through the laboratories, prevention and actual treatment. We have received evidence which does tell us that the infrastructures are very variable. In some cases the horizontal provision—to use that term—is really quite good, but in many areas it is really very weak; and I think you referred to this in your evidence to us, and that you cannot provide the diagnosis and the treatment and even the prevention unless you have actually got the infrastructure in place. A lot of it is obviously equipment but even more so it is people. The other aspect of this which is clearly a problem is that the initial funding sources and roots down to the local level vary again because there can be obstacles

from the country level, down through the regional level, right to the local level, where it is more difficult to filter through. I wondered what sort of solutions UNAIDS perhaps had to some of these problems.

Mr Sy: AIDS has revealed many of those problems without necessarily causing them. The weak health infrastructure in most of the developing world has been there long before HIV but, when this already weak infrastructure has to deal with an epidemic of this magnitude, it is being revealed at a higher level. It is important to note also that we have learned that as far back in 1997, when UNAIDS was established, the very first question was how is it going to be possible to implement a good AIDS response within the health sector in a poor setting. At that time the first thing the programme did was to establish the sites in Côte d'Ivoire in Uganda, in Vietnam and in Chile to study, over a period of time, how within a poor setting can a response to AIDS be developed and also what would be the other activities in and around the health sector that are needed to accompany that response. Three years later, around the year 2000, we came up with very strong evidence that it is possible, through a number of activities, to come up with a very good health response. Those ranged from the treatment of opportune infection, because we saw that tuberculosis was rising and it was due to the co-infection of HIV and TB. We also learned that the treatment of sexually-transmitted infection and that early diagnosis and treatment were also contributing to a good response to HIV. We also learned at that time that, when basic service was being provided in the poor setting, it was giving incentive for people to go for testing. We also learned that what we considered at that time to be a very highly specialised skill could be managed also by healthcare workers, not only in university hospitals but also at the district level. That is where the first port of calls for treatment now come in. These strategies will continue to be scaled, up and now with what we call the healthcare work alliance we will be strengthening the capacities of healthcare workers at the district level and also at the level of the hospitals and the level of even the periphery, to scale up all those activities. I think that what we can say with great confidence is that we have learned from this epidemic what can be done in those settings which is not necessarily what we could find in a developed country setting. The challenge we face is how to scale them up in a large number of countries or even within the countries to reach out to more regions. The only way I hope we can do it now is through partnership with initiatives like the Global Fund, which is now providing more resources to countries to scale up those interventions, and bilateral programmes such as the US President Initiative and the other European bilateral development programmes as well as the ones that they are working together on with the EC.

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So scaling up geographically, scaling up in terms of the variety of the intervention and investing in the basic infrastructure, these are the combined strategies to address those challenges.

Q383 Lord Avebury: We have been talking already about the balance of resources between prevention and treatment. I want to put a question to you, assuming that I am Mr Warren Buffett and I have a hundred million dollars to spend. I come to you and I say, “If I spend this money on treatment, I will get a certain result through the provision of ARVs and so on; or I could spend the money on prevention” (for example, on Page 7 you recommend addressing structural factors that influence HIV/AIDS, such as gender equality, and on Page 8 you say that keeping girls in school for an extra year is effective in reducing the risk of HIV infection). So I have this hundred million dollars and I come to you and say, “Where shall I put it—in ARV or in keeping girls at school for an extra year?” What would your reply be?

Mr Sy: The best illustration to show that there is no dichotomy between treatment and prevention is the prevention of mother-to-child transmission, where you treat and by treating the result is that you prevent the transmission of the infection from a mother to a child. We have also learned that, when we strengthen care activities, prevention works better. As I have said before, people will not develop health-seeking behaviour which is pretty much related to the kind of prevention we want to see if, on the other hand, the incentives are not in place, that you go for testing and after that there is an opportunity to get treatment. If we do not have treatment, we will not have the involvement of people living with HIV in prevention. Evidence has also shown that the best agents of change and the best people who could also deliver the messages that can trigger behaviour change, who can talk to young people, are those who are experiencing the virus in their own bodies and are living that experience. However, in order to recruit a critical mass of those agents of change, the only way we can achieve that is through treatment on the one hand and then fighting stigma and discrimination, so that they can be part of the solution and not the problem, as they put it themselves. We have also learned that, for every person that we are putting on treatment, we are having three or four new infections in some settings, and this is unacceptable. If we do not get the balance right, then I think we will continue increasing the number of people needing treatment while continuing to try to treat the ones we know today, and in the long run the facilities will not be able to cope. I think all those lessons, both from the treatment side as well as from the prevention side, conclude in one direction, that we do not have to make the tough choices between either/or. We definitely need both to make a difference. The only

thing I would like to mention there is that we have also learned that we have to develop some differentiated approaches in our prevention programme because we do not have the same epidemic everywhere in the world. In countries like the ones we find in Southern Africa we have a generalised epidemic and we need a more generalised approach. In more and more countries like Eastern Europe, Latin America and the Caribbean, part of Asia and then in Western Europe the epidemic is now more concentrated among certain groups, groups of men having sex with men or groups of sex workers or groups of drug users. Beyond the common good of prevention and raising awareness for change, there is a need for very direct intervention, depending on the profile of the epidemic. That is the reason why now prevention is developed along the model that you know what your epidemic and then you act on that. We all agree that we need to continue to strengthen our efforts for prevention while maintaining our achievements for care because the two go together.

Lord Avebury: I appreciate that this is not an either/or, but I still think that donors need to have some feel for where the marginal extra dollar is going and whether or not it is better to pump money into, say, ARVs or, in the case of Southern Africa, since you differentiate between the various regions, where we know that keeping girl children in school for an extra year is going to have an effect because you have quoted studies that show that. I still think that, from the point of view of donors, you have to come up with an answer. You cannot just say it is not an either/or; you have to measure the effects of the marginal extra dollar spent on prevention as compared with treatment.

Chairman: I think underlying this question there is another one in the sense of who evaluates the quality of the work or the effect of the work that you are doing, the evaluation process. Again, it is a bigger question which you may not be able to cover now, but there is a question here which I think Lord Avebury is touching on about who evaluates and how that evaluation process is done, and how you then reach a balance. We are a bit pushed for time, but if that is something you could let us know about I would be grateful.

Q384 Baroness Whitaker: Moving on to intellectual property rights, you say in your evidence, rather diplomatically, that continued cooperation, especially regarding the transfer of technology, should be encouraged and strengthened by WTO member States and the IGOs. I wonder if you can say a little bit more about what you would like to see and which are the international governmental organisations that should take action and what should be done?

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Mr Sy: Access to medication, to drugs and to diagnosis is really critical for the response to HIV. On the other hand, we know that development of drugs and vaccines is very long and it is very expensive. There should be an incentive for research and development and then the challenge is how we balance the two—maintaining the interest and incentive for research and development and at the same time advocating for a wider access to treatment that may lead into negotiating prices downwards as well as protection of patents. Then there are all the possibilities that the international agreement provides under the Trade Related International Property Rights (the TRIPS). We work together with a number of partners, including WTO, the World Health Organisation, UNDP (the lead agency) to support countries, particularly developing countries, first of all to understand what the issues are because the capacity around intellectual property rights is relatively limited in many countries and then to build up capacity and support them in their negotiations with the partners, and by so doing make sure that also the two parts are preserved somehow. What we have learned in developing countries is that quite often unfortunately the Trade Ministry does not necessarily know what the Health Ministry is negotiating in terms of the pharmaceutical sector and access to drugs, and then the negotiation on trade is put in a much broader umbrella where drugs and wine are together and we do not have to differentiate it afterwards to see how we can affirm public health. We also know that no least developed country has to be TRIPS compliant until July 2013 and LDCs—do not have to grant any pharmaceutical patent until 2016 thanks to the Doha Declaration. Given that environment which is now provided by the international agreement, how can we facilitate partnerships within the key actors so that we keep incentives for further research and further development and return of investment, which is really critical if you want to ensure that public health will be guaranteed, and at the same help in negotiating greater access. What we see is that the drugs are developed in countries which do not share or carry the biggest burden of disease. Then the market should be the less developed countries. There you cannot have economies of scale if the price is extremely high. The way to go here is to support countries in negotiating differential pricing because we have seen that in some countries some pharmaceutical companies are able to reduce the price of the drugs minus 80 per cent, which is quite substantial. We also saw that the research and development companies are even supporting the production of generic drugs that are reaching now 90 dollars per patient per year compared to the initial 12,000 dollars per patient per year that we used to have. We also know that there is a system which can

be put in place, that you can have prices in middle-income countries which are higher and even higher prices in the developed world. We have different economic forms and different packaging and different distribution systems for developing countries. What we are going to do is to build in capacity, provide the technical resources and information that will guarantee incentives for research and development on the one hand, at the same time have an opportunity for greater access, particularly in the least developed countries through negotiating prices with pharmaceutical companies and also access to generic production.

Q385 Baroness Whitaker: You say this is a task for the UNDP working with WTO?

Mr Sy: UNDP was leading on that in very close collaboration with the WHO and the UNAIDS secretariat.

Chairman: Mr Sy, we may have a vote in a few moments. If we do, I will have to draw this to a conclusion and make some final remarks, but I am going to try to fit in another question if I can.

Q386 Lord Steinberg: I am sure all my colleagues agree that you have given us detailed answers to all the questions, so you will be a bit relieved to know that my question is going to be comparatively short. You referred in logistics to “weak forecasting, procurement and distribution systems”. Would you say that it is because of the disparate nature of all the organisations surrounding you that leads to this weak forecasting? What attempts or suggestions would you make to improve the forecasting?

Mr Sy: Procurement supply management will make or break most of the programmes. How do we find the right drug and bring them to an airport or a harbour of any country in the world? Then the challenge starts. When the drugs reach those harbours, how do they get to the health facilities and then from the health facilities to those patients who need them most. That chain reveals a number of deficiencies in logistics and in forecasting. If people do not have a good grasp of their own epidemic and the number of people needing treatment, they may under-estimate the need or sometimes, even worse, over-estimate the need and by the time those drugs are going to be utilised they expire, because their shelf life is sometimes relatively short. Then the conditions under which the drugs are being stored in many of those places are not the most optimal ones. So forecasting is extremely important, not only to make savings in terms of exactly the quantities we need but also to prevent waste of drugs from happening. The reason why we highlight it even more as a very important issue is also that procurement revealed some other dysfunctions, such as good governance in terms of managing resources and

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managing work and also how you minimise issues like corruption and a diversion of drugs to other destinations where they are not supposed to be going. Or they are used for other purposes outside public health. How do we seek to address that?

Chairman: Mr Sy, I am going to have to interrupt you there. I am sorry. You can probably hear the bells ringing, which indicates a Division. We will not be able to return to this, I am afraid, but thank you very much. The evidence you have been giving is very clear and very helpful indeed. If you have any further comments you want to add, then we would be very pleased to receive them. Thank you very much.

WEDNESDAY 26 MARCH 2008

Present	Avebury, L Desai, L Eccles of Moulton, B Geddes, L	Hannay of Chiswick, L Howarth of Newport, L Soley, L (Chairman) Whitaker, B
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Letter from the Centers for Disease Control and Prevention

On behalf of the Centers for Disease Control and Prevention (CDC), I applaud the work of the Ad Hoc Committee on Intergovernmental Organizations of the House of Lords, Upper Chamber of the British Parliament, to examine the effectiveness of actions carried out by intergovernmental organizations to control the global spread of communicable diseases.

In today's world, it is increasingly clear that infectious diseases pay no attention to borders. During the past five years, SARS, monkeypox, and avian influenza have moved easily from one part of the world to another, threatening lives and economies. Fortunately, outbreaks to date, have been contained and illness and loss of lives, have been minimized, but the urgent need to strengthen public health capacity throughout the world to handle future challenges is very clear.

The scope and intensity of today's global health challenges means that no single country or agency can address them. CDC works in close partnership with a wide array of international agencies and institutions to control the spread of communicable diseases around the world and is committed to ongoing efforts to develop new tools and collaborations that will prevent or reduce the spread of infectious diseases,

In response to your call for evidence, enclosed are web links to information about CDC communicable disease prevention and control activities and our efforts to work with other countries to build their capacity. Attached are summary fact sheets of representative programs. If you are interested in more details on any of the programs, we would be happy to arrange a conference call with one or more of our scientists.

February 2008

Annex A

International Emerging Infections Programs

<http://www.cdc.gov/globalidplan/1-toc.htm>

Field Epidemiology Training Program

<http://www.cdc.gov/cogh/DGPHCD/fetp.htm>

<http://www.cdc.gov/cogh/DGPHCD/FETP/countryPDF/FETPfacts0307.pdf>

Global AIDS Program

http://www.cdc.gov/nchstp/od/gap/program_areas.htm

<http://www.pepfar.gov/press/c19614.htm>

Global Malaria Program

http://www.cdc.gov/malaria/control_prevention/index.htm

Pandemic Influenza

<http://www.pandemicflu.gov/>

<http://www.whitehouse.gov/homeland/pandemic-influenza.html>

<http://www.whitehouse.gov/homeland/pandemic-influenza-oneyear.html>

<http://www.hhs.gov/pandemicflu/plan/>

<http://www.pandemicflu.gov/plan/community/commitigation.html>

Global Polio Eradication

<http://www.cdc.gov/vaccines/about/pibs/downloads/global-polio-eradic.pdf>

Global Measles Program

<http://www.cdc.gov/vaccines/programs/global/measlesinitiative.htm>

Division of Global Migration and Quarantine

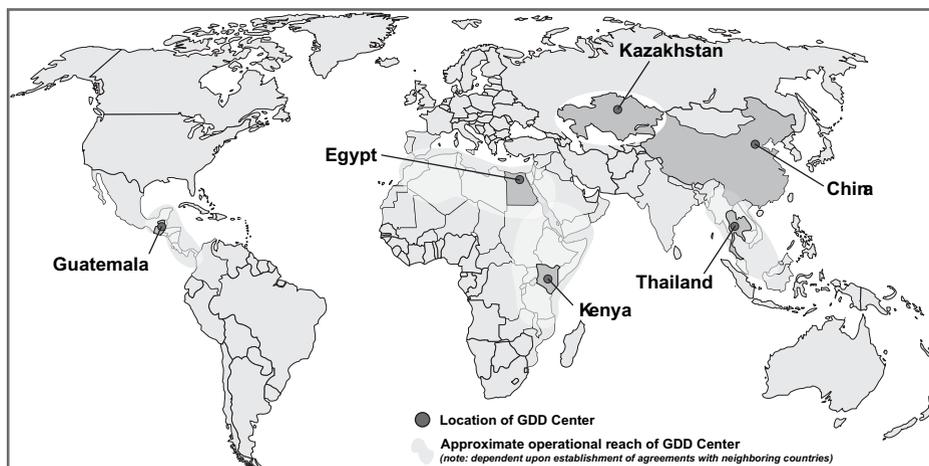
www.cdc.gov/ncidod/dq

Refugee Health

<http://www.cdc.gov/ncidod/dq/refugee/faq/faq.htm>

International Health Regulations

<http://www.globalhealth.gov/ihr/>

CDC-Funded Global Disease Detection Centers

“Since the 1970’s, newly emerging diseases have been identified at the unprecedented rate of one or more per year...It would be extremely naïve and complacent to assume that there will not be another disease like AIDS, another Ebola, or another SARS, sooner or later.”

The World Health Report 2007 - A Safer Future: Global Public Health Security In the 21st Century.

What is Global Disease Detection?

CDC’s vision for the Global Disease Detection (GDD) Program is to protect the health of Americans and the global community by developing and strengthening public health capacity to rapidly detect and respond to emerging infectious diseases and bioterrorist threats. The GDD program was built from CDC’s existing international expertise in public health surveillance, training, and laboratory methods, bringing together three established, proven programs:

- Field Epidemiology Training Program (FETP), which trains scientists and public health workers on field epidemiology and laboratory methods;
- International Emerging Infections Program (IEIP), which integrates disease surveillance, applied research, prevention, and control activities; and
- Influenza activities related to influenza surveillance and detection.

The GDD program effectively coordinates these existing CDC resources to build in—country capacity and enhance rapid response capacity for emerging infectious diseases.

GDD Centers

The central focus of the GDD program is the establishment and expansion of GDD Centers. Strategically positioned around the world, the Centers are CDC-funded international centers of excellence in emerging infectious diseases that focus on five key activities: (1) outbreak response, (2) surveillance, (3) research, (4) training, and (5) networking.

CDC currently operates GDD Centers in Thailand, Kenya, Guatemala, China, and Egypt. Each Center serves as a regional resource to assist the host country and neighboring countries that lack fully developed capacity of their own. Together with host and partner countries’ Ministries or Departments of Health, GDD Centers provide support to national and regional laboratories and epidemiology programs. During emergencies, the Centers typically function as members of the Global Outbreak Alert and Response Network (GOARN) that

is coordinated by the World Health Organization (WHO). In non-emergency settings, the Centers work with country partners to implement disease detection and response interventions.

Locations for GDD Centers are selected in consultation with invited countries, internal experts, and national and international partners, on the basis of these criteria:

- Public health significance: The country has a high population density or history of infectious diseases or expected potential for emerging diseases;
- Country commitment: The country supports and values partnership with CDC and will actively engage in collaborative activities and identify new partners with which to work;
- Established CDC presence: The country has an established, effective working relationship with CDC and supports CDC staff in-country;
- Established regional reach: The country has the infrastructure and regional structure to serve as regional resource, or is already acting as a regional leader in other arenas;
- International partner presence: The country has other US Government agencies and international partners operating in-country.

Global Disease Detection: A Public Health Issue

In June 2007, the revised International Health Regulations (IHR)—the international agreement designed to help contain or prevent serious risks to public health and discourage unnecessary or excessive restrictions on travel or trade—entered into force. The revised regulations acknowledge that public health incidents can pose threats beyond national borders and that Member States bear a responsibility to the global community to identify, report, and when possible, contain public health threats before they become “public health emergencies of international concern.”

Building on CDC’s existing emerging infectious disease strategies, using lessons learned from SARS, and driven by concern about the threat of avian influenza or another virus that could lead to the next pandemic, GDD represents a major U.S. contribution to this new system of global disease protection.

An Urgent Threat: Pandemic Influenza

GDD Centers help detect, confirm, and contain a variety of emerging infectious diseases that pose a substantial threat to the people of the affected country, its regional neighbors, and the world. Foremost among such threats is a pandemic influenza.

In FY2006, GDD Centers trained more than 230 participants from more than 32 countries in pandemic influenza response. In addition, the Centers collectively helped respond to and contain 28 human cases of highly pathogenic avian influenza H5N1; all responses were initiated within the goal of 48 hours.

When avian influenza was detected in Nigeria in 2006, the Kenya GDD Center—with CDC’s Global AIDS Program and the Influenza Division—organized an international training for more than 40 lab technicians and public health staff from 14 African nations. The training included rapid response capacity for containment and hands-on diagnostic training and was modeled after a prototype training developed by the Thailand GDD Center in 2006. The Kenya Center continues to work with countries in sub-Saharan Africa to further enhance this preparedness.

GDD Center Achievements

During FY2006, the GDD Centers and supporting programs at CDC Headquarters have conducted a variety of activities in support of the GDD mission.

Outbreak Response

During 2006, the GDD Centers collectively responded to more than 144 disease outbreaks, including avian influenza, hemorrhagic fever, meningitis, cholera, and unexplained sudden death. These responses resulted in measurable health impact, such as disease control efforts that led to an 83% decline (compared to the previous year) in *Streptococcus suis* cases in one region of China, delivery of botulism antitoxin that likely prevented multiple deaths in Thailand, and investigation and control measures that saved hundreds of people from methanol intoxication in Nicaragua.

Surveillance

GDD Centers are beginning to develop protocols and diagnostic standards for conducting surveillance:

- The Guatemala Center has provided technical assistance to Ministries of Health in Honduras and Guatemala to improve their national reporting systems.
- The Thailand Center expanded an ongoing, active, pneumonia surveillance system in two provinces by adding advanced microbiology diagnostic capacity. Within 10 months of implementation, they had begun to describe the bacterial causes of pneumonia and had identified 26 cases of pneumococcal disease (a greater than six-fold increase over the previous three years combined). This new capacity produces reliable information that can be used to treat patients and identify appropriate public health interventions.
- The Kenya Center is conducting sentinel surveillance for influenza and acute febrile illness, and conducted influenza A (H5N1) surveillance of migratory birds as part of multi-country collaboration.

Research

The Thailand Center discovered three new pathogens in pneumonia patients, including bocavirus and *Legionella longbeachea* for the first time in Thailand, and *Bartonella tamii*, identified for the first time anywhere in the world.

The Kenya Center established diagnostic testing for more than five pathogens and completed testing of 786 human and animal specimens. This capacity was previously unavailable in the region.

Training

Collectively, the Centers helped to strengthen in-country and regional public health capacity for outbreak detection and response by graduating 27 FETP fellows, and providing short-term training for more than 900 public health staff. In China alone, 20 FETP graduates now hold key positions in emergency response or infectious disease departments in 14 provinces and at China CDC.

Networking

The activities of individual GDD Centers can provide benefits to other Centers. For example, the Thailand Center developed and hosted rapid response training for avian and pandemic influenza that was attended by staff of other Centers. The participating countries were then able to provide in-country training to their colleagues and establish greater regional capacity for avian and pandemic influenza.

GDD Operations Center

The GDD Operations Center, located in the Emergency Operations Center at CDC Headquarters in Atlanta, serves as CDC's central coordination point for international outbreak information, and provides support to the GOARN. Information about outbreaks worldwide is collected from a variety of public and private sources, including GDD Centers, CDC programs, WHO, the US Department of State, the US Agency for International Development (USAID), the US Department of Defense (DOD), and the Global Public Health Information Network. Information is analyzed using the expertise of scientists across the agency to help determine the level of threat to public health posed by a given event and guide the appropriate level of response. When a CDC field response is indicated, the GDD Operations Center utilizes its resources to maximise response efforts.

CDC and its Partners: Building a Global Network

GDD represents a partnership between CDC, the host country, and participating neighbor countries. To implement the GDD program, CDC also works with other domestic and international partners, including WHO, the US Department of State, USAID, DOD, the Training Programs in Public Health Interventions Network, UNICEF, the World Bank and non-governmental organizations.

Future Directions

CDC aims to build a global network of strategically located GDD Centers, capable of effectively addressing emerging infectious diseases. Ongoing and planned activities include:

- Continued support of currently funded GDD Centers in Thailand, Kenya, Guatemala, China and Egypt.
- Expanded regional and global coverage through the strategic, incremental addition of new GDD Centers (as resources allow).
- Increased collaborations with WHO, DOD, and other key global and domestic partners.
- Continued monitoring and evaluation of GDD Center activities to measure progress and assess impact.

Examination of Witness

Witness: DR SCOTT DOWELL, Director of Global Diseases Detection Program, US Centers for Disease Control, examined via video link.

Q387 Chairman: Good afternoon, Dr Dowell. Or should I say Good Morning, from where you are sitting, I think.

Dr Dowell: Good afternoon. It is good to be here.

Q388 Chairman: First of all, thank you very much for your time and the papers you have sent us, which have been very informative, very helpful and have already raised a number of questions in our minds. Let me tell you, of course, this session, as you would predict, is being recorded. You will be able to see a transcript of the session before it is published officially. After this session, if there is anything you think we have missed out or anything else you would like to add, please feel free to write to the Clerk, Mr Preston, with whom you have already been in contact and add those comments as you wish. Can I say that the important issue to us is Intergovernmental Organisations. We have been concerned for some time about how well intergovernmental organisations operate together as well as with non-governmental organisations, private companies and so on, in order to deal with communicable diseases. It is the intergovernmental organisation structure which we have most focus on, so that is what many of the questions will be about. Having read your papers, I can see it is something that you have some knowledge of and we welcome that. My understanding is you are the Director for the Global Disease Detection Program, is that correct? Is there anything else you would like to add before we begin?

Dr Dowell: That is correct. I would be happy, if I could take merely a minute, to give you a little bit more background about me. It might help to start off by telling you that I have worked here at CDC for about 15 years. My initial work was focused on respiratory tract infections and international outbreak response. Over the last five or ten years it has broadened a bit. I spent four years in Thailand, assigned from CDC to start a programme called an Internationally Emerging Infections Program, and I have been back here for about two years working on

the Global Disease Detection Program. In terms of the intergovernmental organisations, I have been familiar with and worked with the WHO over this 15-year period. In terms of some of the others—I saw UNAIDS and the Global Fund listed—I would have much less familiarity with those groups.

Q389 Chairman: Thank you for that. I was going to say to you that, if there are areas where you are unsure, just say so and we will pass on that. I have read your CV and it seems to me your experience will be very helpful and could be very useful to us, so many thanks again. Can I begin by saying, in relation to the papers you sent through—and the web links as well, it is very clear that a lot of what you do around the world in the Centers you have to some extent does what people would expect the World Health Organisation to do. One of the things that has been coming up to us as a Committee from various sources is that the architecture of the intergovernmental organisations is very fragmented, there are many groups to it, many parts of it, and we are not quite sure how well it is operating together. That is really my first area to question you on. Are your CDCs, your Centers, doing what you would anticipate the WHO ought to be doing, but maybe cannot do, possibly for funding reasons? Or are they doing something different? How do you see them being part of the intergovernmental structure?

Dr Dowell: I would like to agree with your statement that the CDC is doing what one would expect WHO to do, but maybe take a different angle, and that is in our view of what WHO does. It is a convening and leadership function and they depend on Member States and other organisations to do a lot of the carrying out of the actual work. We hope that what we are doing fits well into the overall umbrella of what WHO is intending to accomplish and that our networks fit into the WHO-led network of networks, if you will.

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Q390 Chairman: Supposing other countries took a view similar to the view taken by the United States, which I understand and sympathise with, that we have to try and deal with these global diseases on a global level and, therefore, we need the Centers you are talking about. Could we not end up with a lot of duplication if we all go down that road? Is there not a case for saying we ought to be doing this through the WHO?

Dr Dowell: Exactly. One could imagine a situation with each country doing what they think is indicated and there would be a lot of duplication and, therefore, there is a very important role of WHO in controlling and convening all these different contributors. You know, of course, about the new International Health Regulations. We see this programme very much as fitting into some of the requirements of the International Health Regulations, which essentially recognise a requirement for each country to do a good job of detecting, reporting and controlling new infectious disease threats as they arise, but also recognise that many Member States simply do not have the resources to do a good job of that by themselves, so there is a component of the new IHRs that requires wealthier Member States to work with less wealthy Member States. As you point out, if that was done in an uncontrolled fashion without the leadership of WHO, you might end up with a chaotic situation. I do agree with what you are saying that it is not just the US that should be doing this, it is other wealthy Member States that should be contributing to this kind of capacity building.

Q391 Chairman: Before I bring in some of my colleagues, can I just ask you this: do you think there is something wrong either about the organisation or funding of the WHO that makes it difficult for them to do what you are doing?

Dr Dowell: My view of WHO's role over the last 15 years or so is that it has grown steadily in its organisation and its ability to organise and convene the responses to these international outbreak threats. In particular, the SARS situation arose when I was out in Thailand and, in my view, in some ways that was the pinnacle of WHO's accomplishments which they had really been working on over a ten year or so period. They were really able to bring together a network of laboratories run by Centres of Excellence from different countries and different places to quickly identify the causative pathogen, they were able to put together diagnostic tests that allowed us to focus very directly on the people who were most affected by SARS and then they put out a regular stream of pieces of advice and documents that allowed case definitions to be agreed on, people to be focused on, and the transmission that was amplified in hospitals to be brought under control. That was a

real example of WHO leadership in what I thought was a real health crisis. When I came back here to the US some people, having seen something like eight cases in the US, thought maybe the concerns about SARS were overblown. But from our perspective out in Bangkok we did not think that was the case at all; we thought this was rather worrisome, and thank goodness WHO was able to convene the groups it was able to and bring that thing under control.

Q392 Lord Hannay of Chiswick: I wonder if I could go to the other end of this piece of analysis, that is to say a developing country with not very bountiful resources for handling the inflow of assistance, advice, aid and so on. Perhaps drawing on your experience in Thailand you could answer this question. Do you not think that for a developing country it is pretty confusing that the world is so ill-organised, albeit with quite a lot of resources, to deal with these infectious diseases, that there are so many different programmes coming at them from slightly different angles with slightly different acronyms, all seeming to do much the same thing? Does this not make life rather difficult for a developing country which is trying to organise its own response but needs external resources and which is trying to focus on its own health problems and how other people can help them?

Dr Dowell: This has been a challenge for a long time for the poorest of the countries. They have not just not very many resources in terms of money but not very many resources in terms of personnel, and the few talented and qualified personnel they have in the Ministry of Health, for example, have to do this enormous job of managing lots of well-intentioned groups from outside with different priorities. The thing that I think has changed a lot in the last five or ten years or so is the magnitude of funding, beginning with the Gates Foundation really changing the level of funding from millions of dollars here and there to tens of millions and then hundreds of million dollar chunks at a time; and other large funding groups, whether it is the Global Fund or the PEPFAR programme, bringing in hundreds of millions of dollars at a time has changed the way that these developing countries are facing the same problems they have been facing for a while, just on a different order of magnitude.

Q393 Lord Hannay of Chiswick: Could you just say a little bit more about whether you think that slightly less diversity in programmes, donors and so on might make it easier to get better results in developing countries. Or do you think it is fine that there are people coming at them from all different angles and they have 75 consultants descending on them each year?

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Dr Dowell: No, I agree that it would be better to focus. One question one might ask is where that focus should come from. Should the external organisations get together and decide what is most important for these countries? Or should we make sure that the countries themselves have the capacity to decide what is most important for them. My view might be transparent in that it is better, if possible, to build the capacity within the developing countries to decide for themselves what are the most important health problems in their areas and thereby bring focus.

Q394 Baroness Whitaker: Good afternoon. I just wanted to ask you about an area of work which I am not aware WHO does and perhaps they ought to and, if not, to ask who ought to do it. This is the area of viral forecasting—to find out which microbes might make the jump from animals to people. I have been reading about an organisation called the Global Viral Forecasting Company, which I think is being piloted at the University of California. Can you tell us whether this ought to be the subject of more international attention and, if so, which organisation ought to deal with it.

Dr Dowell: It has been a topic of discussion around here even in the last couple of weeks. There was a conference in Atlanta last week called the ICEID, the International Conference for Emerging Infectious Diseases, and there were a number of groups at the conference that presented a variation on the issue you are raising, viral forecasting, or some sort of risk-based approach to predicting where the next emerging infection might come from. It seems to me that this is an interesting area of investigation and also it is a field that is early in its infancy and there is a lot of work to be done on the future on viral forecasting. It is an exciting area for people to be working in. I am not sure we are at the point right now where we can take any of the forecasts that people come up with and say, “That’s where we should direct our resources” and be confident that we can predict that, for example, the next threat will come from a corona virus.

Q395 Lord Howarth of Newport: On the question of increased magnitudes of funding which you touched upon just now, I noted that the budgets of your own organisation and your staffing have increased very substantially in recent years and that clearly enables you to do more very important work, but I wondered what the background was to that. Am I right in thinking that is federal funding?

Dr Dowell: My specific programme, the Global Diseases Detection Program, started in 2004 with about \$11 million from the US Congress and this year the budget is about \$30 million. So it is true that it has grown but it remains a relatively small

programme compared to some of the others we have mentioned.

Q396 Lord Howarth of Newport: Taking the budgets of the CDC in all, there has been a very large increase in recent years. I wondered if you were able to say what the background is in terms of why the Federal Administration and Congress, should have concluded that so much more funding was needed and, if so, why they have chosen to route it through your own organisation rather than through intergovernmental organisations.

Dr Dowell: I am not the best expert on the overall CDC budget. There have been increases over the 15 years I have been here and in the last couple of years the budgets have been relatively flat. What I would say is the perception that it is appropriate to invest US taxpayer dollars in global activities has grown and the lessons from the SARS outbreak of 2003 and other recent outbreaks have not been lost—the idea that one of the ways the US CDC protects the health of American citizens is by strengthening the ability of other countries to protect the health of their citizens. I have seen a gradual shift, independent of particular administrations, over the last ten or 15 years towards increased funding of international health and global health activities.

Chairman: I think underlying this was some puzzlement I have had too as to why the US Government was choosing to work through the CDCs rather than the WHO, but I understand also about the governmental policy approach too.

Q397 Lord Geddes: Dr Scott Dowell, you said in reply to Lord Hannay that in your opinion the initiative, if I can use that word, should come from the individual countries, in other words upwards rather than be imposed upon them downwards; and, if that is your view, it is one with which I concur. To whom would such countries make their views known and make their requests known? This comes back again to who is it worldwide who should be co-ordinating the whole of this effort? Is it the World Health Organisation? Is it yourselves? Or is it the Gates Foundation? Where should the decisions be made?

Dr Dowell: If by who should be co-ordinating this effort, the effort refers to the effort to identify, control and contain new infectious disease threats, to me it seems clear that should be co-ordinated by the World Health Organisation. My view of the evolution of the World Health Organisation’s capacity in that regard has been that they have continued to strengthen their ability to co-ordinate those activities. Those threats, threats like SARS and other new emerging infectious diseases, by their nature are not threats that are dealt with one government at a time but, as SARS, the HIV epidemic and others have, they quickly cross national

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boundaries. So there is clearly a necessity for a transnational organisation to deal with them when they occur, and to me that is exactly what the leadership role of WHO is and what they have moved towards doing over the last few years.

Q398 Lord Geddes: The \$64,000 question, if I can put it that way, is: in your opinion is the World Health Organisation properly equipped to deal with that role?

Dr Dowell: I think the WHO has steadily improved its ability to deal with that role. Do I think the job is done and no more is needed? No, certainly not. We have increased our funding to WHO over the last few years to help with them carrying out that role, but that is only a small part of what is needed. If, for example, we look forward and ask what is the next big threat that we are concerned about, I would say the answer is clearly H5N1 influenza at this point. Is WHO adequately equipped and resourced to deal with a pandemic of H5N1 influenza, to me the answer is they are far better equipped than they were two years ago but nowhere near ready to deal with a pandemic in the way that one would like.

Q399 Lord Avebury: Could I come back to the answer you gave to Lord Howarth a couple of questions ago concerning your budgets and the fact that the amounts of money you were getting from the Federal Government over recent years were relatively flat. Do you think this is a reflection of the fact that new money is coming in, particularly from the Gates Foundation—you mentioned them earlier on as being a major contributor? I wonder whether there is a temptation for not only the US Government but for everybody else to think, “Well, if Gates is pumping billions of dollars into this field, then we do not need to bother so much?”

Dr Dowell: That seems possible to me, but I have not been party to those kinds of discussions on those budgetary decisions, so I cannot give you a very good answer about why the overall budgets have been flat. It seems possible to me, but I do not think I am the one to give you any more of an informed answer than that.

Chairman: That sounds like a wise answer in your circumstances, thank you.

Q400 Baroness Eccles of Moulton: Good afternoon, Dr Dowell. You were talking about how well WHO have responded to SARS, and I suppose one would put the avian flu pandemic possibility into the same category as SARS. You say there is still considerably more work to be done on that front, but they are moving forward and presumably the SARS experience has proved useful. The other three diseases that we are particularly looking at—Malaria, TB and AIDS—fall into a rather different

category in that they are chronic and ongoing, as it were, whereas these pandemic diseases come and go—and, in the case of SARS, went rather quickly because it was so well-handled. I suppose my question is; WHO is not doing too badly on the pandemics, but what about their progress on dealing with those other three diseases?

Dr Dowell: Now we are straying a little bit beyond my expertise. The issue of the Global Fund and dealing with HIV, TB and Malaria epidemics is not an area that I deal with on a daily basis. I might just mention that the HIV epidemic, although it is a chronic and ongoing epidemic as you say, started out as an emerging infectious disease outbreak, as we thought in the early 1980s. But now we find out that probably for two decades or more before that it must have been circulating in West Africa undetected and uncontrolled.

Q401 Chairman: Thank you. Before we move on to the next section, I just want to be clear. The World Health Organisation, UNAIDS and the Global Fund for AIDS, TB and Malaria, are all in a way either expected to work together or to work efficiently individually. It might be a bit outside your knowledge, but I get the feeling you have some experience of how they co-operate. Do you think they are working well together? Or do you think there could be improvements there? Are there other organisations which are, if you like, part of that synergy or not functioning as they ought to? Perhaps you could also comment on PEPFAR, and the US Presidential Initiative for Malaria

Dr Dowell: As you say, it is not a part of my daily work but I do see those organisations working on some of the same things in parallel. I do not see the competition but there may be people who know more about the interactions of those organisations who would give you a different answer than that.

Chairman: Thank you very much. I want to move on to this issue of horizontal healthcare versus the vertical treatment of disease.

Q402 Lord Desai: Many of our witnesses have emphasised that intervention in a specific disease is not very effective unless you can do something about the basic health infrastructure. Your GDD Centers are dedicated to “build in-country capacity” by training local people. Do you think there has been too much emphasis on vertical intervention and not enough on horizontal health capacity building?

Dr Dowell: I personally believe that both are indicated and are useful. As you point out, part of the Global Disease Detection Program is in building capacity horizontally, if you will, by training epidemiologists, for example, in the Field Epidemiology Training Programme, or by training laboratory scientists or by providing diagnostic

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capacity to the country to broaden their capacity to identify new and different pathogens. There are also vertically-oriented components to the programme, focused on population-based surveillance for pneumonia, for example, with an eye towards understanding of the disease burden from influenza and thereby promoting domestic vaccine production capacity in that country. This mix of horizontal and vertical approaches is part of our programme and more broadly part of CDC's approach. We have some parts of the agency that are focused on horizontal capacity building and other parts, like the polio eradication programme or the PEPFAR programme, that are very much vertically oriented programmes.

Q403 Lord Desai: The PEPFAR programme has been criticised, of course, as being too vertical at the expense of public health infrastructures. Do you have any specific comments on PEPFAR and what lessons have been learned from PEPFAR?

Dr Dowell: Again, this is a little bit outside my area. As an observer, I am an unapologetic supporter of the PEPFAR programme. From what I have seen, there have been some fantastic accomplishments already. As you probably know, there is a proposal to expand the budget for the PEPFAR programme this year and, in doing so, it will do some of the things you are alluding to, which is to expand the horizontal reach of the PEPFAR programme by incorporating broader approaches to disease control than simply anti-retroviral treatment for people with HIV.

Q404 Baroness Eccles of Moulton: I just wanted to ask you, Dr Dowell, whether when you are establishing and maintaining GDD Centers in-country, there is a big difference in the extent to which you are assisted by the ministries of those countries, the interaction between your Centers and the various in-country governments that will inevitably be playing a part in the success of your Centers?

Dr Dowell: Each of the Centers is a collaboration between the host country government and US Government, in particular the Ministry of Health and CDC, and there are agreements between the two about what to do together. In practice, it varies a little bit as to the extent to which the host country government both resources and drives the collaboration. We have a GDD Center in China, for example, which has got plenty of resources on its own and can contribute a lot and drive the agenda, and we have one in Kenya, which is much less wealthy than China, that contributes relatively less to the collaboration. At their core, they are all collaborations between the host government and the US, with additional partners, the first of which is WHO; the Country Office, the Regional Offices play

a greater or lesser role and Geneva plays a greater or lesser role.

Q405 Baroness Eccles of Moulton: So it is quite a complicated set-up in that sense?

Dr Dowell: I suppose you could look at it that way.

Q406 Chairman: But it works or not, in your view?

Dr Dowell: I think overall the system works very well. This is what I do day-to-day and I am very much involved in especially the parts that do not work very well, so I am aware of the things that do not work very well. If I stand back and ask whether these Centers work, I would say overall, yes, absolutely.

Q407 Baroness Eccles of Moulton: Would you say, that by and large, where those Centers are on the weaker side, gradually progress is being made. Or in some areas is there a certain amount of slipping back?

Dr Dowell: Of the five Centers, the oldest is in Thailand; that has been there since 2001, and I would say that is the most accomplished in terms of what it is doing for global disease detection and control, and also the easiest because the working relationships are very well ironed out between the host country government, the Regional WHO office and others. The newest ones—Egypt, China and Guatemala—are the ones that have fewer accomplishments for having been there less time and the mechanisms for working between the host country government, CDC and WHO regional offices are still in the process of being worked out. To answer your question more directly, yes, over time we will see the challenges smoothing out and progress being made.

Q408 Baroness Eccles of Moulton: Is it your ambition to open more Centers?

Dr Dowell: Yes. Roughly speaking, we looked at the six WHO regions and said approximately three per WHO region would be an appropriate number given the ability of each of them to serve not just the country they are sitting in but neighbouring countries as well. That is a rough approximation of how far we think this could evolve. That is three per region, a total of 18.

Q409 Baroness Eccles of Moulton: That would seem to be a very good addition to the necessary horizontal part of the structure.

Dr Dowell: We hope so.

Q410 Lord Avebury: I am not sure whether I am putting words into your mouth, but you were comparing China and Kenya as being at the opposite ends of the spectrum, as it were, regarding the contributions that were made by the host governments in terms of, presumably, technical and financial inputs to the GDDs that were located in

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their territories. I wondered whether that is a consideration in the establishment of Centers, that you have to have a certain minimum degree of competence to consider putting a GDD in a particular country. The second part of my question is whether, in a place like Kenya, where there has been recent political instability, that makes any difference to the degree of collaboration that you have with the host Ministry of Health.

Dr Dowell: You guessed correctly. We did not place these randomly, they were placed in areas where we thought there would be success or there was a good chance of success. The early ones were placed where we already had good partners and good collaborations. Kenya is not a wealthy country; however, there is a long history of collaboration between CDC and Kenya in a number of different areas, beginning with a Malaria Field Station and collaborations on HIV/AIDS programmes and others, that set the stage nicely for this Center to land there and be successful.

Q411 Lord Avebury: What that strategy means is that in an area such as East Africa, where Kenya was seen as a beacon of stability in a region that was otherwise somewhat unstable, the threat of emerging diseases would be greatest in the areas that did not have a GDD, such as Somalia?

Dr Dowell: This goes back to the question of whether we can predict where the threat of emerging infections is greatest. There was a recent paper published in *Nature* about a month or so ago that put forward a model for predicting where diseases were greatest. It was interesting to me because the conclusion of the paper was that we ought to invest more resources as you are saying in Equatorial Africa, South America, places that are the poorest parts of the world. However, when they put up a map as one of the figures in the paper and showed where the emerging diseases have been detected worldwide, the hotspots were the East Coast of the United States, London, and another little hotspot around Hong Kong! So it seemed to go against what they were saying about where you would expect to find emerging infections. I think probably the answer to that is the emerging infections are being detected where the light is being shone most brightly and that is why the map looks the way it does.

Chairman: I hope you are right, otherwise we are going to have to move!

Q412 Lord Hannay of Chiswick: When you choose a new site for a GDD Center—you say you are trying to expand the network all the time—is that a joint decision between you and WHO? Or is it entirely dictated by US Government priorities? Or is there a consultation of WHO? And, if so, is that WHO in Geneva or WHO in the regions? Secondly, these

GDD Centers, once they have been set up, are they sharing everything that they find and produce with the WHO? Or is there some limit to the amount that WHO finds out from these GDD Centers?

Dr Dowell: The decision about starting a new GDD Center is primarily at the invitation of the host country. The first issue: is does the host country request this? And do they want it there? We also work with the WHO Office in Geneva, so we have a monthly call, for example, with Geneva where we talk about these issues, update on the GDD Centers and thereby get their views on what is needed and how we modify things. In terms of the question about the information that is collected from these Centers and whether it is shared with WHO, this goes back to the International Health Regulations. They are different, in that they do not simply require the reporting of smallpox, cholera and yellow fever as the old ones did; they define a public health event of international concern as one that requires reporting to WHO. All of those public health events of international concern are reported to WHO and it says no matter who becomes aware of it. Ideally they are reported by the host country, but if another country becomes aware of it technically IHR requires the other country to report that to WHO as well. We have not run into that situation so far, thankfully, but it is possible that would be the case in the future. The short answers to your questions are (1) primarily a decision about basing a new GDD site is a decision by the host country, and (2) communication with WHO about these outbreak events is an open one.

Q413 Lord Hannay of Chiswick: You must presumably have more requests for these Centers than you have funds to put them in place, so there must be some element of choice as to where you decide to put them?

Dr Dowell: True. We are at our budget this year, so we are not in a position to add a new one in the near future. In the strategic document that I think was sent to you all, there are five criteria laid out, and I may not be able to remember them all, for the selection of a new site. They are: public health importance of the country; the presence of strong partnerships, including WHO, other universities, Department of Defence laboratories in some cases; ability to serve as a regional hub or regional centre, and that relates both to the country's relationships to its neighbours and also to more practical things like the ability to travel in and out of the country. There may be one other I cannot think of right now.

Q414 Lord Avebury: Can I refer to the publication, *Protecting the Nation's Health in an Era of Globalisation*. That suggests that in the years ahead there should be an expansion of the regional surveillance networks and their interaction and

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evolution into a global “network of networks” that provides early warning of emerging health threats. My first question is: is that not exactly what GOARN is supposed to be doing?

Dr Dowell: Yes, you are correct. You will recognise the language because the language is used similarly by GOARN and the Infectious Disease Strategy of the CDC. We do use a lot of the same words. The concept of a “network of networks” is one that has been promoted both by WHO and us for at least ten years or more now.

Q415 Lord Avebury: So that means you see some deficiencies in the way that GOARN is structured if you think that it should be evolving into something else?

Dr Dowell: To clarify: we see ourselves as one of the networks that is part of the network of networks, if that makes sense. GOARN is interesting. It is not actually a part of WHO, although it is convened by WHO as its secretariat. It is a conglomeration of the different groups involved in these kinds of activities. GOARN, in effect, is the network of networks and it is convened and chaired by WHO, but it is made up of individual networks, some of which are like ours, governmental networks, and some of which are not governmental, they are private. I am thinking of *Médecins Sans Frontières* and other groups that contribute.

Q416 Lord Avebury: So there can be additional components coming into the network at any time and there is an evolution of the network of networks? Could you say how that will relate to the regional offices of the WHO.

Dr Dowell: I can try. As we talked about earlier, one can imagine an uncoordinated evolution of different partners coming in and resulting in chaos. I think back to the first outbreak I was involved with, way back when I was in training in 1995, which was Kikwit, Zaire, which was the first real emergence of Ebola virus for probably 12 years or so after the 1976 discovery and a couple of outbreaks after that. This new virus emerged in Equatorial Africa, it was rather frightening, certainly newsworthy, and it attracted lots of news media and lots of different international organisations to the outbreak. WHO was at the centre but was trying its best to control this chaos in Kikwit and it was somewhat successful, and ultimately the outbreak was brought under control. I think that experience and similar experiences with haemorrhagic fever outbreaks in the early 1990s was what drove WHO to develop this GOARN concept and to push for the revision of the International Health Regulations that seek to impose some sort of order on these chaotic events. Some of the progress I was alluding to earlier over that time was imposing some sort of order on the chaos.

Q417 Lord Avebury: So, if you had a new outbreak today, it would be handled quite differently, GOARN would be capable of approaching it in an orderly manner which would bring the most effective resources of the international community to bear on it?

Dr Dowell: I think you can point to concrete steps where there has been progress since those days in the early 1990s. For one thing, there is an agreed—on set of International Health Regulations that requires countries to report this early, so we should get an earlier signal about this new threat than we did in the past. In the past, all that countries were required to report were smallpox, cholera and yellow fever; now, if it is a new corona virus causing SARS, they are required to report that as well and anything else that comes up that might be a public health event of international concern. I see that as real progress. A second thing, and I do not know how much this has been discussed, is this idea that the WHO can use sources of information besides the officially reported sources that the countries send in. In the past, in some ways WHO’s hands were tied because the only thing they could act on was what the countries officially reported to them. First, there was sort of tacit acknowledgment that WHO could use open-source information from media reports and others to pick up on these things, but that was formalised in the new International Health Regulations and now WHO can go to a country and say, “You have not reported anything about this, but we are reading media reports from your country about such and such an outbreak, we require you to tell us something more about that”. They can go to other partners if they do not hear from the country and ask the other partners what they know about it. All of that has been approved through this process and codified over time. There is a lot in the way this has evolved that is real progress in this area.

Q418 Lord Hannay of Chiswick: We have had quite a lot of evidence given to us that in medical terms there is not really any particularly significant difference between a bioterrorist event—ie one caused by human activation—and a surprising and sudden outbreak of some new pandemic disease that occurs, I suppose naturally would be the word. Could you perhaps comment on whether that is true, whether the two are rather similar both in the way they would hit the world and in the sort of response that would be needed to cope with them? If that is so, is not the treating of bioterrorism in a kind of separate stovepipe from infectious diseases a bit counter-productive, particularly since a lot of developing countries do not take anything that comes with a hyphenated terrorism terribly seriously? Would it not be better to deal with the

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phenomenon as a single phenomenon rather than two different ones?

Dr Dowell: Yes, I fully agree and I think that reflects the approach of our program as well as a number of other programmes, and that is strengthening the capacity of countries to respond to a naturally occurring outbreak and believing that gets you most of the way there in addressing the threat of bioterrorism. There are some minor exceptions where you have to think a little bit more about intentional outbreaks. I use as an example the difference between biosafety in the laboratory and biosecurity in the laboratory. Biosafety is focused on safely handling dangerous pathogens in the laboratory, ensuring that your laboratory staff do not inadvertently get infected or inadvertently spill or release some of these dangerous pathogens that might affect other people. That is the biosafety aspect. The biosecurity aspect is being aware that this might not just happen by accident but that somebody might do this intentionally, get into the laboratory and take things or do something malicious with those. The biosecurity approach requires some slight modifications to your thinking about biosafety, like making sure there are locks on the doors and those sorts of things. By and large, I think your point is well taken. If we focus on strengthening capacity to deal with naturally occurring events, then we have got most of the way there to dealing with bioterrorist events as well.

Q419 Chairman: On this issue, am I right in thinking that at the present time, leaving aside what might happen in the future, the difficulty of weaponising biological elements makes it difficult to spread deliberately in the sort of way sometimes envisaged?

Dr Dowell: I am not an expert in that area. There are people here who could give you a better answer on that. What you just said is my understanding as well, but I would not be speaking as an expert in the area.

Q420 Chairman: Thank you very much for that. Finally, can I ask you one last question, which is this. If you stand back from all of this and look at it with your considerable experience, what changes would you most like to make within the intergovernmental

organisations dealing with communicable diseases? If you could change something, what stands out in your mind as to what it would be?

Dr Dowell: Interesting! Again, I am focusing not on all of the intergovernmental organisations but I am focusing my thinking on WHO in particular, which is the one with which I am most familiar. I am reflecting on the fact that, as I said, I have seen a lot of progress in what WHO has been able to do over the last 10-15 years or so. I also said I do not think they are all the way there and more could be done. What more could be done? WHO in the last one or two years has been going through a reorganisation, which is not yet complete. We are very sympathetic to that because we went through a reorganisation a couple of years ago and ours is finally becoming complete. But it is a disruptive process and has an impact on the ability of the organisation to do what it should be focusing on doing. In particular, I am thinking about the WHO leadership of GOARN and the need for them to continue to play a strong role in leading GOARN. I would predict that, as they emerge from their reorganisation, they will take a firmer hand on guiding the GOARN process and leading that process for the future.

Q421 Chairman: The leadership role is essential to that and that is what you would focus on?

Dr Dowell: WHO's leadership role for GOARN is absolutely essential, especially if there is a big outbreak threat. It has been disrupted somewhat by the reorganisation and lack of clarity about who is in charge of what at WHO during the last 18 months or so. As I said, I see them emerging from that and that problem solving itself, and we are looking forward to that when it happens.

Q422 Chairman: Dr Dowell, thank you very much indeed, you have been very helpful. We are very grateful for your time. If you do have any more thoughts that you want to add after you have finished this session, then please send them through to us; we will be glad to receive them. You will get a transcript of this sent to you in due course. Thank you very much for your time and your effort.

Dr Dowell: Thank you.

Copy of email correspondence between the House of Lords Committee Office and the US Centers for Disease Control

GLOBAL DISEASE DETECTION CENTERS

I wonder whether you could be so good as to offer us a comment on something that WHO witnesses told us last month in regard to cooperation between WHO's GOARN and CDC's GDD Centers. I attach the weblink to our transcript of evidence with the WHO on 21 April, and the paragraphs on which a CDC comment would be helpful are contained between Pages 37 and 40. We have looked at these comments alongside Dr Dowell's

own (earlier) evidence, and much of what he says appears to explain CDC's position. But I am not sure what CDC's reaction would be to WHO's comment on the non-sharing of viral and bacteriological samples.

I am sorry to have to make this request, but I feel you would want an opportunity to comment briefly on WHO's comments before we record them in our report.

Robert Preston
Clerk to the Committee

6 June 2008

Dear Mr Preston,

Thank you for the opportunity to comment on the comments by WHO. We agree in general with the characterization of the WHO-CDC collaboration by David Heymann and Pat Drury on pages 35-39 of the transcript. We have discussed the challenges quite frankly with David and Pat many times over the years and will continue to do so, as the relationship couldn't be more important to us. We appreciate their note that there is a close level of cooperation, and that we at CDC are very interested in seeing that the GDD Centers are a part of the international infrastructure supporting IHR and functioning within GOARN. This is the essence of the matter from our perspective.

As for the specific matter of sample sharing, the principle is similar.

When samples are shared and the international network functions collaboratively, as with the discovery of SARS coronavirus under WHO leadership and with CDC support, the world benefits. There are more than 37 WHO collaborating laboratories at CDC that take this approach to sharing reagents, knowledge, and samples as part of their daily work.

If there are exceptions to this collaborative approach (and there may well be specific examples I'm not aware of), we would like to know about them and to help address and resolve the problems.

Scott Dowell, MD
Chief

Global Disease Detection and Emergency Response Branch Coordinating Office for Global Health CDC

11 June 2008

MONDAY 31 MARCH 2008

Present	Avebury, L Desai, L Eccles of Moulton, B Falkner of Margravine, B Geddes, L Hannay of Chiswick, L	Hooper, B Howarth of Newport, L Jay of Ewelme, L Soley, L (Chairman) Steinberg, L Whitaker, B
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Memorandum by the Terrence Higgins Trust

Terrence Higgins Trust (THT) is the largest and oldest HIV service organisation in the UK, currently providing advice, social care health promotion, testing and policy services across England, Scotland and Wales. Although this service remit is UK specific, THT has always collaborated with intergovernmental organisations in sharing expertise and supporting global initiatives to reduce the spread of HIV, to increase understanding of it and support for the human rights of people with HIV and communities at greatest risk.

Apart from the European Union, the two intergovernmental organisations with which THT has most contact are the World Health Organisation and UNAIDS. For the former, we have most recently undertaken a review of the impact of the Dublin Declaration on Partnerships for an Effective Response to HIV for the most vulnerable and at risk populations across Europe. For the latter, we have conducted a survey of criminal laws relating to HIV transmission (with the Global Network of People with HIV) and we are to serve on a new Task Team on global travel restrictions for people with HIV. We are also responsible for co-ordinating the UK Civil Society report on progress to the UN General Assembly Special session (UNGASS).

It is THT's belief that these bodies, both in the work we have been closely associated with and elsewhere (such as the Global Fund for HIV, TB and Malaria) have provided vital support and co-ordination in the global fight against HIV. Clearly, like all bureaucracies (particularly multinational ones) there are times when talk appears to overwhelm action but in general we have been much better off with them than we would have been without them.

In particular, the emphasis of these bodies on not only clinical and epidemiological issues, but also on humanitarian and legal concerns and social constraints have made a significant impact on what is, in every country, a stigmatised and discriminated against condition. Because of the nature of HIV transmission, it thrives on denial, secrecy and silence and, in particular, has in recent decades grown fastest in countries whose governments have denied its existence or extent: South Africa; Russia; China and, until recently, India.

The work of both the WHO and UNAIDS has challenged governmental silence, given levers that can empower communities to act for themselves and ensured that people's rights—to health, to basic necessities and to legal protection and family life—have been supported and the subject of international scrutiny however great the national stigma of HIV.

Controversy has dogged HIV throughout the 25 years in which it has been known, and continues to do so. Global surveillance figures have been challenged; treatment availability and cost has caused strong debate and even civil action; the causes of the virus distorted or denied. Yet throughout this, intergovernmental organisations have played a vital, often under-acknowledged role in ensuring that HIV is not forgotten or relegated and that recalcitrant governments are coaxed into facing their responsibilities to those within their boundaries with HIV and at heightened risk of it.

It is the view of THT that while there are many causes for the ongoing spread of HIV—poverty, ignorance and stigma—the greatest block to action against them is a deficit in political leadership on the issue and in governmental willingness to consider something which combines a number of social taboos. Intergovernmental organisations such as UNAIDS and WHO are therefore vital in creating pressure for improved political leadership, because few governments care to be found lacking or ineffective by their peers.

Despite the positive role which these organisations have played, HIV (sometimes in tandem with TB or Hepatitis C) continues to be a major global problem. But without their, and other NGO, work in drawing attention to growing in country epidemics and in ensuring attention was paid to resourcing education and prevention, this could well have been—and could well still be—considerably worse.

In addition to coordinating and contributing to direct action on HIV, intergovernmental organisations also play a role in shaping international legislation and regulation. This impacts in areas such as human rights, access to HIV treatment, the continuing development of new drugs and ongoing HIV research. For example, the cost of HIV drugs has historically been the biggest barrier to access to treatment in developing countries and has been overcome through the WTO TRIPS Agreement and the granting of generic licenses for drug manufacture. This has meant that countries such as Thailand and India have been able to supply drugs to those who need it at a vastly reduced cost. The continued work of organisations such as the WTO will be vital to ensure continued access to medication, as in-country intellectual property legislation develops and new political and commercial pressures are brought to bear on developing countries with HIV epidemics.

HIV will continue to be a major international concern for decades to come, with 2.5 million people newly infected in 2007 alone. With continuing improvements in the spread and accessibility of effective treatments, this means increasing numbers of people living with HIV each year. It will be vital for governments to continue to make and improve provision for people with HIV within their health and social care, and to fight for the eradication of social stigma which helps to spread the virus and hinders outreach to prevent its transmission.

The future role of intergovernmental bodies in addressing this stigma and other human rights abuses which fuel the spread of HIV, as well as their support in rolling out treatment availability and best healthcare practices, will continue to be an important one. It is THT's view that the United Kingdom should continue to play a strong guiding and supporting role in these organisations in order to fulfil our international duties, in particular through the excellent work of DFID and in supporting the Global Fund to fight AIDS, TB and Malaria.

February 2008

Memorandum by International HIV/AIDS Alliance

1. THE INTERNATIONAL HIV/AIDS ALLIANCE'S INTEREST IN THE ROLE OF INTERGOVERNMENTAL ORGANISATIONS TO CONTROL THE SPREAD OF HIV/AIDS

The International HIV/AIDS Alliance ("the Alliance") is a partnership of civil society organisations working together to strengthen community responses to AIDS. Established in 1993, the Alliance has a secretariat in Brighton, UK, and civil society partners in 32 developing countries in Africa, Asia, Latin America, the Caribbean and Eastern Europe.

The Alliance receives Programme Partnership Agreement (PPA) funds from the UK Department for International Development, and is supported also by development funding from the US Government and the European Union, along with development funding from the Governments of Sweden, Norway, Canada, Denmark and the Netherlands, along with support from private foundations and the Global Fund for AIDS, TB and Malaria.

For over five years the Alliance has had a collaborative centre agreement with UNAIDS, the global coordinating organisation of the UN response to AIDS. The agreement acts as a focal point for our many joint activities. We also have a long history of working closely with WHO and Unicef to advance community based HIV treatment and care, and to advocate for child-centred responses to the needs of orphans and other children affected by HIV/AIDS.

This work with these intergovernmental agencies on AIDS is "fed" by our HIV programming experience at the grass roots. Working with communities in 32 countries who are delivering HIV prevention, treatment and care services brings with it much valuable experience and insights.

We therefore think that the Alliance is uniquely placed to respond to this inquiry—as an organisation that is responding to AIDS "on the ground", as well as working in partnership with intergovernmental organisations, and observing the practice of others.

2. THE GLOBAL HIV/AIDS EPIDEMIC

UNAIDS/WHO estimate¹ that the number of people living with HIV in 2007 was 33.2 million. Of those 33.2 million, they estimate that 2.5 million were newly infected in 2007.

The number of people who died of AIDS in 2007 was 2.1 million, despite advances in anti-HIV treatment.

These figures mean that on average 6,800 people become infected with HIV every day, and over 5,700 people die from AIDS, mostly because of inadequate access to HIV prevention and treatment services.

¹ UNAIDS (2007) AIDS Epidemic Update
<http://www.unaids.org/en/KnowledgeCentre/HIVData/EpiUpdate/EpiUpdArchive/2007/default.asp>

These figures provide a compelling answer to the Committee's question as to the progress being made to reduce the spread of communicable diseases.

UNAIDS and WHO continue to assert that the HIV pandemic remains the most serious of infectious disease challenges to public health.²

3. THE MAIN UNDERLYING CAUSES OF HIV INFECTION, AND CHANGES IN INCIDENCE AND PATTERN

HIV continues to be spread largely by unprotected sex and injecting drug use. The global prevalence of HIV infection is remaining at a steady level, although the number of people living with HIV is increasing because of ongoing new infections with longer survival times, measured from a continuously growing population.³

In the recent past UNAIDS has illustrated a reduction in AIDS-related deaths, partly attributed to the recent scale up of treatment access.⁴ Some localised reductions in HIV prevalence has been observed in some countries, along with a reduction in the number of annual new HIV infections.

Global and regional trends in HIV epidemiology point to two main patterns in the evolution of HIV/AIDS⁵:

- Generalised epidemics—affecting large numbers of people from the general population—exist in many sub-Saharan African countries, particularly Southern African countries.
- Epidemics in the rest of the world that are primarily concentrated amongst marginalised populations—men who have sex with men, injecting drug users, sex workers and the sexual partners of sex workers.

4. THE MAIN NON-HEALTH CAUSES OF HIV/AIDS

Vulnerability to HIV/AIDS is shaped by a range of social and cultural factors. These vary in different settings, reflecting different cultural and social processes. Sexuality, the status of women, cultural traditions or taboos in relation to drug use, poverty and access to health care are all social factors that influence HIV vulnerability. Some of these particular social processes are described here.

4.1 *Men who have sex with men*

Sex between men, particularly anal intercourse without a condom, is one way in which HIV and other sexually transmitted infections are transmitted. Although HIV prevalence rates among men who have sex with men are high in some countries; due to the relative invisibility of male to male sex, sex between men is likely to be an unrecognised factor in many national and regional epidemics.

In a few societies sex between men is widely accepted; in some it is tolerated, and in many it is the subject of strong disapproval, legal sanctions and social taboos. Official indifference or hostility means that there are few HIV prevention and care programmes for men who have sex with men in developing countries. It also means that little research has been undertaken to discover HIV prevalence rates, how many men are at risk and how best to provide them with the information and skills they need to protect themselves and their sexual partners.

4.2 *Sex workers*

Sex workers are key to the dynamics of most HIV epidemics; the potential for a large number of sexual partners increases the likelihood of exposure to HIV for sex workers and/or the possibility of exposing others to HIV.

HIV prevention in the context of sex work rests on a range of factors including the legal and policy environments in which sex work occurs; the legal, social and economic status of sex workers; and the capacity of sex workers to organise themselves and to identify and implement effective responses to the challenges they face, including HIV.

Although many countries criminalise sex work and thereby subject the act of buying or selling sex for money to criminal sanction; sex workers have the same human rights as everyone else, particularly rights to education, information, the highest attainable standard of health, and freedom from discrimination and violence, including sexual violence.

² *ibid* p 4.

³ UNAIDS (2007) AIDS Epidemic Update
<http://www.unaids.org/en/KnowledgeCentre/HIVData/EpiUpdate/EpiUpdArchive/2007/default.asp>

⁴ *ibid*.

⁵ *ibid*.

4.3 *Injecting drug users*

Injecting drug use is estimated to account for one-third of new infections outside Sub-Saharan Africa.⁶

Despite the importance of preventing HIV among injecting drug users, coverage of HIV prevention for this population is at best 5% globally.⁷

Use of contaminated injection equipment during drug use is the major route of HIV transmission in Eastern Europe and Central Asia, where it accounts for more than 80% of all HIV cases. Unsafe injecting is also the entry point for HIV epidemics in a wide range of countries in the Middle East, North Africa, South and South-East Asia and Latin America.

Beyond the physical risks associated with drug injection, drug users are vulnerable to HIV because of their social and legal status. Ironically, in many countries this means that HIV interventions are not legally available to drug users, or that drug users are unable or unwilling to access them for fear of recrimination or arrest.

4.4 *Prisoners*

Prisons are sites for drug use, unsafe injecting practices, tattooing with contaminated equipment, violence, rape and unprotected sex. Conditions in most prisons make them extremely high-risk environments for HIV transmission, leading them to be called “incubators” of HIV, hepatitis C and tuberculosis. They are often overcrowded and offer poor nutrition with limited access to health care.

Both male and female prisoners often come from marginalised populations, such as injecting drug users or sex workers, who are already at increased risk of HIV infection.

4.5 *Women and girls*

The vulnerability of women and girls to HIV/AIDS is particularly significant in sub-Saharan Africa where 60% of those living with HIV/AIDS are women. That figure increases to 75% amongst 15 to 24 year olds. Sexual violence, early marriage, sexual harassment and harmful traditional practices such as female genital mutilation all increase women's vulnerability to HIV/AIDS.

The reproductive rights of women living with HIV/AIDS are regularly violated. HIV positive women experience generally very poor access to services to prevent mother to child HIV transmission, and HIV positive women are stigmatised for both not having children when social norms require that of women, as well as discouraged from for having children because of their HIV status.

4.6 *HIV/AIDS is fuelled by human rights violations and human rights violations exacerbate the impact of AIDS*

Despite the fact that we have understood the relationship between HIV and human rights almost since the beginning of the epidemic,⁸ human rights abuses continue to fuel AIDS and human rights violations continue to exacerbate the impact of the disease.

The destruction wrought by HIV/AIDS is fuelled by a wide range of human rights violations, including sexual violence and coercion faced by women and girls, stigmatisation of men who have sex with men, abuses against sex workers and injecting drug users, and violations of the right of young people to information on HIV transmission.

HIV prevention programmes continue to be stalled and undermined by these abuses, and assessments of the effectiveness of particular interventions continually fail to address the problem of the abjectly hostile policy environment for HIV prevention, treatment and care in the countries in which we work.

Human rights violations only add to the stigmatisation of people at highest risk of infection and thus marginalise and drive underground those who need information, prevention services and treatment most desperately.

Abuses also follow infection. People living with HIV/AIDS are subject to stigmatisation and discrimination in society, including in their communities, in the workplace and in accessing services.

One of the most prominent and enduring insights arising out of the Alliance's HIV programming in the last twelve years is that effective prevention of the epidemic will be impossible as long as the human rights abuses that fuel infection, and follow it, go unaddressed.

⁶ UNAIDS (2006). Report on the global AIDS epidemic. http://www.unaids.org/en/HIV_data/2006GlobalReport/default.asp

⁷ UNAIDS (2006). Report on the global AIDS epidemic.

⁸ UNAIDS, *HIV/AIDS and Human Rights: International Guidelines*, September 1996.

4.7 *No commitments to vulnerability reduction*

Global HIV prevention efforts continue to prioritise risk reduction and impact reduction interventions over vulnerability reduction interventions.

Programmes that provide information to drug users about safe injecting, but then jail drug users for the possession of clean injecting equipment, only to rapidly intensify their vulnerability to HIV in prison. Programmes that provide sexual health services to sex workers but then provide no protection from violence and coercion to engage in unsafe sex. Programmes that educate girls about HIV transmission undermined by inadequate police and judicial responses to rape and by social and cultural norms that condone rape. Programmes that seek to educate men who have sex with men about HIV transmission undermined by violence, imprisonment and social exclusion.

Just as human rights are essential to reducing vulnerability and mitigating the impact of AIDS, effective HIV programming depends on good governance, supportive laws and policies and the transparent and comprehensive application of the rule of law.

In many of the countries in which we are working there is a profound and widening gap between what is said about the importance of human rights in relation to fighting the epidemic, and what is actually being done.

4.8 *The global AIDS services gap*

The latest available data for coverage of services for HIV/AIDS prevention, care and support in low and middle income countries provides a compelling demonstration of the HIV services gap for sex workers, men who have sex with men and injecting drug users.

Data from a UNAIDS/USAID/WHO/Policy Project study⁹ estimates coverage of basic HIV services for injecting drug users at an appalling 5%. The same study estimates coverage of basic HIV services for men who have sex with men at 11% and for sex workers, 16% coverage. In the UNAIDS report for 2006¹⁰ they cite coverage data from 2005 that shows only 9% of men who have sex with men received any type of HIV prevention service in that year, and that less than 20% of injecting drug users received any HIV prevention services.

5. THE PRINCIPAL BLOCKAGES TO ACHIEVING PROGRESS IN THE PREVENTION AND CONTROL OF HIV/AIDS

The July 2005 G8 commitment to universal access to HIV treatment, care, support and prevention marked a significant development in global AIDS policy. From that momentous commitment followed the 2005 World Summit Outcome (resolution 60/1), whereby all UN Member States committed to a massive scaling up of HIV prevention, treatment and care with the aim of coming as close as possible to the goal of universal access to treatment by 2010 for all who need it.

And on 2 June 2006 at the High Level Meeting on AIDS, the UN General Assembly committed to scale up towards the goal of universal access to comprehensive HIV prevention, treatment, care and support by 2010.

These commitments underline the imperative for rapid scale up of services to prevent and treat HIV/AIDS, and that support and care for those affected by AIDS.

One of the chief tests of the commitment to universal access both at the national and international level must be to close the HIV services gap for those most at risk of HIV.

Closing the HIV services gap, and improving the legal and policy environment for effective AIDS responses, requires significantly more resources than those that are available,¹¹ along with better instruments to deliver those resources to those most in need.

The Alliance asserts here that neither the resources, nor the instruments to properly invest in fighting AIDS, are currently available.

⁹ USAID, UNAIDS, WHO, CDC and the POLICY Project, *Coverage of selected services for HIV/AIDS prevention, care and support in low and middle income countries in 2003*, Washington, June 2004.

¹⁰ UNAIDS (2006) *Report on the Global AIDS Epidemic*.

¹¹ UNAIDS, in *Financial Resources Required to Achieve Universal Access to HIV Prevention, Treatment, Care and Support* (September 2007) estimate that the global resources gap for AIDS in 2008-09 is \$20.2 billion.

6. PATENT AND INTELLECTUAL PROPERTY LAWS ARE IMPEDING ACCESS TO ANTI-HIV MEDICINES

The high cost of anti-retroviral treatment (ART) has been a significant barrier to universal access. This barrier has been substantially overcome in many countries at the onset of competition from generic manufacturers. Generic competition has reduced the price of first-line ART from \$10,000 per patient per year to the current level of approximately \$130 per patient per year. The impact on access to ART as a result of these price reductions cannot be overstated.

New and future ART¹² will not be so cheap. New intellectual property legislation in countries like India is pricing treatment beyond the reach of poor countries and poor people.

Flexibilities within the TRIPS Agreement should be supporting countries to import and export generic medicines to protect public health. Yet the technical complexity of these flexibilities, along with political pressure—that often accompany Free Trade Agreements—undermine the ability of countries with high HIV burdens to benefit from these flexibilities.

“Patent pooling”, which allow for the collective management of intellectual property rights, offer some important potential solutions to overcoming the barriers to generic drug production.¹³ Patent pooling is on the agenda of the WHO-led Intergovernmental Working Group on Access to Medicines, due to conclude its plans and recommendations at the end of April. Progress on patent pooling, along with other measures to advance generic competition and to strengthen the global research and development effort, will be crucially important to the future of access to ART.

7. UK GOVERNMENT COMMITMENT TO INTERGOVERNMENTAL BODIES FOR THE FIGHT AGAINST AIDS

7.1 *UNAIDS and WHO*

The Alliance welcomes the UK Government’s support for UNAIDS and WHO as key technical agencies in the fight against HIV/AIDS. The normative guidance on HIV prevention, treatment and care provided by both agencies is vitally important, and in the main, of a high quality and drawing on the latest available evidence of effectiveness.

WHO have importantly set out the evidence base for controversial but effective approaches to preventing HIV with, for example, injecting drug users. The Alliance welcome this guidance, but are advocating for a much bolder and active role for WHO in country dialogues with national governments who continue to ignore best practice and favour less controversial, less effective AIDS interventions.

Discrimination in health care settings is widely reported by people living with HIV. WHO can play a much greater role in challenging HIV-related stigma and discrimination in health care settings by addressing the unscientific and discriminatory attitudes to HIV/AIDS held by health care workers across the world.

7.2 *Unicef*

In a similar way, the Alliance values the normative and co-ordination role played by Unicef as the global technical lead agency on HIV and children and young people. The UK Government supports this global co-ordination and leadership role played by Unicef. However, the UK Government also supports Unicef’s operational role as a programmer of services to children affected by HIV and AIDS at a country level. It is this role—as an operational programming agency—that is questioned here.

The programming of services at national and sub-national levels is best undertaken by organisations that can promote sustainability and that can build capacity. The Alliance holds that UN agencies offer only limited potential as operational agencies, they have high transaction costs, and are unable to demonstrate impact. In the period of the last UK global AIDS strategy, the UK Government invested substantially in Unicef as the lead agency to deliver programmes to children affected by AIDS in Southern African countries. The success of this investment is unclear.

¹² Newer ART may be safer, more effective and/or necessary as second-line therapy for those developing side effects or resistance to first-line drugs.

¹³ Discussed in more detail in the Stop AIDS Campaign briefing *Shaping the UK’s HIV/AIDS Strategy*, <http://www.stopaidscampaign.org.uk/IfNotNow/documents/ShapeUKHIVStrategy4Page.pdf>

7.3 UNODC and the International Narcotics Control Board

The UK Government supports the UN Office on Drugs and Crime (UNODC) as the UN agency responsible for co-ordinating international illicit drug control activities. The illicit drug control system that the UNODC advances has as its primary purpose the restriction of the production, distribution and use of controlled drugs. This international system of law enforcement and drug control often clashes with and undermines the more health-oriented “harm reduction” approach to drug use, particularly in light of the particular vulnerabilities to HIV of drug users. This clashing of approaches results in the routine and large scale incarceration of drug users, and undermines needle exchange services, access to methadone and other opiate substitution treatment for drug users, as well as peer outreach services that educate drug users about HIV prevention.

In amongst this clashing of approaches, UNODC are increasingly acting as operational agents—like Unicef—of HIV and harm reduction programmes across Asia. Whilst other parts of UNODC support governments who continue to routinely incarcerate drug users.

UNODC policy on HIV/AIDS, harm reduction and drug use is variable, and often unscientific. And UNODC practice often undermines the commitments made by UNAIDS and its co-sponsors to advance the human rights of marginalised populations vulnerable to HIV/AIDS.

This inconsistency is costly—both in financial and human terms. The Alliance urges the UK Government to play a much more active role in pursuing cohesiveness and consistency in UN policy on HIV/AIDS and drug use, which means for UNODC, a greater focus on protecting health and reducing the harm caused by drug use.

7.4 The Global Fund to fight AIDS, TB and Malaria

The Global Fund is a crucial source of international funding for health, providing approximately 21% of funding for AIDS, 67% of malaria funding, and 64% of TB funding. By mid-2007, and since 2003, it has disbursed US\$3.7 billion in 132 countries. These resources have provided ART for 1.1 million people, TB treatment for 2.8 million people, and distribution of 30 million insecticide-treated bed nets to protect against malaria. Many millions have received counselling, care, support and training. The Global Fund estimates that programmes supported by their funding have saved 1.8 million lives to date.¹⁴

The UK Government has always been a strong supporter of the Global Fund and we assert that this must continue, and expand. We acknowledge some of DFID’s concerns about the Global Fund—that an additional financing institution adds to transactional costs, and adds to the complex task of donor harmonisation at a national level. But the performance of the Fund, to make a substantial AIDS impact in only four years, is impressive. It is difficult to see comparable impact from some of the other intergovernmental agencies that DFID supports.

The Alliance, along with other UK based international development NGOs,¹⁵ are calling for a tripling of the UK Government’s current annual contribution—from US\$200 million in 2007 to US\$600 million in 2010, in order to achieve the universal access commitments made in 2006.

The Global Fund is a uniquely transparent and accountable financing mechanism that promotes *country-led* as distinct from donor-led or government-owned approaches. A cross-section of interests, particularly those of people with HIV/AIDS and other representatives of civil society, is represented in the governance of Global Fund. These open governance structures are supported by a variety of systems and processes—critically at both country level and internationally—that explicitly promote transparency and accountability. This is valued highly by global civil society and other stakeholders.

This culture and practice of openness contrasts sharply with the culture and practice of other international institutions.

7.5 The World Bank

The World Bank’s progress on addressing AIDS has been variable. Its “business as usual” approach in the first decade of the AIDS epidemic, whereby AIDS was mainstreamed into broader development programmes, has been widely critiqued. In response to this criticism, the World Bank’s Multi-country AIDS Programme (MAP), was established to resource much more substantial AIDS-focused programmes.

The Alliance supports programmes such as the World Bank MAP that elaborate clear and precise AIDS targets, and that involve a range of stakeholders, including governments, but also importantly, civil society, in the planning and delivery of interventions.

¹⁴ *Results at a Glance*, Global Fund for AIDS, TB and Malaria, June 2007.

¹⁵ Stop AIDS Campaign www.stopaidscampaign.org

Given the UK Government's substantial investment in the World Bank as an intergovernmental agency involved in the global AIDS response, the Alliance urges much greater transparency—in terms of the UK Government investment, and in terms of the Bank's AIDS programmes and their impact.

8. THE LIMITATIONS OF GOVERNMENT-TO-GOVERNMENT RESPONSES TO HIV/AIDS

Whilst there is demonstrable progress in the amount of global resources available for HIV/AIDS, and progress on the number of people receiving anti-HIV treatment, UNAIDS evidence vast gaps in access to basic HIV services, particularly for those most marginalised.

DFID acknowledge the special needs of these marginalised populations, yet invest large proportions of AIDS resources in national governments and in intergovernmental institutions that relate primarily to governments. This will never be enough to stop AIDS.

The problem of national governments and their inability to direct resources to marginalised populations is evidenced by Sharma et al¹⁶ who demonstrate the inability or unwillingness of national governments to know about or respond to HIV epidemics amongst marginalised populations:

*... most countries surveyed are providing few resources to prevent or reduce epidemics amongst groups most vulnerable to HIV infection. In some cases, epidemiology and resource allocation are going in opposite directions. In most cases, some resources are provided, but at such low levels they are unlikely to have any significant impact on epidemics.*¹⁷

This problem is also recognised by UNAIDS:

*While funding for HIV programmes has increased in recent years, many countries fail to direct financial resources towards activities that address the HIV prevention needs of the populations at highest risk, opting instead to prioritise more general prevention efforts that are less cost effective and less likely to have impact on the epidemic.*¹⁸

The independent evaluation of the UK Government's global AIDS strategy identifies this problem as well:

*There are concerns that PRSPs may not be an effective mechanism for reaching priority groups, as a result of poor national prioritisation and political barriers to addressing sensitive and contentious issues.*¹⁹

The reviewers go on to recommend a flexible mix of financing instruments to address this problem.

The National Audit Office, in its enquiry on global AIDS spending by the UK Government, highlighted how weak DFID's performance management of multilateral institutions was.²⁰ There has been little progress to address these weaknesses since they were identified in 2004.

The Alliance acknowledges that national governments should always be the principle partners of the UK Government in AIDS and other development efforts. We also acknowledge that intergovernmental organisations provide critically important technical support to governments, along with important leadership and co-ordination roles. But to really reach the hard to reach—the criminalised, the marginalised, the hidden and at-risk populations—the UK Government needs to diversify its range of investments beyond national governments and intergovernmental institutions that relate primarily to national governments, to more substantial investments in civil society-led responses. Its investments in intergovernmental institutions should be performance-related, transparent and consistent with its commitments set out in its global AIDS strategy.

February 2008

Examination of Witnesses

Witnesses: MR NICK PARTRIDGE OBE, Chief Executive of the Terrence Higgins Trust, and DR ALVARO BERMEJO, Executive Director of the International HIV/AIDS Alliance, examined.

Q423 Chairman: Good afternoon. Welcome. Can I first of all tell you that our main focus in these hearings is on intergovernmental organisations and how well they are functioning. We obviously have an interest in the diseases per se, but only in as much as this general issue of how well are the relevant intergovernmental organisations responding. This session is being recorded. You will be able to see a

¹⁶ Sharma, McCallum and Burrows, *Is there anyone left in the general population?* AIDS Projects Management Group, August 2005, www.aidsprojects.com

¹⁷ Ibid p 6.

¹⁸ UNAIDS, 2006 Report on the Global AIDS Epidemic.

¹⁹ Drew R and Attawell K, *Interim Evaluation of Taking Action: the UK Government's Strategy for Tackling HIV and AIDS in the Developing World*, February 2007.

²⁰ *Responding to AIDS*, National Audit Office HC 664 Session 2003–2004: 18 June 2004.

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record of your comments and make any factual corrections. If there is anything you have missed out or think later you would have liked to have said, please write in with those details. I understand, Mr Partridge, you are the Chief Executive of the Terrence Higgins Trust; and, Dr Bermejo, you are the Executive Director of the International HIV/Aids Alliance. Is there anything you would like to say first, briefly, before I go into the first question?

Mr Partridge: No, that is fine.

Dr Bermejo: No.

Q424 Chairman: One other matter. It is just possible we will have a vote in a moment, so if you hear bells ringing we will get up and leave and come back in about ten minutes.

Dr Bermejo: We should wait?

Q425 Chairman: I am afraid so. You will stay, I hope. Can I, first of all, focus on the World Trade Organisation and the TRIPS Agreement, which I think you are both familiar with. My understanding, and that of the Committee, is that it plays an important role in lowering the cost of HIV drugs, but there is some suggestion now that as a result of trade agreements that flexibility is being eroded. I would like to hear a little bit more about whether that is your view, first of all; and, secondly, if so, why, and what should we be doing about it.

Dr Bermejo: Thank you, my Lord Chairman. I would like to contribute a little bit of our experience to that question. Certainly our view has been that the flexibilities introduced into the TRIPS Agreement on paper have been very good, they are the type of thing that we need; but it has been the implementation of them that has been difficult, complicated by, if one wants to call it, the bullying behaviour of some of the big players in trade. In particular, around the link with Free Trade Agreements is that a number of countries, when signing up to a Free Trade Agreement, either have been asked to introduce in their domestic legislation some legislation that would prevent the exercising of those flexibilities or that has been written into the Agreement themselves. This is particularly worrying from our perspective, the HIV perspective, because while TRIPS and the pressure from advocates and the production of generics have lowered the price of first-line drugs, in any country, as has happened here in the UK, as treatment rolls out resistance begins to be generated to those first-line drugs and one needs to move to second-line drugs. The price of those second-line drugs has not yet been reduced and, unless we can exercise these flexibilities, they will not be reduced and the treatment will thus become unsustainable. We have already seen that in a number of countries. If one looks at Thailand, for example, they are spending

around about 40 per cent of their budget for anti-retroviral drugs on buying second-line drugs for the eight per cent of those on treatment that need second-line drugs. So the ability to implement these flexibilities without retaliation from the countries where some of these pharmaceutical companies are based is critical.

Q426 Chairman: Before I bring in Lord Hannay, can you tell me which international organisation do you think would be best placed to intervene in order to address that problem?

Dr Bermejo: WTO remains a key player, but probably from the point of view of anti-retroviral drugs in particular it is UNITAID, a newly created international intergovernmental organisation which has a specific mandate to reduce the price of second-line drugs and which is looking at doing that through pooled patents mechanisms, in a way would take the pressure away from individual countries that have very little negotiating power when trying to implement this and bring it to an intergovernmental organisation that has been created particularly with a niche, if you want, in this particular area.

Q427 Chairman: The World Trade Organisation would not take the lead even though presumably they are aware of the problems you are flagging up?

Dr Bermejo: I think it is more difficult to see them taking the lead.

Q428 Chairman: Why?

Dr Bermejo: Because of the politics, I guess, the dynamics and the difficulties they have had first to reach the Agreement. Reopening at the WTO and further rounds would probably mean a move backwards rather than forwards. I think that is particularly likely.

Q429 Lord Hannay of Chiswick: I think part of the answer is that WTO does not negotiate Free Trade Agreements; it is the framework within which countries bilaterally negotiate. Could I just ask, because there are an awful lot of Free Trade Agreements now around the world, which ones specifically are those in which there are the problems you have identified about lack of flexibility and pressure being put on countries to commit themselves not to have these generic drugs?

Dr Bermejo: The ones I am more familiar with that have this are with most of the Latin American countries.

Q430 Lord Hannay of Chiswick: Sorry, between who and the Latin American countries?

Dr Bermejo: The United States and Latin American countries, Central America and South America.

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Q431 Lord Hannay of Chiswick: You mean Chile and Colombia?

Dr Bermejo: And Central America in their negotiations for trying to get a fast track, this was included there. Thailand clearly saw after they—

Q432 Lord Hannay of Chiswick: Again, and the United States?

Dr Bermejo: Yes. All the cases we are aware of are with the United States.

Q433 Lord Hannay of Chiswick: I see. That is rather an important point because the European Union has a considerable number of Free Trade Agreements around the world and it is rather important to know that you are not talking about the European Union.

Dr Bermejo: Yes.

Q434 Chairman: Basically UNITAID would be the best one to actually say, “This is the problem and this is what needs to be done about it”. Are they doing that or not?

Dr Bermejo: They are. It is certainly part of their new strategy and they are coming up with a way to do it. It is early days. It is a fairly new intergovernmental organisation, but it has got it in its strategy and we will see how far it can get. We think that it needs to be supported to do that.

Q435 Chairman: You are fairly optimistic about them having the clout to influence people necessarily, or not? I am pushing you a bit on this because I am quite interested.

Dr Bermejo: I am not sure that too many organisations have the clout to change the trade policy of the United States of America, but if one has then probably that is one of them.

Chairman: That is helpful, thank you.

Q436 Lord Desai: During our evidence the question of integration of HIV and TB treatments has come up, and UNAIDS said to us that opportunities to integrate are being missed because of poor collaboration between TB and HIV programmes. Is that your view?

Dr Bermejo: I would agree with that generally. It was truer in the past than it is now. Intergovernmental organisations have come late to an issue that shaped the response, certainly in its first 15/20 years, of very little collaboration between the two programmes, even though it was very clear from the beginning of the HIV epidemic that it would be the main cause of resurgence of the TB epidemic. In spite of that, for many years we have seen little to no collaboration. That has changed and the intergovernmental organisations have played an important role in that change, particularly WHO; and the Global Fund, by the nature of picking up funding for the three diseases

has tended to generate some greater integration. UNAIDS, to their credit, at the next Programme Co-ordination Board Review of UNAIDS to take place later this month, in April, in Thailand have selected TB/HIV integration as the main thematic area on which the UNAIDS Board will focus. We are seeing movements at the international community level as well as at national level, where we are seeing greater integration. One can certainly argue that it has come late, but we feel it is happening now and there is growing realisation that without it the TB epidemic will not be controlled and, at the same time, TB continues to be the main killer of people living with HIV.

Mr Partridge: I would agree with that. Experience within the UK is that, even though the links are clearly recognised between HIV and TB, it has still been very hard to get general practice recognising these links, particularly in African communities living in the UK, so opportunities for earlier diagnosis of HIV have been missed. It is not solely an intergovernmental issue but, right down to GP practice level for the integration, understanding and recognition of the closeness of HIV and TB. There is still much more we could do to ensure that is more closely brought together.

Q437 Lord Desai: Is there a turf war between doctors? Or is there a turf war between organisations?

Mr Partridge: Between doctors sometimes.

Q438 Lord Avebury: The statement by UNAIDS was about integrated care, and you answered the question in the sense of the medical care that has been given, or not given, in an integrated manner. Who is doing anything about the integration of prevention in terms of TB and HIV/AIDS? Which organisations are responsible for that matter?

Dr Bermejo: UNAIDS is responsible mainly for the prevention of HIV and there is a whole range of organisations that are related to the prevention of TB from the WHO to organisations like ILO and others. I think the issue of diagnosis and care, in our experience working in the field, is one where the issue of integration and missed opportunities is really there in people coming up to test at a facility for HIV that does not do TB testing, for example, and you cannot diagnose if they are co-infected, or the lack of screening for HIV in TB clinics where they are separate. I think that is still the main area where we are missing major opportunities to improve the health of these many people with co-infection. That is why I focused on that, because I think it is more an issue than the joint prevention, even though I would still argue, as I did 15 years ago, that the best way to prevent TB today is by preventing getting an HIV infection.

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Q439 Lord Howarth of Newport: Good afternoon. The Alliance was eloquent in their evidence to us on this matter on the contradictions between policy on HIV/AIDS and on drug use within the UN, and obviously that applies in individual countries. So that, if drug usage is criminalised, as you note, drug users can be jailed for possessing clean injecting equipment, prisons become incubators of HIV, and HIV intervention is not legally available to drug users. How do you think this tension should be resolved? And what would you wish to see our own Government doing to contribute to this resolution?

Dr Bermejo: The reason we were so eloquent was because we see this as a major impediment to the work of the Alliance in supporting HIV control in many of the countries where we work, whether it is Ukraine, Thailand, China, many places where the HIV epidemic is fuelled by injection of drugs with unclean equipment. We need to remember that is still responsible for one-third of the new HIV infections outside of Sub-Saharan Africa. What is happening is that we have countries supported by UNODC instituting and being given guidance and technical support around drug control for measures that really criminalise drug users and those in possession of drugs. What we see in many cases is services that need to meet their targets waiting outside some of our clinics, for example, where methadone is being prescribed as substitution maintenance therapy or where drug users are coming to get their treatment and they are being detained outside the doors. This is while the clinics are being run at the same time by the health services, so you have this contradiction at country level which is equally apparent at the intergovernmental organisation level. So, while we have WHO with a harm reduction policy which is evidence-based and which has been standing for a long time and approved by the World Health Assembly, we have UNODC which until January this year had very little to say as to the evidence behind harm reduction approaches and was really taking a drug control approach and contributing to these kinds of responses at country level. What can the UK do? Our feeling has been that the UK Government has been pretty consistent in terms of its policy being evidence-based and advocating for that, and we saw them working two or three weeks ago on the Commission on Narcotics advocating a policy that would recognise both the evidence behind harm reduction approaches and the human rights implications of some of the approaches that UNODC has taken. The truth is that UNODC still spends three times more money on drug control and criminalisation than it does on prevention and treatment. I think one thing is the policy effort the UK is doing, which is probably in the right direction, and another thing would be to look at where the money is going and whether or not it is supporting

those same policy objectives, and our view is that part of it certainly is not.

Q440 Lord Howarth of Newport: Some might take the view that you are quite charitable about our own public policy stance in that we are not without this contradiction ourselves?

Dr Bermejo: Yes.

Q441 Lord Howarth of Newport: If at UN level you have the World Health Organisation and UNODC, the left-hand not knowing what the right-hand is doing, or at least the two hands pulling in opposite directions, do you have any thoughts as to how, the governance of the UN, this kind of issue could be resolved? What would you wish to see?

Dr Bermejo: That is going into the whole issue of UN reform, which I would not know. I cannot go too deeply into that. Clearly something needs to be done, as you say, because it is just making the response so much more difficult. Certainly in many countries the epidemic will not be controlled like this. With the best political will, if we look at the Ukraine programme, where certainly well over 60 per cent of those infected with HIV are active drug users, if one looks at those who are receiving treatment, it is less than five per cent of their active drug users and that is because (a) they have to register with the state and recognise that they are active drug users, which already puts them at a major disadvantage in many ways given the criminalisation, and (b) because no substitution therapy has been available to ensure that they can adhere to this treatment. That is right on the borders of the European Union, the fastest growing epidemic in the world right now, and it will not be controlled unless there is policy change.

Lord Howarth of Newport: I do not criticise you for not embarking on the question of how you reform the UN. We will have to ask Lord Hannay to move round and be a witness!

Q442 Lord Avebury: I wonder if you can quote any evidence-based studies comparing the relative effectiveness of crime-based and health-based approaches to HIV prevention and stabilisation?

Dr Bermejo: In particular to drug use or ---?

Q443 Lord Avebury: We are talking about drug use, yes.

Dr Bermejo: All the evidence that exists—and we could quote much, and it was recognised by the Surgeon-General in the US even during the Clinton Administration, when it was still illegal—is that crime reduction approaches do not increase the use of drugs, as has been said, and do reduce the new infections amongst drug users. In the country I come from, Spain, the success in the AIDS response has been mainly through the introduction of harm

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reduction measures in prisons with a conservative government. That has caused a dramatic reduction. There is plenty of evidence around about how this, from an HIV perspective, is the right response from Australia and from the US itself. It is not lack of public health evidence, it is political will that is not there, and it is the difficulty of people saying, “Well, that’s OK, I just don’t want these Centres in my constituency or in my backyard” and all these things that are the daily realities with which we are confronted. It is not lack of public health evidence.

Mr Partridge: The public health evidence within the UK, where you can track very clearly the criminalisation approach in Edinburgh in the early 1980s, causing a very substantial spread of HIV through injecting drug use, shared needles and syringes, was completely turned around through the introduction of harm reduction techniques, the availability of clean needles and syringes, and the introduction of substitution programmes. That utterly and completely changed the course of the epidemic. This is a very real and clear example of how policy change has meant that within the UK the level of HIV infection as a result of injecting drug use has remained very low, consistently about five per cent, since 1985. That is a very real life and clear example in the UK.

Q444 *Baroness Whitaker:* I think Mr Partridge has totally answered my question, which was whether clean needles would not make all the difference.

Mr Partridge: They do make a huge difference.

Q445 *Chairman:* Having experienced, as an MP in a previous existence, the opposition to having such Centres in your constituency, is that really where the opposition comes from? Or are there other strong voices in the medical community or intergovernmental organisations saying, “No, harm reduction is not the right road to go down”? Where are the strong voices against? Or is it more general?

Dr Bermejo: In our opinion, in the countries where we work the health professionals are generally in favour of these approaches. It is not within the health profession that the resistance comes; it comes from law enforcement agencies and bodies. In the general public I think there is uneasiness with the subject which contributes to that, but we have not seen it really in the health profession.

Q446 *Lord Jay of Ewelme:* Thank you, my Lord Chairman. I was interested in what you said in the paper from the Alliance in Section 7 on the UN agencies. You talk specifically about UNICEF, but then generalise it out to talk about UN agencies more generally, and you praise their co-ordination role but express a degree of scepticism about their

effectiveness at the operational level. I just wondered if you could say a little bit more about that and the evidence you have that they are not really operating effectively at the operational level and whether you would draw the conclusion from that, which does seem to be a logical conclusion, that the British Government, for example, should be focusing more on their co-ordination role and rather less on their operational role and spending what funds they have got available on the more effective operational role of other organisations, which we will come on to later I think? I would be interested in your comments on that.

Dr Bermejo: We would certainly agree with that conclusion and that is what we were driving towards in the paper. We believe that, as an intergovernmental body on which the governments sit, they have a key role that cannot be substituted around co-ordination as well as setting norms and policy guidance on what best practice is and the standards that should be met. In that sense we believe that, if they did not exist, they would need to be invented now, so we are very much in favour and have seen the benefits of that, and a lot of the civil society organisations that we work with look to WHO or UNICEF for guidance on how programming should be done and for the policy framework in which we operate. I think where their efficacy is much more questionable—and we have seen that particularly with UNICEF and that is why they are quoted here as an example, probably because they are, of all of them, the most operational on the ground—is that in that role they are much less efficient, first because their costs are much higher than many other actors who can implement those things, and because in the most enlightened cases where UNICEF itself realises that, they hire other organisations to do that implementation and the Alliance is sub-contracted in many countries to implement some of the UNICEF programmes at country level. But then you realise that, of course, the UK Government’s money is going to UNICEF to then contract the Alliance to then implement a sort of loans programme in Mozambique and that is not a cost effective way of doing business. None of these UN bodies is cheap, so we think there need to be better mechanisms through which to do that. There is also an issue that operations that are run by the UN agencies at country level do not really leave lasting capacity behind in the same way as operations that are run by local government or local civil societies do. There are those two reasons, one from a short-term cost effectiveness point of view and the other one from a longer term sustainability point of view, leaving an enhanced capacity behind. Needless to say, we believe that in the UN reform process these operational interventions should not be where the UN sees its niche is.

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Q447 Lord Jay of Ewelme: So your model would be that the British Government, or indeed other aid donors, should give the money directly to the people who are more effective at the operational level and then it would be for them to carry it out or for them to work on behalf of UNICEF, as it were, without the money having gone down through UNICEF to start with?

Dr Bermejo: Yes.

Q448 Lord Jay of Ewelme: You said earlier on that, if WHO and UNICEF did not exist, they would need to be invented. I do not want you to get into UN reform again, but I presume that you would not say that they had to be invented exactly as they are now?

Dr Bermejo: No.

Q449 Lord Desai: You know we have this purchaser/provider distinction in national health elsewhere. Are you suggesting that those who purchase the health should not provide it, that the UN is very good at purchasing but not at providing it, and we should just bypass them and hire anybody who is good at providing it?

Dr Bermejo: I think we should hire whoever can do the job better, and better not just from a short-term perspective but also from the long-term perspective of building capacity on the ground and leaving it behind. I would not say as a matter of dogma that they need to be separated. I would just say let us purchase from the most effective providers, and I would say that domestically here as well as internationally.

Q450 Lord Desai: Is that what the Gates people do?

Dr Bermejo: I know Gates very well, but that is another big story. I do not think they really do that, no.

Q451 Chairman: It is a very good story.

Dr Bermejo: I do not think they really do that. They are still setting up their systems. They are a pretty new organisation.

Chairman: Can I move on fairly logically from that to the effectiveness of some of the intergovernmental organisations?

Q452 Baroness Whitaker: Staying with the long-term success, the Alliance says that the performance of the Global Fund is impressive, and I think I agree with you. But do you think it has made the machinery to continue after the Global Fund has departed? Is it sustainable, do you say?

Dr Bermejo: Yes.

Q453 Baroness Whitaker: As part of that, you also say, I think, that effective prevention of the epidemic will be impossible as long as the human rights abuses

go unaddressed. Is the Global Fund capable of leaving behind it that kind of organisation too?

Dr Bermejo: I think with the Global Fund one needs to understand the principles on which it is set up and two key principles in response to this are important.

The Committee suspended from 4.10 pm to 4.21 pm for a division in the House

Q454 Chairman: Can we resume, please? Hopefully you have had a little more time to consider your answer to Baroness Whitaker, Dr Bermejo, so perhaps you would continue from where you were interrupted. My apologies!

Dr Bermejo: Thank you, my Lord Chairman. There are two principles that are important for the Global Fund. One is the principle of additionality, and it was from the very beginning understood by the donor community and everybody who set up the Global Fund that their resources should be additional to what the country was spending on HIV and to what donors were already providing on HIV. The second important thing, and it had a number of conceptual changes in the way we looked at aid in the Global Fund, was the whole issue of pitching sustainability not at country level but at the international response level. The Global Fund is built on the idea that the response has to be sustainable but sustainable not just from a country perspective but from the international community perspective. It is not based on the principle that it will only fund interventions that the country can then continue funding on its own. Some of them were very clear. Some of these operations will need input for many years to come, for a generation at least, and inasmuch as the countries that are still operating on ten dollars per person per year investment for health are concerned these responses are not sustainable just with the country resources. It is based on the principle that we will as donors continue funding the Fund for many years to come, and that is the basis on which the Global Fund was created. I think that, when we discuss sustainability, we need to look at it in that context. Many of the responses around HIV treatment in particular will not be sustainable if the Global Fund were to withdraw tomorrow or in two or three years' time or when a particular grant comes to an end, so they are looking at even changing the procedure so that it becomes, rather than a round-by-round project approach, more of a credit line type of approach, that as long as the country is performing it will continue to receive that credit. It is important to understand that in the way it is operated and it has in a way changed the perspective with which we see international health and the joint responsibility that in a globalised world we have. That is particularly true for TB and less so for malaria. Malaria interventions are probably more sustainable in the traditional sense because they are short-term and

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because we will see, very quickly I hope, a reduction in transmission. So in that sense, although not going as far as the Gates Foundation have said, which is malaria eradication and which I do not believe will happen shortly, we will get close to that so the interventions will be more sustainable. On TB it is the same thing. We need to understand, and others will talk about it more later, that we cannot control TB, within our own boundaries. If we want to control TB we need to look at investing abroad and the Global Fund is a good mechanism for it.

Q455 Baroness Whitaker: So you say it could be internationally sustainable?

Dr Bermejo: Yes.

Q456 Baroness Whitaker: I was also thinking, in connection with the human rights aspects, of the participative nature of the Global Fund, that maybe that could, as it were, embed an idea of human rights protection?

Dr Bermejo: Yes. I am sorry; I did not comment on that. That is another key issue of the Global Fund, the way in which it has defined participation and national ownership beyond national governments to include civil society in that governance of the board at the international level but also at the national level of programme oversight, and that in particular the most affected groups are represented in the committees at national level and that design proposals oversee implementation, et cetera. If one looks at the proportion that the Global Fund is contributing to national responses, it is about a third of the HIV response and higher than that of the TB response. If one looks at the resources that are reaching the most vulnerable groups, the proportion is much higher. The Global Fund is a key provider of support to communities which are highly vulnerable, whether they are sex workers, men who have sex with men, drug users or prisoners. For many of these groups the Global Fund is one of the very few that are actually getting the resources to that level and they are key to the solution to the epidemic. The Global Fund's programmes go beyond just health interventions to address some of the human rights issues that are causing the vulnerability of these groups to HIV.

Baroness Whitaker: That is very helpful.

Q457 Lord Hannay of Chiswick: You spoke as if the statement that the Global Fund's funds were going to be additional was enough in itself. But additionality is a remarkably slippery concept, as anyone who has had to deal with it will have found, and the further out you get the more slippery it becomes. What criteria would you apply in judging this? And to what extent can you be sure that this is additional not just with respect to existing programmes for AIDS or TB

but also with regard to primary healthcare and so on? Can we be quite sure that the Global Fund is not sucking money away from assistance for primary healthcare in developing countries?

Dr Bermejo: That is a very good question and, as you say, it is a difficult one to be sure about. I think we can be sure of several things with Global Fund support. One that is very important is that it is not subject to the same ceilings and limitations as the IMF and other intergovernmental organisations apply to direct budget support to sector-wide schemes because they are seen as a project-specific grants. In that sense it does not get capped and then put into the pot of money that budget support does. Whether it really is all additional, from a donor perspective or from a recipient country perspective, is hard to measure but I think we know enough to know that it is not all additional, even though that is one of its principles. We have seen many donors—for example, the EU in Ukraine has made a public statement saying it is not going to continue funding HIV/AIDS intervention because it already supports the Global Fund. Clearly there the principle of additionality from a donor perspective is not operating. We have seen elements of what you say also at country level, though I still think the more general reaction that we have seen is the opposite one, which is governments saying, “The money we were already putting into HIV/AIDS from our own budget we are no longer going to put in because there is the Global Fund money and we are going to use it for primary healthcare or for something else”, which is also worrying because it reduces the political commitment from the national level to the issue and that sort of substitution, and it also undermines the additionality.

Q458 Baroness Whitaker: I think you also say that DFID's money seems to be better spent with the Global Fund than in some of the other intergovernmental agencies. We have seen a National Audit Office report highlighting weaknesses in DFID's management of international institutions. I wondered if you had any views on the two institutions DFID made to ameliorate this, that is, the Multilateral Effectiveness Framework and the Multilateral Development Effectiveness Summaries. Do you think this is important in DFID's investment strategy, as it were?

Dr Bermejo: On this one I have to confess that I personally had no idea what these two were, even though we do work closely with DFID, and I did ask around the office and none of us knew. We did call a couple of colleagues at DFID saying, “What is this, because we might get a question on it?”, and again they could not answer, so they might be very important and useful but we are just not aware of them.

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Q459 Baroness Whitaker: They are not very old organisations; they are only a few months old. They will be reported on later but they are meant to bring all these different facets together.

Dr Bermejo: But we are concerned, which is what I think the statement was saying, that we think DFID has not valued this enough. In particular, its last contribution to the Global Fund was below expectations and below what we thought we said we had seen committed in the past. When one contrasts that with the huge increase that the World Bank has got from DFID it is hard to understand the logic of that, and certainly from the perspective of the control of infectious diseases it does not make any sense. It might make it from others but from that one it does not.

Q460 Baroness Whitaker: The usual complaint is that DFID puts too much into direct credit support and not enough into the Global Fund. I will not go into this now, but there is clearly something we have to disentangle here.

Dr Bermejo: Yes, though I would say that in the last year our perspective is that that is probably driven as much from a strategic approach as from the reality of DFID having more money but fewer human resources. They are making decisions to increase the amount that is going to multilateral organisations as well as bilateral support, but that is in a way a reaction to the wrong incentive, which is trying to do more with fewer resources, but it does not make sense from a strategic perspective.

Q461 Chairman: Just before I bring in Lord Avebury, can I make sure, Mr Partridge, that your understanding of the DFID point that was raised by Baroness Whitaker is the same as Dr Bermejo's?

Mr Partridge: Yes, it is.

Q462 Lord Avebury: I just want to go back to a point you were raising earlier about the Global Fund being very good at targeting vulnerable groups. I was wondering whether you were saying that in contradistinction to UNAIDS which is a vertical programme. The Global Fund does work with the vulnerable, such as the sex workers and prisoners and so on, and that is one of its major advantages. So, if you had a marginal extra £100 million to spend in DFID, would you be putting money into the Global Fund rather than into UNAIDS? As a corollary to that question, are the Global Fund funds specifically working on the problems of women and girls that you identify in Paragraph 4.5 of your paper, where early marriage, sexual harassment and harmful traditional practices, such as female genital mutilation, increase women's vulnerability to HIV/AIDS? Is that something which the Global Fund is specifically addressing? And are they alone in doing that?

Dr Bermejo: The Global Fund has one principle that is important, which is country ownership and country design of the programmes, which they have taken beyond what others who say they have this principle have done. What they call country ownership is not just governmental ownership; it is a broader constituency at country level where these groups themselves are represented, so that influences their ability to get there. UNAIDS was the first UN agency, I believe, to create a Board that had civil society participation on it, but it is participation that has no vote and that is still a small minority. The Global Fund took it further by giving them a vote and by having effective communities on the Board, and that has contributed to shaping the programme mix, not just on the international Board but it is also true at national level. I think that explains why the affected communities and the most vulnerable groups are better represented in the programming that they implement. UNAIDS is not channelling resources in the same way, so they are more a technical response at country level; they are not a grant mechanism in the same way as the Global Fund. UNAIDS, I think, has also embraced the realities of marginalised groups and of women and children, but they have not been able to take it this far, partly because the mechanisms that the UN has made that more difficult and the Global Fund has a set-up that allows it to do that better.

Mr Partridge: I would just mention if I may, certainly from my perspective, the bravery and the leadership that UNAIDS has shown in demanding that governments really do tackle the needs of those most vulnerable to HIV infection. It goes back to its creation. Its first director, Dr Jonathan Mann, had a very clear leadership role in recognising that many governments have found it very hard to engage with men who have sex with men and with those with a history of injecting drug use, sex workers, genital mutilation and so on, and I would not wish to underplay the impact that UNAIDS has had at that policy level in leadership and in tackling very early on and consistently that which many governments wish to duck.

Q463 Lord Avebury: Can either of you quote any specific examples where any IGO has persuaded a host government to address in a practical way these specific examples that you give of the vulnerability of women and girls, the cultural disadvantages that they suffer?

Dr Bermejo: UNAIDS, for example, at the policy level took a decision to create a coalition on HIV women and girls which had seven key tracts, and Mary Robinson and a few others were part of the committee that was leading this, which I think did change the perspective. It first made people realise when it happened that the epidemic had feminised

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and had a female face now in many of the countries, and that the interventions that we were doing needed to adjust to that in many countries where that was not happening. I think they have been quite successful in doing that, in changing policy. Today, if one looks at the lists of people on treatment and the numbers of people in treatment around the world, we thought females were going to be under-represented and that is not the case because I think there has been a conscious effort to ensure that women and girls had access to treatment in many of these countries in the same way as men had, and that has been achieved. So I think there are policy interventions that have been successful in that sense, but of course, in terms of changing the gender relations that make women particularly vulnerable to HIV, I cannot say that I have seen lots of examples or that we have been really successful.

Q464 Lord Steinberg: I am one of those people who believe that prevention is better than cure, and yet it seems as if the amounts of money spent, which are vast, are much more on treatment and much less on prevention. I presume that on prevention you would say that education would be the principal factor of prevention? Would you agree that that balance, which has focused mainly on treatment, is the right way to go? Or do you agree with what I am saying, that it is much better to spend a lot more money on prevention?

Mr Partridge: Shall I start with the experience we have had in the UK, because I think it is one that helps understand the dynamics of what happens when effective treatment is brought in to any country? Certainly, we at the Terrence Higgins Trust campaigned very hard to ensure that effective treatment was made available for those for whom it was clinically needed and appropriate, knowing that in doing so—and going back to 1996 when the cost of therapy then was much greater than it is now—that was going to create difficulties for the NHS in how it funded both treatment and ongoing prevention work. What has happened since then is that clinical effectiveness and the cost effectiveness of HIV therapy are so good that we have not needed to focus on campaigning for treatment access within the UK. It is very obvious that it needed to be done, but we have seen, particularly at local primary care trust level, a significant drop in funding for prevention, continued difficulties in getting sexual relationship education as part of the core curriculum and little continued leadership around the need for ongoing HIV prevention campaigning work, both for those communities at greatest risk and more generally. There has been a financial trade off in the cost of therapy in the overall pot. Therapy has taken up a progressively larger amount of money. Also, good therapy makes people with HIV less visible in any

community because you are healthier; you can remain in work if you have stayed in work. There is less reason to be articulate and open about being HIV-positive. At a political level, when therapy is introduced which makes people healthier it does not reduce but increases, the prevalence of HIV overall. That can then easily be misunderstood as a failure of prevention. It also creates an ongoing need for funding drug therapy which can squeeze out funding for good prevention campaigns. What is vitally important is that both go hand in hand. There is, to a degree, a prevention dividend through good therapy as undetectable viral load reduces new infections. However that is balanced against a growing number of people with HIV who are sexually active for longer as they live more productive lives as a result of therapy. It is a complex interrelationship which I do not think, either in this country or internationally, we have yet cracked as to how we manage to continue investment in prevention because it is much better than going on to a lifetime's work of treatment.

Q465 Lord Steinberg: You talked principally about your experience in the UK. On the basis that the vast majority of HIV occurs in uneducated communities, wherever they are in the world, is it not time that a switch occurred? Or are you perfectly happy that the treatment and therapy come before the prevention?

Dr Bermejo: No, we are not happy in that sense. I would echo what Nick was saying. It is true internationally. There is not enough money for prevention. There is no doubt about that, but I do not think that is because there is too much money for treatment. I think it is just because there is not enough money for prevention. That is not exclusively a health ministry or health sector area. As you have highlighted, those are resources that probably need to be best invested outside of the health sector and the health ministry. That is where there is not enough money being allocated to these issues of HIV prevention. Partly it is because we tend to see HIV/AIDS just as a health issue and a disease and partly also it is because we have this myth that HIV prevention is cheap. Everybody understands that treatment is expensive, that it is for a lifetime, that you have to buy drugs, that you have to keep providing them, but people think that HIV prevention is something you do once and then you have done it and it should not cost a lot of money. You run a few campaigns, but it does require resources and we have under-funded it and under-invested in it. That is what we need to look at, as to how we put more resources into HIV prevention. That is the big question.

Mr Partridge: Oddly enough, treatment delivery is the easy part. Now, prescribing pills is not that complex. Changing behaviour long term is

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immensely complex and weighted with a whole load of moral, political and cultural stuff that is very tough to do. Prevention has become consistently more complex over the years, whereas treatment has become simpler, clearer and cheaper.

Q466 *Chairman:* My understanding is that in 2000 in the UK there were 3,000 new cases and by 2007 there were 9,000. Is that a problem about prevention?

Mr Partridge: The figures are slightly different. 3,000 goes up to about 7,800. What we need to be really clear about is that those are diagnoses. They are not directly linked to infection within the UK. Part of that considerable increase has been a result of better diagnosis services and a very minimal impact of the global epidemic within the UK through migration. We need to unpick what is happening within the UK. The bulk of transmission is between gay men in the UK and we have seen an increase in that, but that which has levelled off in the last three or four years. It is about how we ensure that those campaigns which are targeted at groups which are most vulnerable within the UK are sustained and increased.

Q467 *Lord Howarth of Newport:* It is difficult to alter cultures and in many parts of the world education provision all in all is pitifully inadequate. But should not sex education be an absolutely major preoccupation and a major drive? I do not see why it need be particularly expensive. One must assume that, if it can be effectively designed and delivered more and more extensively, it really would make a huge difference. I would be completely authoritarian about this and absolutely refuse to allow people to opt out of sex education. I would not be tolerant of schools that neglected it. It is one thing to picture how it might be done in this country and obviously a very different thing to picture how it might be done in countries in sub-Saharan Africa, but surely this must be a crucially important key to prevention?

Mr Partridge: Absolutely, yes. I totally agree with you. However, we failed to do that within the UK with all of our resources and so on, not least because of the cultural, political and religious issues. To expect that to have happened in Nigeria or Uganda or elsewhere—

Q468 *Lord Geddes:* Four weeks ago we had no fewer than four professors of medicine giving evidence to us, one of whom, Professor Johnson from University College London, told us. “In the field of AIDS, in one area you may have several different programmes operating in one town. That may have advantages, but it may have significant disadvantages if they are operating in different ways.” In the Alliance evidence, right at the end of main Paragraph 5, there is an assertion that neither the resources nor the instruments to properly invest in fighting AIDS are

currently available. Ignoring the horrors of the split infinitive, are those two bits of evidence compatible? Or are they saying different things? Is there in your opinion a need for rationalisation of the different programmes and actors, if you like, including both the IGOs and the NGOs? Are you saying the same thing there? Or are you saying something completely different?

Dr Bermejo: What we were saying was that we still do not have all the instruments. There is clearly a need to invest in more instruments, particularly on the prevention side. We have technologies and instruments now with which we have to do the best we can, but that does not mean we can stop investing in new instruments, whether it is microbicides or vaccines etc., without which the epidemic cannot be defeated from a technological point of view. In terms of the organisation set-up and architecture, Ann in her statement, which I read, is saying it can be one way or the other. Our view is clearly we need effective local responses and that is where the coordination needs to happen. This is not about some central coordination up here; it is at the community level. Communities need to be in the lead. We have seen that in a lot of the places where the Alliance works: we need local authorities to create some coordination committees that ensure that the interventions that happen in one locality complement and support each other. In that sense, we believe it is more of a local coordination issue and response, this one of a multiplicity of actors, more than something you can do at international level or national level. We have seen that work very well. Some of the new figures that are coming out of Andhra Pradesh in India, which show a dramatic reduction in the number of new infections, have been driven by multiple actors. You had there the Indian Government and many donors working with Melinda Gates, with a huge programme, the Alliance and many others, but the local authorities were very clear in assigning coordination and complementarity. That has worked well. Our view of how to respond to that has to be not with international architecture, where that is very difficult to correct, but making sure that at the local level there are coordination mechanisms that ensure that we are working towards the same national response and local response there.

Q469 *Lord Geddes:* I take your point. Concentrating on this local level, who coordinates this? I think I heard you say just now local government.

Dr Bermejo: We think it has worked better where local government creates coordination committees that involve other actors, so it is not just them dictating but creating local AIDS coordinating committees, where the mission hospital, the public hospital, the clinic, the education system, the NGOs, the sex workers' collective if there is one, all sit

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around and coordinate that response. That is what we have seen work best and in most cases it is chaired by local government.

Q470 Lord Geddes: The actors themselves are traditionally prima donnas. From experience, do you find that those prima donnas will take such coordination from local government?

Dr Bermejo: There are prima donnas, and you are right that they are not easy to coordinate; but the majority of the local response is not really one of prima donnas. We see them at international level and some organisations behave like that, but they are not the majority. With strong governments, like the Indian Government or some others, it is easier to impose that than it is with weaker ones, but the experience we have seen has been positive.

Q471 Chairman: You are using the Indian Government but there is good governmental structure in India. That is not the case with some of the African governments, for example. That would not apply?

Dr Bermejo: Yes, but we have seen the same. We have had a great evaluation in Madagascar, which is not one of the strongest governments. It is true that in Madagascar there are fewer prima donnas than in Tanzania or Kenya maybe in the response, but still we do see these things working and that is what we need to support. We really believe that is the answer.

Mr Partridge: I did wonder whether Professor Johnson was thinking about the 33 Primary Care Trusts in London!

Chairman: Much as it may seem otherwise, it is not an intergovernmental organisation.

Baroness Eccles of Moulton: This is a thread that has run through in great detail and it has been very informative. I suppose it is just worth saying that there is still a great amount to be done in building secure, horizontal health structures with—words you have used—sustainability and capacity for surviving. You have told us a great deal about that. Thank you very much.

Q472 Lord Desai: On prevention and cure, is the problem that prevention cannot be measured and therefore nobody will pay for it? Cure can be measured?

Mr Partridge: It is partly that, and that goes back to what I was trying to say about treatment that is very measurable. You have clinical trials and you can see the differences.

Q473 Lord Desai: If you want value for money, you do not prevent; you cure?

Mr Partridge: We know the value of any single, saved HIV infection, any HIV infection prevented. You have to throw a lot of prevention money in for it to become not cost effective, but it is because it is so difficult to measure and to have the right kind of trials to identify its impact that it is much tougher to do compared to drug trials.

Dr Bermejo: The prevention constituencies are not as powerful as the treatment constituencies and we need to understand that.

Chairman: Can I thank you both very much? You have been very helpful and you have given us some very clear, concise arguments. If you have any more thoughts, please write in as I have indicated.

Examination of Witnesses

Witnesses: DR SYLVIA MEEK, Technical Director, Malaria Consortium, MR ALASTAIR BURTT, Chief Executive, Target TB, MR PAUL SOMMERFELD, Chair of Trustees, TB Alert, and MS TINA HARRISON, Awareness Officer, TB Alert, examined.

Q474 Chairman: Can I welcome you all? Our focus is on intergovernmental organisations, the effectiveness of them and how that can be improved. Your comments are being recorded. The transcript will be sent to you for any factual corrections. Again, if you want to add anything that occurs to you after this session, please feel free to do so. The first question is about the fragmentation and confusion that is alleged to be the case in intergovernmental organisations dealing with these infectious diseases and whether there needs to be some rationalisation of those organisations, whether they are overlapping, competing or contradictory in some way, or whether it is working quite effectively. Within that question

there is also the obvious one of the leadership of the WHO.

Mr Sommerfeld: Talking from the perspective of tuberculosis, we would say that there is no particular problem of fragmentation. We clearly deal with the World Health Organisation and its adjunct partners, Stop TB Partnership, as the lead agencies at an international level for talking about tuberculosis matters. We are well aware of other players—the Global Fund, the World Bank, UNITAID, UNAIDS and so on—but that is the way the world is. We are not perceiving any big, terrible, territorial battles between any of these that are causing difficulties to us.

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Ms Tina Harrison**Q475 Chairman:** Or overlapping?

Mr Sommerfeld: Or even serious overlapping. Every now and again there are some boundary issues but they are not particularly significant or major ones. It is more that we perceive the WHO as the centre of this little world and we are well aware of some of the other players. We deal with them and occasionally find ourselves having to deal with small boundary questions between them. There sometimes are issues because the Global Fund has slightly different criteria about the ways in which it wants to behave or to give out grants which do not quite tally with the way that we are running things like the Global Drug Facility, but these are not major, fundamental problems.

Dr Meek: Looking at the malaria side, in the past there have been major problems perhaps of a certain amount of competition between intergovernmental organisations. The problem is diminishing, partly as a result of efforts by all the organisations and NGOs and others to work through the Roll Back Malaria Partnership which, although it has had its ups and downs, has helped the different organisations to think through their roles more clearly. Although the WHO is clearly the technical lead organisation in controlling malaria, the control of malaria has required a lot of interventions which are not technical, much more related to delivery. For instance, bringing in the private sector, a lot of issues related to other sectors which perhaps the World Bank has a comparative advantage in. It is a problem that is getting under control better than in the past.

Q476 Chairman: Do you see the World Health Organisation as being an effective leader, or not?

Dr Meek: It varies from time to time, depending on individual personnel within different parts of the organisation. I used to work for them for several years. That is its role and it has some very strong parts and some less strong parts. It was in a certain amount of competition with the Partnership about two or three years ago but I think people have moved on from that, so its leadership is getting clearer. There are one or two areas where perhaps they need a bit more technical strength and they have set up groups to advise them.

Q477 Chairman: Mr Burtt, you speak for Target TB. Do you have a different view to those just expressed?

Mr Burtt: No. I would say we agree, not least because we managed a word about it beforehand. The messages that we give and that intergovernmental organisations give are the same. We do not find ourselves saying things that contradict each other, which perhaps is an indication of the coordination between the different organisations. They do work well together, in our opinion.

Mr Sommerfeld: Dr Meek raised the importance of these partnerships. In the TB world it is called the Stop TB Partnership. Roll Back Malaria and equivalent bodies are very effective, informal groups through which a lot of collaboration and coordination take place. I am here because I am Chair of TB Alert but for the past two years I have also been Chair of the Advocacy and Communication Working Group of the Stop TB Partnership and so I sit on its Coordinating Board, where many of the other players are represented. Once every six months we all sit down together and the leading lights of the world hear all the same papers, reflect on them and a lot of informal collaboration just simply happens.

Q478 Lord Hannay of Chiswick: All the questions have been answered so far from the point of view of donor organisations or donor governments or donor international organisations. Could you perhaps answer the question from the point of view of a small, developing country which finds itself in the presence of an extraordinary multiplicity of organisations, all doing different variants of the same thing? To what extent are you as confident as you are about donor coordination about the ability of a not necessarily very strong developing country to cope with this multiplicity? To what extent, if they cannot cope, are they liable then to become very easy to manipulate by whatever donor's consensus there is?

Dr Meek: It is a useful perspective. There is an issue in some countries. A lot of it boils down to how much money different technical organisations bring to the table. In countries where people are not getting enough to pay a living wage, clearly they have to prioritise the use of their own time, so that does become quite an issue. There are efforts in most countries to try to have some mechanisms of coordination among the different technical agencies. They work quite well in some countries. In others they do not. We do sometimes see examples of conflicting advice being given to countries. The malaria world is trying its best to move to a much more harmonised way of working. Through Roll Back Malaria, they have set up a harmonisation working group at international level. At regional level, which is multi-country and groups of countries, they have networks which aim to coordinate technical assistance. Within countries there is usually some mechanism of coordination, but it is variable and there are examples where it could be improved. Finance is a major part of it.

Mr Burtt: My experience is mostly of working alongside local partner organisations. Certainly one of the principles that we follow is that these organisations must be working within the national TB control programme. It is true to say that in the

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countries in which we are working the national TB control programmes have perhaps sorted that out. If there are conflicts, they seem to be higher up and we are not seeing it down at local level. There are sometimes issues. For example, the implementation of what is called DOTS in TB control, Directly Observed Therapies. It is sometimes seen to be too prescriptive from the top.

What is prescribed by international organisations is not always easy to implement at a local level so perhaps there is not a sensitivity to local conditions.

*The Committee suspended from
5.09 pm to 5.17 pm for a division in the House*

Q479 Lord Howarth of Newport: I am encouraged by what Mr Burt has just said. You have been painting a very rosy picture of the beauty of the coordination between intergovernmental organisations, which does not entirely tally with some of the evidence that we have previously heard. Whether or not they are perfectly harmonised, there is the question of what kind of effective coordination is achieved on the ground, particularly among NGOs. I draw from an observation that I made in Uganda three years ago, where there was a plethora of UN organisations and NGOs operating up in the north of the country with devastating incidence of malaria and particularly child mortality. If mosquito nets are provided, they are cheap and useful and yet they would only be provided on a pitifully inadequate scale; and yet there were all these players, all these organisations, paddling in the pool. What sort of coordination is that? Why is it not better and how should it be made better?

Mr Sommerfeld: I would make a distinction between that which is coordination between intergovernmental organisations and—

Q480 Lord Howarth of Newport: They should be coordinating further down the line, should they?

Mr Sommerfeld: You have to also bear in mind what is the function and role. If you are talking about a body like the World Health Organisation, they are not a directive organisation. They are a body to give technical advice to government. I absolutely agree with you that there are many, many issues about what happens on the ground. Some of us, as NGOs, can be as territorial as the next person, let alone what is happening between all the many different donor agencies and so on. That is the attempt with the present Government initiative of the International Health Partnership, to try to develop a more effective coordinating framework. We will see if that has much impact. Again, as regards tuberculosis, because of the strength that has been built up over the past 20 years of national tuberculosis programmes, almost all of us

understand that, whatever we are doing, we work with the national programme. Sometimes that is a somewhat difficult relationship.

Q481 Lord Howarth of Newport: In the case of Uganda it is, where in the north you have no administrative capacity and no governmental goodwill that I could discern. Where does the responsibility lie for ensuring better coordination and effective use of the energy and the resources that have been put into that region?

Dr Meek: My organisation was the first working in that particular part of northern Uganda giving out mosquito nets. I know exactly what you mean.

Q482 Lord Howarth of Newport: Were you not frustrated?

Dr Meek: More and more came in. Each time a new organisation comes in, there are the start-up processes. It seems to be a fact of life because of the way the funding is structured. It was almost like the donors were competing among themselves to fund organisations to support a cause. There was a real need there and the mortality was way above what it should have been. In terms of who can take on that coordinating role, it is extremely difficult. In Uganda it should be the national government there because it is not a refugee situation exactly.

Chairman: This is an important issue. I understand there will be a difference between different countries depending on the governmental structure but if you have any more thoughts on that and on Lord Howarth's questions please send them in.

Q483 Baroness Eccles of Moulton: We have heard a lot over the last few weeks and quite a bit in the last evidence session about the relationship between horizontal health structures and the vertical application of treatment. I do not think very much has been said about the need within the horizontal health structures for having diagnostic ability, because unless you have the diagnoses it is presumably much more difficult to pinpoint the correct forms of treatment and also prevention as well. All that is so dependent on there being the facilities at absolutely local level to get on and prevent and treat. I wondered what your individual and collective views were on this very big question and what ideas you might have about a way forward which would make this very important part of the whole subject we are talking about so vital.

Mr Burt: We need a combination of the two. We need good vertical health systems. We need the specialist inputs, but they have to be embedded within a good horizontal system. For example, in the Mkushi district of Zambia until recently you had to travel 300 kilometres from that district to get an HIV

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diagnosis. Much the same was the case for tuberculosis, particularly a diagnosis of Multiple-Drug-Resistant tuberculosis. Now, a great deal of input has been put in on the HIV side, so there is lots of local provision but there is none in the tuberculosis field. In a way, we are beginning to see a disparity there, whereas in fact it should be happening together, particularly because as you know there is a close association between TB and HIV.

Mr Sommerfeld: You have to focus on the training and the competence of the staff at the periphery. The poorly trained person or the person with limited training and often limited facilities and back up is often the person somebody will go to. In other words, the paramedical worker in the clinic in the village. From our perspective the interesting thing is: does that person have the competence, not to diagnose TB, but to suspect that there might be TB and to refer the potential patient on to someone else who will begin to do a proper diagnostic job? If that awareness is there, it is a matter of have they been trained and is there somewhere for them to refer the patient to, which is not necessarily 300 kilometres away.

Dr Meek: On the malaria side, there has been a very long and rather fruitless debate for decades on the balance between horizontal and vertical. Again, it depends on who holds the resources. In the 1970s, 1980s and early nineties, there was very little money going into malaria. There was quite a lot going into general system strengthening, so there were complaints then. Now the balance has switched a bit, so the other side is complaining but it is definitely an issue. You cannot have control of malaria without strong systems and those systems need to be strong enough to undertake malaria interventions. It seems to me that there is a bit of an issue at national level in terms of who controls the information, the resources and the performance. Within ministries of health who is performing depends on who has the resources to be able to perform. The disease control initiatives are pulling quite a lot of resources in which are being used to strengthen health systems, and what I think is very good at the moment is that, if the disease control programmes can start to articulate and quantify what the systems parts of doing their jobs are, then we could really make good progress. People are very ready to say, "This is how much the drugs cost", but getting the drugs to the people is often less well quantified and I think more emphasis on that part of it could get the two sides realising that they are the same people in the end.

Q484 Baroness Eccles of Moulton: How much of it is dependent on the national and regional local governments playing their part, which must vary hugely from country to country?

Mr Burt: It does. In India, for example, which is a federation, the state governments vary enormously in what they do. In terms of the diagnostic facilities, the delivery of treatment, it can be very different, because it has been delegated down to state level and different states have very different ways of operating.

Q485 Baroness Eccles of Moulton: You think that within a unified country, as it were, you get these big differences?

Mr Burt: Yes.

Q486 Baroness Eccles of Moulton: Presumably in Africa the differences are even more pronounced?

Mr Burt: They can be.

Q487 Baroness Hooper: Because of climate change, apparently malaria is now becoming endemic in countries where it was not formerly known. Do you see this relationship between vertical and horizontal being sorted out in any way in relation to these countries?

Dr Meek: Climate change has not really shown much evidence for increasing the range of malaria, fortunately.

Q488 Baroness Hooper: Paraguay, for example, as a country has been experiencing malaria where it never had it before.

Dr Meek: In some countries you see more malaria at higher elevations. How climate change will change the patterns is a bit unpredictable because, together with increased temperature, you may also get less humidity and the two will work against each other. There are a lot of effects in terms of what people are doing in terms of land use, but in terms of how that relates to the vertical and horizontal debate one big issue, when the malaria goes down rather than when it goes up, is that when there is less malaria around there is much less justification for having strong workforces dedicated to malaria. That is always quite a difficult time and a number of countries in Asia have been through this, where you have to redeploy your workforces so that you do not have the strong malaria control teams you used to have, but to do that without maintaining adequate surveillance means you lose the gains, because in a number of places you do start seeing that there are gradual increases in malaria. It is a very difficult issue to work out what is the best kind of deployment of these disease-specific staff and how to redeploy these people when they are not needed and yet still stay on top of the problem. A lot of it boils down to having good surveillance.

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Q489 Lord Hannay of Chiswick: I hope I am not being unfair but it strikes me, not only listening to this group of witnesses today but to others on other occasions, that everyone subscribes to the view that there is a need to balance horizontal programmes in public health and vertical programmes dealing with individual diseases; and, even within the vertical ones, to balance the public health aspect of it with the drugs and so on. No one seems to have any idea what that balance should be over time and no person or organisation seems to have identified it and set it down. The application of the balance on the ground seems to be totally haphazard and depends on a series of inputs over which no single individual, group or person has any control, so it just comes out as it comes out. Is that wrong?

Mr Sommerfeld: I would be happy to forward to the Clerk a very useful document produced about six to nine months ago by the World Health Organisation Stop TB Department, precisely trying to give chapter and verse to what we mean as the balance between vertical and horizontal—i.e., in what ways should a decent, national TB programme work as part of an overall horizontal programme? What are the essential things that you do not want to lose from the point of view of the vertical concerns? And why is it extremely important to work closely with the horizontal aspect?

Q490 Baroness Eccles of Moulton: Does that involve AIDS?

Mr Sommerfeld: That document is largely concerned with TB but, of course, when you are starting to talk about sub-Saharan Africa, the HIV and TB pandemics are really one and the same thing.

Q491 Lord Desai: Do you think your answer to Lord Hannay is life as it should be?

Mr Sommerfeld: Life is never as it should be. It can be very depressing sometimes talking to a particular clinic or seeing a situation in a particular country, but I think that there is sufficient understanding of what is a reasonable approach and sometimes one has to rather insist upon it when you go out and visit a clinic. I am neither a doctor nor a manager of a national programme but there have been times when I would be saying to people, "Why are you not doing X, Y or Z?" That said, I do not think the framework is too bad.

Q492 Baroness Falkner of Margravine: We know it is a sensitive issue, the imposition of travel restrictions on people with infectious diseases, and we also know from other witnesses that in general one has to stop being politically correct about this, so we are getting quite different signals. Mr Burt, I wonder whether you might be able to tell us what your views are about

the WHO's revised guidelines and whether IHRs in general are adequate in addressing these? What is your view on screening? I notice that your written evidence suggests that there is not as big a problem because a lot of the migrant population that you are seeing with this are a lot later on and they have been in the UK for a while. Could you clarify any confusion there might be with regard to that, because perhaps we need not be as sensitive as this?

Mr Burt: On the World Health Organisation guidance, I am perhaps not terribly well versed on that.

Ms Harrison: We did mention that 77 per cent of the cases occurred more than two years after arrival in our submission. That is a fairly standard figure used by the Health Protection Agency. It is important to understand the difference between latent infection and active disease in tuberculosis. We have one third of the world's population estimated to be latently infected with the disease but around 9 million people a year with the active infection. What we are finding is that people are coming into this country, they are staying for several years without their disease activating, and at some point later on they are either acquiring new infection or their latent disease is activating. It is very difficult for us to say what that true picture is, but certainly, if you look at Heathrow in 2004, 270,000 people were coming from high-risk countries. The total number of referrals was 175,000, and 70,000 x-rays found 92 cases, so we are talking about very small numbers from a new entrant screening programme. That is simply because the majority of people are not entering this country with active tuberculosis. Their disease is activating at some later point, probably due to the conditions they are living in this country in.

Q493 Baroness Falkner of Margravine: Rather than having brought it on first arrival?

Ms Harrison: Yes.

Q494 Chairman: This is because, presumably, they are going into multiple-occupied housing?

Ms Harrison: Yes. You are seeing a change in diet; you are seeing very overcrowded housing; you are seeing stressful working conditions. All of these things can affect the immune system, which is when a latent infection is more likely to activate.

Q495 Chairman: This brings out the point that poverty is an underlying factor, whether overseas or here?

Ms Harrison: Absolutely.

Mr Sommerfeld: It is worth remembering that, for those of us in this country who are in their late fifties or sixties, we grew up at a time when TB was still very common in this country. It is highly probable

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therefore that a reasonable proportion, well over 30 per cent of us, are likely to have latent TB infection that is not a problem to us all our lives as long as our immune system keeps active.

Ms Harrison: That is certainly borne out by the epidemiology as well. What you will generally see in the UK is at 25 to 39 you will get a peak. Then it will go back down, and at the 60 plus age range you will see it is likely to peak again.

Mr Sommerfeld: There is a steady cohort of people in this country in their eighties and beyond who develop TB, who probably were infected 50 or 60 years ago.

Q496 Baroness Falkner of Margravine: Do any of you have comments on the WHO's revised guidelines or on the efficacy of International Health Regulations overall?

Ms Harrison: I do not feel that there has been a major test case or any active case yet found.

Q497 Baroness Falkner of Margravine: There was the US man?

Ms Harrison: No. He was very well publicised but he did not have active TB.

Mr Sommerfeld: Also, the notable thing was he was never infectious, so it was something of a storm in a teacup. Notably, there has not yet been a documented case of active TB developed as a result of sitting in an aeroplane. There have been documented cases of people becoming infected, but that is a very different issue than developing active disease.

Q498 Baroness Falkner of Margravine: I think the guidelines were about how the surveillance and notification was working rather than specifically tuberculosis.

Mr Sommerfeld: The International Health Regulations also relate specifically to particularly serious situations, and in the TB world that would mean dealing with multi-drug resistant cases.

Ms Harrison: It is about a perception of the level of infectiousness. With tuberculosis, airlines studies are the things that inform us on this. It is estimated that you need eight hours plus close, prolonged contact, so the majority of flights are not affected by this. The guidance does very clearly state that for those of over eight hours there should be another exercise.

Q499 Baroness Hooper: I think we can all agree that the quality of drugs is essential and the problem of fake drugs and that sort of thing is something that has to be dealt with. The WHO Prequalification Programme was designed as a solution or at least as a means of control in both these areas. Doubts were expressed by the Malaria Consortium about the efficiency of that prequalification process and about the time that is taken over it. Do you have any idea

about the reasons for these delays? And do you have any recommendations to improve and to speed up the process? If I understood him correctly, one of the witnesses earlier said that UNAIDS was the only organisation that had representation from civil society. I just wondered what your contact with, say, the WHO was on this sort of thing. Are you consulted? Do you have your own contacts within the organisation? Or is there any straightforward process by which your views can be heard?

Dr Meek: The prequalification and fake drugs are slightly separate issues. When I wrote the written submission, there were real concerns that there were only two manufacturers globally that were prequalified to allow their drugs to be bought using funds from global funding, some of the big, multilateral buyers. At that time, one of the issues was that there was not the capacity of the people who have to check the factories and the products and product lines to provide the prequalification status. It seemed that not enough suppliers were there to supply a hugely increased need for these relatively new antimalarials. Since then things have moved on quite a lot, in that the Gates Foundation and UNITAID have given funding to the WHO, which manages the prequalification system, to increase their capacity. Now there is not a backlog there. The problem is perhaps more at the manufacturers' end. A number of manufacturers are not submitting all the information that is needed to be able to become prequalified. If they do, the delay will not be from the monitors in the WHO but more from how they provide the information. There has also been another fairly recent change in the antimalarial world in that there is about to be this initiative called the Affordable Medicines Facility for Malaria, trying to bring the cost of medicines right down through a co-payment to the manufacturers. There has been a lot of debate over the last three months on how to make sure that the people who manufacture the drugs are reputable but also that you do not create a complete monopoly. They have come up with criteria for accepting companies to be providers which are quite stringent. There is a worry because a number of developing countries have their own pharmaceutical manufacturing companies and we do not want to crowd them out or suppress their development by having the big player always at a competitive advantage. For these particular drugs, it seems that what is happening now is that a number of the Indian and Chinese companies are investing in African pharmaceutical manufacturing capacity. There is quite a nice technology transfer going on which does need investment, but most of the funding for it is coming from the Indian and Chinese pharmaceutical sector. It does not seem to be reliant on aid from donor organisations. It is kind of complicated, but it

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seems that some of the earlier problems are being ironed out. The fake drug issue, which is quite different, is where drugs produced mostly by the Chinese are getting into the market, and that is something that needs a lot more attention. That is where collaboration between intergovernmental and different governmental organisations is going to be crucial, because that could really destroy the progress that is being made, certainly in the malaria control field. It is a problem at the moment in South East Asia, where there is not that much malaria these days, much less than before; but already they are starting to find it infiltrating parts of the African market. There was a report recently discovering fake ladies' handbags in Lagos and that probably is a sign of things to come, so anything to encourage this involvement of Interpol and others, together with the WHO, needs to be encouraged and supported.

Q500 Chairman: It is the WHO and Interpol that you would see working together better on this?

Dr Meek: I think they should be working together more on it. They are both very keen to do so but, again on the WHO side, it is probably relatively limited resources. They are open to any opportunities to do more and Interpol seems to be enthusiastic about it as well.

Mr Sommerfeld: The picture for tuberculosis is very similar to that for malaria as far as prequalification is concerned. The real block is the WHO's ability to handle the requirements of a number of cases coming forward. That is becoming increasingly important for us in TB because we have new diagnostics coming on board. We are beginning to see new drugs or new formulations, and new vaccines are coming closer to a trial, so there are new developments where the whole issue of prequalification will be more important. The only way we have so far got round it is exactly the same as in the malaria world. We have managed to try and find some money from somewhere to give a bit of extra money to the central WHO operation to do the prequalification. That is not a very satisfactory way. It is a bit of horse trading and it is likely to lead to unfairness between diseases. A general remark would be to strengthen the funding available to the WHO to have a large enough prequalification team.

Dr Meek: From what I hear, that is working now.

Mr Sommerfeld: And there have been improvements in the past two years. On the false drugs, again it can be an issue in tuberculosis but crucially for us has been the strength of the Global Drug Facility, which is the purchasing agent of the Stop TB Partnership, either given free or at a very low price to major, high burden countries. The fact that a very high proportion of TB drugs come through the Global Drug Facility means that they are properly

controlled and checked. False drugs are an issue. You can go into any chemist in many countries of the world which are high burden TB countries and you can buy all sorts of things that claim to be Rifampin and Isoniazid and so on, but largely in the public sector that itself is not an issue. It is notable that the Global Drug Facility is one of the success stories of the Stop TB Partnership, and DFID just over 18 months ago agreed to fund through the Global Drug Facility and is paying for all of the TB drugs of the Indian National Programme, which means potentially a third of the world's TB sufferers.

Q501 Lord Avebury: I was wondering, on the funding, why there has been no corresponding mechanism to pneumo-aid as you have with pneumococcal disease and funding of new vaccines, so that payment can be made in advance to manufacturers to produce larger quantities and therefore bring the price down. That seems to be a mechanism that is working very well in pneumococcal disease. As far as I know, it has not been applied to any other disease group. Can you explain that?

Dr Meek: At present there is not a malaria vaccine yet.

Q502 Lord Avebury: Or medications generally?

Dr Meek: They are just about to introduce a mechanism like that but a slightly different one, which is promoting access in the private sector. This is the Affordable Medicines Facility. We have a report on it and I can leave you a copy. It gives quite a lot of detail about how it would work but it is the same kind of idea and it does seem that some of those barriers are overcome.

Q503 Lord Avebury: What about TB?

Mr Sommerfeld: It is a question of how close is something potentially to market. At the moment there are debates going on. It is a strange body. I have never yet managed to pin down quite the international committee that is the legal agency. It has gone through one particular drug and we are beginning to talk about what will be its next one. We had a debate in the Coordinating Board of the Stop TB Partnership as to whether or not we should be pushing for a TB drug to be the feature of an advance market commitment. We suspect in a way that we are not quite at the point or that it would be an appropriate mechanism, but we should be rather soon. I believe there are issues which are worth exploring about what is the nature of the advance market commitment international agreements

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because they seem to be controlled by a slightly amorphous body. When this came up at the Coordinating Board of the Stop TB Partnership, I said, "Can somebody tell me exactly what is this committee? What is it an agency of?" Nobody seemed to be able to answer me.

Chairman: Can I thank you very much your evidence, both written and verbal? If you feel that anything has been missed out, please write to the Clerk. You have already been in contact with him. Please send those comments in. You will get your transcript to look at before it goes out in public form.

Baroness Eccles of Moulton: Could we possibly ask Mr Sommerfeld if he could let us know a bit more about integrating the HIV and TB programmes?

Lord Desai: I thought we had talked about that.

Q504 Chairman: If you feel there was anything that was not covered on that, perhaps you could send it in.

Mr Sommerfeld: I think it was dealt with in the evidence of the people before us.

Chairman: I agree it was covered to some extent but, if there is anything you want to add to that, please send it in.

MONDAY 21 APRIL 2008

Present	Avebury, L Desai, L Howarth of Newport, L	Jay of Ewelme, L Soley, L (Chairman) Whitaker, B
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Memorandum by World Health Organisation

Question 1: A recent report on Communicable Diseases by the UK Department of Health stated that “post-war optimism that their conquest was near has proved dramatically unfounded”. What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis?

1.1. Given available information at the time, post-war optimism was not totally unfounded. Great progress has been made in reducing morbidity and mortality from infectious diseases, especially in less developed countries. There has been a major reduction in the incidence and mortality from vaccine-preventable diseases. However, there was also an unrealistic expectation that once morbidity and mortality from communicable diseases were reduced, they would not return. Constant vigilance, surveillance, and prevention are required to keep old infectious diseases under control and to prevent new ones emerging. Experience in Africa with malaria illustrates this point.

1.2. Post-war optimism did not recognize that many transmissible diseases were endemic in resource-poor settings with health systems that were too limited to effectively control and then eliminate many infectious diseases

1.3. The premise also was that social and economic conditions would dramatically improve and hasten the reduction in burden of infectious diseases. This patently has not happened in many poor countries and changing socio-economic conditions, especially globalization, which have developed since the war have facilitated the emergence of new pathogens such as HIV, SARS, Ebola, avian influenza (AI) and MDRTB. Changes in population growth, migration, urbanization, persistent poverty, and environmental change, among other factors, have resulted in conditions which facilitate spread of old pathogens such as dengue fever and influenza and promote the emergence and spread of new ones. The threat of climate change on human health, as reported by WHO in 2003 (<http://www.who.int/globalchange/publications/climchange.pdf>) has recently been brought to the fore as a result of it’s likely social, economic and human health consequence.

1.4. There is limited evidence that the global situation is actually deteriorating, but conditions are changing and infectious disease threats have certainly not lessened.

1.5. Prevention and control strategies for major disease killers such as malaria and HIV have improved, but implementation of sustainable programs incorporating these advances lags behind.

1.6. A major challenge is to improve our ability to detect and rapidly respond to the emergence of these pathogens.

1.7. Without ability to detect and respond to these pathogens throughout the world, then it would not be an exaggeration to call the current situation a crisis, the weakest link in the chain being a threat to all. For example, extensively drug-resistant tuberculosis (XDR-TB) could spread widely in Africa without being detected, and this could be a severe threat to health elsewhere in the world.

Question 2: What reliable data exist regarding the numbers of people infected globally with the four diseases¹ on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?

2.1. For the last five years, because of the degree of uncertainty in the data, HIV/AIDS epidemiological estimates have been published by WHO and UNAIDS with ranges.

2.2. Methods and tools for estimates have been improved over the last few years. More and better data are available in many countries thanks to efforts to strengthen HIV surveillance systems, especially in countries with generalized epidemics.

¹ HIV/AIDS, Tuberculosis, Malaria and Avian Influenza.

- 2.3. At global level, WHO and UNAIDS have revised the estimation of the global number of people living with HIV/AIDS to 33.2 million (30.6-36.1), two thirds of them living in Sub-Saharan Africa.
- 2.4. The global HIV epidemic seems to have peaked at the end of the nineties, including in Africa. However in groups of high risk populations the HIV epidemic continues to increase in some countries.
- 2.5. HIV has become an endemic disease in some settings. Even high income countries have difficulties in reducing significantly the annual number of new cases; therefore the perspectives of reaching zero growth in new HIV infections in the short run are not realistic.
- 2.6. Overall at a global level the percentage of women infected is 50%. The proportion of women infected in different regions may increase slightly as more men are infected and sexual transmission rates increase in countries with concentrated epidemics.
- 2.7. The main mode of transmission in the African region is heterosexual contact and will remain so, even though there are increasing pockets of IDUs in some countries, especially those with major ports and transport hubs. Overall, patterns of transmission and epidemiology are not likely to change substantially in the near to mid-term future. HIV will remain a threat to specific vulnerable populations such as IDUs, sex workers and their clients, and men who have sex with men (MSM). The HIV epidemic among MSM is likely much more global than has been realized and has been inadequately addressed.
- 2.8. WHO estimates that one third of the world's population is infected with the mycobacteria that causes tuberculosis, and nearly nine million people newly fall ill with active TB disease each year. Based on a strong surveillance system with 200+ countries reporting annually on TB case notification, WHO estimates that worldwide TB incidence (new TB cases per capita) is now beginning to fall, although levels are largely stable in Africa and Eastern Europe after very rapid increases over the past 15 years, and falling far too slowly in all regions.
- 2.9. HIV infection was the main cause for the rapid increase in TB rates in Africa at the end of the 20th century along with weakened health systems and social crises. The levelling off is linked to the associated peaking of the HIV epidemic. In the countries of Eastern Europe, TB disease and multidrug-resistant TB rapidly emerged with the breakdown of the Soviet Union due to high underlying levels of TB infection, the breakdown of health systems, especially drug supplies and service financing, dire conditions in large prison populations, and high population-wide levels of substance abuse. Improving economic conditions are likely contributing to the stabilization of incidence, although multidrug resistant TB is a large and worsening threat in much of region. Asia, given its vast populations, still carries the greatest burden of TB although rapid scale up of TB control services has seen a major improvement in treatment success and treatment coverage in that region.
- 2.10. Malaria data is difficult to capture due to the rural and inaccessible nature of many of those infected. In addition, in some countries up to 60% of malaria cases are treated in the private sector making it difficult to track cases. Treatment based on clinical diagnosis of those most severely affected, namely children under five years of age, is yet another complicating factor.
- 2.11. The difficulty in estimating the numbers not captured by the public health system remains problematic. However, malaria incidence is estimated to have remained mostly stable since the 1990s because of lack of access to effective treatment as well as to preventive measures sufficient to cover at least 80% of entire communities and increasing resistance to commonly used drugs (particularly chloroquine).
- 2.12. With the introduction of effective antimalarial drugs (artemisinin-based combination therapies (ACTs)), concentrated efforts to distribute preventive measures (particularly long-lasting insecticidal nets (LLINs)) and the reintroduction of indoor-residual spraying, many countries are beginning to show some success in the response to malaria.
- 2.13. The main underlying causes of malaria infection are 1) the continued reservoir of the parasite in the human body—ie lack of sufficient treatment to eliminate the parasite from the bloodstream of infected individuals within biting range; 2) the continued presence of infected vectors; and 3) the lack of sufficient infrastructure to ensure sufficient community wide coverage both with effective treatment and preventive measures.
- 2.14. Data for AI infection are not definitive but provide an indication of the human impact. The most severely symptomatic cases are likely to be identified. The number of people with acute illness and laboratory confirmed H5N1 infections occurring since 2004, is 350. Human infections with H5N1 occur where poultry are infected. H5N1 infections tend to be more common in the winter months of the Northern Hemisphere and the virus is unusually persistent in animal populations.
- 2.15. Massive and intense agricultural control programmes have reduced human infections with H5N1. Notable examples are China, Thailand and Vietnam. However H5N1 infections have continued to occur in some of those countries. The widespread persistence of H5N1 continues to increase the chance that a mutation

will occur and the virus becomes more easily transmitted among people. If this occurs, H5N1 will move from being primarily an animal infection that sometimes infects people to a human virus with the capacity of infecting most of the world's population.

Question 3: What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? And what improvements might be made?

3.1. Due to the long silent period of the virus in the human body and limited access to early testing, early warning of outbreaks of HIV is limited internationally.

3.2. Countries have endorsed Second Generation Surveillance System as the strategy to monitor HIV infection. It includes surveys among vulnerable populations or populations with high risk behaviours, and attempts to link behavioural data with biologic measurements. Adequacy of the system depends on availability of resources.

3.3. There is a strong global surveillance system for TB control with over 200 countries annually providing standardized routinely-collected age and gender-specific data from primary health services around the globe.

3.4. WHO also leads a global TB drug-resistance surveillance network that will produce in 2008 a comprehensive global analyses of baselines and trends in prevalence of multidrug resistant TB. This latest report includes the largest ever cohort of surveys and data on the emergence of extensively drug-resistant TB, a highly lethal form of disease. The surveillance network includes "supranational" laboratories, based in national public health services in selected industrialized and developing countries, across all six WHO regions, which offer quality assurance services and help build capacity and laboratory safety standards in requesting countries. Many countries, especially in Africa have yet to initiate their first surveys. This region faces a substantial threat of rapidly emerging drug-resistant TB which could be disastrous for those already vulnerable with high HIV infection levels. Surveillance data is urgently needed to help African countries prepare for prevention and treatment needs.

3.5. Where not impeded by lack of financing, civil strife or other causes for lack of infrastructure, most countries have in place a system for malaria surveillance. However, in many poor countries, there are insufficient resources—both human and financial—to ensure adequate monitoring.

3.6. Countries in the pre- or elimination phase are most at risk from lack of surveillance as malaria is easily reintroduced particularly given difficulties in eliminating the malaria vector. Entomologists and malaria specialists are in short supply and re-emphasis of training in these disciplines would also help to improve malaria surveillance.

3.7. Epidemiologic capacity in developing countries is seriously inadequate. Much more investment in all aspects of strategic information, including conducting surveys more regularly, is critically needed.

3.8. The WHO Global Alert and Response System works and uses many innovative tools and networks to detect, verify, assess and respond to outbreaks under the framework of the International Health Regulations (2005). However there is gross underinvestment in this system and it depends on strong, capable and transparent national systems which again are subject to underinvestment.

3.9. For zoonotic diseases the Global Early Warning System for Major Animal Diseases, including zoonoses (GLEWS) was officially instituted in Feb 2007.

3.10. The Global Polio Eradication Initiative (GPEI) has established an international surveillance and laboratory network which has the goal of detecting and investigating sufficient cases of "acute flaccid paralysis (AFP)" to identify and track all chains of wild poliovirus transmission in the world. The GPEI's AFP network has been successfully expanded in most areas of the world to facilitate the investigation of other communicable disease outbreaks such as H5N1 Influenza, SARS, Marburg Fever, cholera and Ebola.

Question 4: Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years?

4.1. Projections for the HIV epidemic are uncertain in the long-term, as they depend on increased survival resulting from treatment coverage, and on the success of prevention programmes in reducing the number of new infections.

4.2. Different factors are converging to influence trends towards continued growth albeit slow in the overall number of people living with HIV: more people are being treated with ARV and live longer; prevention programs are poorly or insufficiently planned and carried out; progress in HIV vaccine research is limited and prospects to implement an efficacious vaccine in the short-mid term are remote.

- 4.3. Some pockets of new HIV infections can occur in countries with drastic social changes, lack of prevention activities or failure of the health services to carry out proven effective preventive actions.
- 4.4. Fewer HIV infections in children are expected as PMTCT program coverage increases over the next few years.
- 4.5. Vigorous implementation of programs for female sex workers and for drug injectors is capable of reducing or preventing HIV epidemics in these populations. Success has been much more limited among MSM, in whom a resurgence of unsafe behaviour and perhaps HIV transmission is being witnessed in the industrialized world.
- 4.6. Eight countries in Southern Africa with a general population prevalence in excess of 15% account for about one third of the global burden of HIV/AIDS. An extraordinary and special effort will be required to impact on the epidemic in these countries.
- 4.7. The Global Plan to Stop TB, 2006–2015 includes epidemiological projections documenting the potential to reach the 2015 Millennium Development Goal of reversing TB incidence, and halving both TB mortality and TB prevalence globally. If the plan's agenda is followed, which lays out the implementation approach for the WHO Stop TB Strategy, then at least 14 million lives could be saved by 2015 and the targets can be reached. If not, then there is major risk of a renewed deterioration in TB indicators especially in the poorest and most vulnerable populations, and for an increase in rich and poor countries alike of multidrug-resistant TB. The greatest challenges across regions are to maintain the scale up of good quality TB services while also expanding those services to adequately address TB/HIV and MDR-TB treatment and first and foremost ensure that poor and unsafe services are halted to pre-empt the further emergence of drug-resistant strains.
- 4.8. Based on recent successful country experiences, evidence is accumulating that the global burden of malaria could be reduced by at least 70% in the next 3–5 years, if there were sufficient resources (financial, human and technical) devoted to malaria control. However, a concerted push will need to be made to ensure adequate and sufficient coverage of entire populations with malaria treatments (eg ACTs) and preventive tools (esp. LLINs and IRS).

Question 5: What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?

- 5.1. The coverage of prevention interventions remains inadequate. Few countries have set targets and indicators for prevention programmes and systematically increased coverage of prevention interventions in the public and private sector.
- 5.2. In HIV, the lack of coverage can be addressed through addressing better-targeted prevention programmes aiming at saturation coverage of populations at high-risk first while preparing for saturation coverage of prevention interventions to other vulnerable populations such as young people and migrants.
- 5.3. In malaria, coverage with long-lasting insecticidal nets (LLINs) is still generally extremely low, even though this is the best protection available, and rapid progress is being made in some areas. Many countries do not have adequate resources—particularly human—to manage distribution campaigns.
- 5.4. Likewise, indoor residual spraying (IRS) is the most effective means of rapidly reducing malaria parasite transmission. However IRS is labour intensive, requiring good planning and effective deployment to achieve rapid reductions in malaria morbidity and mortality. Many countries do not have the internal capacity to plan and implement spraying campaigns even if provided the necessary equipment.
- 5.5. Ensuring that effective treatment for HIV/AIDS, TB and malaria is available at all levels of service delivery down to the community can in many situations be extremely difficult. In TB control, for example, many private sector institutions are offering inadequate and often unsafe TB treatment which can lead to treatment failure and drug resistance.
- 5.6. TB tools in widespread use today are 40-125 years old. Drug-resistant TB and HIV-associated disease are woefully addressed with these old tools.
- 5.7. For avian influenza, lack of action, transparency and intersectoral collaboration of Ministries of Agriculture and in some cases Ministries of Health (MOH). Although MoHs have become much more responsive and engaged in human AI. There needs to be fundamental investment in surveillance, preparedness and response architecture at national regional and global level for avian influenza, pandemic influenza and other severe emerging and epidemic-prone diseases. Member States are committed to achieve this through the implementation of the IHR (2005).

5.8. Significant blockages to control of the four diseases can be addressed by:

- Strengthening health systems to: improve access to well-staffed quality services and health systems overall in the poorest areas of the world; expand uptake of proven strategies; and engage the private sector, as well as affected communities themselves to increase impact.
- Financing public health institutions and control programs that provide essential surveillance, stewardship, capacity-building, robust programme assessments and other analytic functions.
- Supporting research and development for new diagnostics, drugs and vaccines.

Question 6: What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?

6.1. WHO plays its essential functions, including articulating policy options, setting norms and standards, shaping the research agenda, providing technical support to countries, assessing epidemiologic trends, monitoring and evaluation and harmonizing and aligning partner implementation strategies and goals with national health sector plans and initiatives.

6.2. WHO works in collaboration with governments, bilateral donors, civil society, the private sector, multi-lateral organizations and partnerships including GFATM, UNAIDS Secretariat and cosponsors, the Roll Back Malaria Partnership, the Stop TB Partnership and UNITAID, which it hosts.

6.3. Overall, there is a strong level of synergy in the actions of the range of partners, but synergy is not complete. WHO plays a key role in developing a global vision for responding to the four diseases and assuring strong coordination.

6.4. WHO needs additional high-quality technical personnel and more flexible funding to be able most meaningfully to deal with its global mandate.

6.5. There is an imbalance between specified funds which tend to focus on a limited number of well funded activities (eg HIV drug resistance, provider initiated testing and counselling) and unspecified funds critically needed for core WHO mandate activities, including surveillance and strategic information which currently are insufficiently funded.

6.6. WHO's offices at global, regional and country level comprise a strong network which is well structured. However the network is inadequately staffed, especially at country level. There are increasing demands for implementation support from governments, other technical agencies, NGOs and civil society partners, as well as donors supporting disease control at country level.

Question 7: What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient "joined-up" thinking in approaching the problem?

7.1. Population increase, persistent poverty, gender inequality, urbanization, wars, disasters, food insecurity, increased international travel, migration, lifestyle changes, other forms of economic globalization, social and economic crises, changing farming practices and other environmental changes contribute to the spread of HIV, TB and malaria as well as to the emergence and/or spread of more lethal forms of them.

7.2. International cooperation is absolutely necessary to effectively respond to the four diseases.

7.3. The Global Outbreak Alert and Response Network needs to be strengthened and governments need to work together at the regional and global levels.

7.4. Other work by WHO and partners has reinforced the lessons learnt on how poverty breeds HIV, TB and malaria and how they lead to further impoverishment of families, as well as how disease control efforts can dovetail with poverty alleviation and human rights initiatives. More explicit attention to disease prevention and rights to health care in prison reform, refugee response, oversight of labour conditions, gender equity efforts, immigration, and substance abuse policies all can make a difference.

7.5. High density populations combined with subsistence husbandry of mostly small livestock with poor sanitary infra-structure are key drivers of H5N1. This is exacerbated by traditional close contacts between humans and poultry with often shared housing environment and by the widespread small scale and home slaughtering of poultry or in wet markets. The movement (legal and illegal) of poultry, poultry products and

captive wild birds and migration of wild birds that act as reservoirs for influenza viruses without necessarily showing signs of disease can also contribute to the spread of the disease.

7.6. While climate change is sometimes quoted as an underlying reason for the spread of malaria, the evidence is patchy. While the rise of average temperatures (in particular, of the average minimum night temperature) may cause malaria transmission to move to higher altitudes, there are as a rule many confounding factors to which change can also be attributed. Changes in rainfall patterns are more conclusive, such as the 1997 (El niño) rains in Kenya which led to major malaria outbreaks—so in this context, extreme weather conditions are important in the intensification of malaria transmission.

Question 8: Cases of Tuberculosis fell progressively in the UK until the mid-1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of Tuberculosis infections in Britain? And how could intergovernmental action help to reverse the trend?

8.1. Important contributors include: urban deprivation and poverty; high rates of immigration from high incidence countries; an increasing refugee population; HIV; and inadequate public health infrastructure to deal with TB in hard-to-reach populations.

8.2. Intergovernmental action can help: (a) ensure timely surveillance data to monitor trends in TB control globally and in Europe specifically, as well as trends in drug-resistant TB; (b) increase preparedness and response when facing incidents of travel into or through the UK of persons with MDR/XDR-TB that could pose especially significant risks to public health; (c) increase consensus-building and fast adoption of effective global policies for improved TB prevention, treatment and control; and, (d) enable far earlier development and introduction of new tools to fight TB.

8.3. A study published in 2005 in the *New England Journal of Medicine* estimated the substantial health sector savings in the United States and Canada if investments were made in TB control in the top countries of origin of the rising share of foreign-born TB patients in Canada and US. UK aid to global disease control and surveillance efforts and in-kind UK institutional support (eg engagement of top public health laboratories, academic institutions, development agencies, and the corporate sector in the UK) are important contributions.

Question 9: Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions—eg HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?

9.1. WHO estimates that globally the new TB case rate has peaked, and in most regions it is beginning to fall albeit too slowly. In Eastern Europe and Africa, case rates have stabilized after rapid increases over more than a decade, due principally to economic/social transition in the former Soviet Union, and due to the HIV epidemic in Africa.

9.2. Over 30 million people worldwide were treated over the last 11 years applying the DOTS approach and treatment success globally is now near the target of at least 85%, proving TB is largely curable even in the poorest settings. Globally, DOTS-based programs are reaching almost two-thirds of estimated cases globally (compared with less than 10% a decade ago). Anti-TB drug supplies have greatly improved for patients in the public sector in low-income countries, due to increased financing sources, domestic policies and the Global TB Drug Facility.

9.3. The WHO Stop TB Strategy lays out the proven approaches to reach more persons ill with TB and making treatment less onerous including: community-based care; better diagnostic capacity for earlier identification of drug-resistant TB and HIV-associated TB; better treatment protocols; and strengthened health systems for more truly free TB care and earlier service access. Overall, WHO estimates that for 2008 alone there remains about a 50% gap in financing for TB control implementation of over US\$2 billion, for national control efforts and global technical assistance.

9.4. Globally, under 5% of the TB burden is attributable to HIV infection, but up to 70% of TB patients are HIV+ in the African countries hardest hit by HIV infection. Policies and field best practice models of integrated TB/HIV care are being applied but need faster scale up and high level commitment to make a difference in the highest HIV burden settings. Tobacco use is linked to increased TB disease and mortality

given prior TB infection. Other immune-compromising diseases such as diabetes and malnutrition also contribute to the TB burden.

9.5. TB breeds in settings of poverty, overcrowding, economic and social instability and where migration and travel are rapidly increasing. Good TB control practices need to be scaled up further especially in the poorest countries, and new tools are needed to ensure patients are detected earlier and treatment barriers are reduced.

9.6. Intergovernmental action is already making a profound difference through commitments, including by the UK Government, technical agencies, academics and civil society organizations, to the Global Plan to Stop TB, 2006–2015. Intergovernmental collaboration with partners supports: national scale-up of proven control policies; harmonized approaches aligned with national health sector plans and initiatives; coordinated technical assistance that meets the demands of recipients; strengthened surveillance; awareness raising and urgently needed research.

Question 10: To what extent do you believe that the 2004 Stockholm Convention limiting the use of DDT against Malaria-carrying mosquitoes has been a factor of increases in the spread of the disease? Has any risk analysis been carried out comparing the relative dangers to human health posed by DDT and Malaria?

10.1. The Stockholm Convention only allows the use of DDT for public health purposes such as vector disease control. Therefore, the Convention cannot be a factor causing increase in the spread of malaria. Rather, it has helped to focus on the options for vector control in support of reducing the burden of malaria.

10.2. No risk analysis has been carried out comparing the relative dangers to human health posed by DDT and Malaria. WHO continues to coordinate international research and monitoring of the risks posed by DDT to human health.

Question 11: What intergovernmental action is planned or in hand for early detection of the transmission of Avian Flu from birds to humans and of human-to-human transmission in potential source countries? Is this proving sufficiently effective to prevent an Influenza pandemic? What more could be done?

11.1. The recognition through modelling that it may be possible to prevent the development of a pandemic of influenza has led to the development of a Rapid Containment Protocol including the use of non-pharmaceutical interventions such as isolation, quarantine and social distancing, anti-virals for treatment and prophylaxis of contacts and vaccine if available.

Question 12: To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?

12.1. Increased drug resistance is not driving an increase in the incidence of HIV infection. While a certain proportion of new infections (5–20%) in industrialized countries are with viral isolates showing some genotypic resistance, there is no obvious evidence as yet of an increasing rate of premature treatment failure.

12.2. Drug resistance is immensely important in tuberculosis, and manifests as resistance to single drugs, multidrug-resistance, and extensive drug resistance. Antituberculous drug resistance, including MDR and XDR, has been associated with HIV infection in some settings. HIV-infected people, once exposed to tuberculosis, including drug-resistant strains, are vulnerable to rapid progression to disease following infection. Drug resistant tuberculosis is therefore an important threat to HIV-infected persons, especially in congregate settings such as prisons and hospitals, and can result in tuberculosis outbreaks in such settings. This has likely happened in South Africa in recent time.

12.3. WHO has not found that overall TB incidence trends nationally and globally have been affected by rising levels of drug-resistant TB. However, the overall control of TB is at great risk, as well as public safety, if drug-resistant TB is not prevented, quickly identified and contained. Global efforts are focusing on: providing effective TB treatment to prevent the emergence and spread of drug-resistant strains; large-scale improvements in laboratory networks worldwide; introduction of new diagnostics and research; surveillance to monitor the emergence and trends of drug-resistant TB locally, regionally and globally; and expanding treatment of drug-resistant TB.

12.4. Resistance has developed to almost all of the previous antimalarial medicines that were used, sometimes taking just a few years to spread worldwide. Therefore it is critical that the efficacy of artemisins, the only effective medicines against drug resistant parasites, be protected. Malaria-bearing mosquitoes are also becoming resistant to the insecticides deployed to kill them.

12.5. WHO is stringently monitoring drug and insecticide resistance, and is working closely with countries to implement systems to avert these

Question 13: In a number of countries, including the UK, there is a problem with hospital-acquired infections. What intergovernmental sharing of knowledge is taking place to help bring this problem under control?

13.1. HIV and TB may be acquired within a hospital or other medical facility by either health care workers (HCWs) or patients.

13.2. HCWs, due to exposure to infected body fluids, are at risk of acquiring multiple types of infection from patients, including HIV.

13.3. It is estimated that approximately 327,000 HCWs throughout the world are percutaneously exposed to HIV with the highest numbers of exposures being in sub-Saharan Africa and South-east Asia, where HIV testing and post-exposure prophylaxis are far less readily available. An estimated 4% of HIV infections in HCWs may occur from occupational exposure.

13.4. To lessen infection in health care settings, WHO develops or shares intergovernmental knowledge by: issuing guidance on evaluating risk of HIV infection from exposure to body fluids and the use of post-exposure prophylaxis; performing annual global surveys of blood collection, blood screening and transfusion practices; providing guidance on means of lessening risk of HIV infection via blood transfusion; hosting the Global Collaboration for Blood Safety (GCBS) an international network of all major international organizations working on global blood safety to improve safety of blood and blood products, and to promote safe and rational blood transfusion practices; hosting the Safe Injection Global Network (SIGN), an international effort to decrease the use of injections and eliminate unsafe injections, and to enhance safety of the health care setting; hosting the World Patient Safety Alliance which aims to coordinate, disseminate and accelerate improvements in patient safety worldwide; providing guidance on precautions to lessen exposure to body fluids in health care settings.

13.5. Recent evidence in Southern Africa has shown that the spread of extensively-drug resistant TB (XDR-TB) in hospitals serving as antiretroviral treatment sites can be highly lethal. WHO is leading work with a wide range of partners to rapidly provide updated policies for infection control engineering, health worker practice and overall models to reduce the need for in-patient or ambulatory TB care in concentrated congregate settings.

Question 14: Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?

14.1. There are no new drugs for tuberculosis near readiness for introduction to the market so there are no patent/IP issues yet, but if early trials of new drug compounds are successful, in the next decade these issues may become highly relevant for TB control. Too few R&D firms are engaged in TB and malaria drug research relative to the vast need.

14.2. It is important to note that of the various ACTs available only Coartem© produced by Novartis is under patent. However, generic copies have been produced in various centres worldwide. There are currently only three Long Lasting Insecticidal Nets (LLINs) which are quality approved by WHO (Olyset©, Permanet© and Interceptor) of which Permanet©, produced by Vestegaard-Fransen and Interceptor produced by BASF are under patent. At present, given the complexity of the technology to produce actual long-lasting nets no generics which pass the quality tests—duration of insecticidal activity, durability of the material, etc.—to qualify as LLINs have been produced.

14.3. The 2006 report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) concluded that although intellectual property rights (IPR) provided important incentives for the development of new medicines and medical technologies, IPR do not provide an effective incentive when patient populations are small or poor.

14.4. The Commission's recommendations resulted in creation in 2006 of the Inter-Governmental Working Group on Public Health, Innovation and Intellectual Property. The Working Group's mandate is to draw up a global strategy and plan of action aimed at, inter alia, securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, and submit this to the Sixty-first World Health Assembly in May 2008.

Question 15: What interchange exists between States in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?

15.1. WHO sets global standards and provides technical collaboration with member states at the global, regional and country levels for diagnosis, prevention, treatment and control of the four diseases, including dealing with outbreaks.

15.2. While great progress has been made in establishing a global framework for detecting and responding to treatment, prevention and control, increased intergovernmental collaboration and cooperation are needed at the regional and country levels to strengthen surveillance and disease control activities.

15.3. The UK has in the past seconded staff to WHO which have made significant contributions to the different diseases. More could be done to facilitate and support such secondments—particularly from academic and public health institutions. Policies need to support incentives that increase the pool of public health and clinical expertise in the four diseases and sustain engagement, particularly in developing countries.

15.4. In the short term, ongoing support to WHO and national technical agencies to continue to hold consultations, to sift through the scientific and other relevant literature and experience, and to make this information understandable, is critical.

15.5. To ensure sustainable outcomes, intergovernmental action must continue enabling poorer countries to build their own technical capacity to directly access (and produce) scientific and technical information and to communicate this to their populations.

15.6. States should share experiences and data related to: the analysis of historical health-facility data and if possible data derived from prevention means and case management at community level; method for calculation of thresholds; agreed set of data/indicators to be collected and the meaning of representative data and the periodicity of reporting and feed back; standardized case definition, diagnosis (laboratory services quality) and treatment; improvements in public health surveillance for trend monitoring and early detection; past experiences in dealing with outbreaks (timely response, human and financial resources capacity, commodity accessibility, use of health facilities, and educational messages).

Question 16: The International Health Regulations 2005 are intended to provide a global framework for the rapid identification and containment of public health emergencies. How effective do you consider this response system to be? Do improvements need to be made?

16.1. The International Health Regulations (2005) (IHR) are a legal framework to better manage the collective defences against acute public health risks that can spread internationally and have devastating impacts on human health as well as unnecessary interference on trade and travel. They are binding on all WHO's Member States. Given that IHR (2005) only took effect in June 2007, evaluation would be premature, however, their broad global acceptance greatly enhances the potential for effective world wide impact.

16.2. The IHR provisions addressing the detection, assessment, reporting and response to public health events are generally formulated to complement and support the WHO global alert and response system. The IHR provide specific mandates for WHO in this context, including access to critical public health information about emerging events.

16.3. Under IHR, WHO member states have a responsibility, not only to develop their own infrastructure but also to help less developed countries do the same.

16.4. The World Health Report 2007 states that “A more secure world that is ready and prepared to respond collectively in the face of threats to global health security requires global partnerships that bring together all countries and stakeholders in all relevant sectors, gather the best technical support and mobilize the necessary resources for effective and timely implementation of IHR (2005)”.

Question 17: What intergovernmental planning has been undertaken to cope with the impact of an outbreak of infectious disease caused by deliberate release of micro-organisms into the environment? Is there adequate liaison between the various agencies involved, including intelligence, law enforcement and health care professionals? How could action by intergovernmental bodies help further?

17.1. WHO has issued preparedness guidance for public health in the event of a bioterrorist release and has developed operational protocols for its own actions during such events. WHO continues to liaise with military and policing organizations to ensure that its public health mandate can be delivered during such an event and adequate arrangements for co-ordination are in place.

Question 18: Though our remit is focused specifically on known infectious diseases, we would be interested to know how you view the global threat from new or previously unrecognised ones and from the transmission of infections from animals to humans.

18.1. The most significant new, emerging diseases that have occurred mostly during the past ten years, have been of zoonotic origin. These diseases have been transmitted to humans mostly by close contact with affected live animals or their carcasses, or through the consumption of their tissues. The trend is likely to continue in the foreseeable future. It is very difficult to predict the outcome on public health of these emerging zoonotic diseases both before their zoonotic nature is confirmed and even after since transmission patterns are not always sufficiently understood to assess this impact accurately. The financial losses of zoonotic diseases (recorded in both human and animal health) and also the societal non-monetary losses caused by these diseases is usually very high as demonstrated by the bovine spongiform encephalopathy, severe acute respiratory syndrome and avian influenza epidemics.

18.2. Altering human behaviours, environments, human and animal movement trends, extent of food trade, adaptation and evolution of infectious pathogens are just a few reasons that impact the fluid phenomenon of emergence and re-emergence of zoonotic diseases eg SARS. History shows we cannot fully predict occurrence and spread of disease that is why early warning systems and emergency preparedness are so important. Dealing with a disease epidemic in its early stages is easier and more economical than when it is widespread. Sometimes signs in animals pre-empt human disease and so early warning in animals is an efficient way to avoid human disease occurrence.

18.3. Health threats arising from natural disasters, technological incidents (eg chemical or radio-nuclear accidents) and from conflict and terrorism are common. This burden and global health security threats can be greatly reduced if countries have in place measures to prevent, prepare for and respond to such events.

Question 19: What resources (subscriptions, staff, training, medicines etc) does the UK Government commit to intergovernmental bodies to help in the fight against the four diseases listed?

19.1. WHO receives funding from DFID for Avian Influenza. However, the main investment by the UK in international alert and response is through contributions of science and public health agencies and institutions acting as WHO Collaborating Centres, and provision of experts to committees, reference services and staff who go to the field as part of Global Outbreak and Response Network (GOARN) teams.

19.2.

Disease	UK Contributions				Other
	2004–2005 biennium		2006–2007 biennium*		
	WHO-HQ	PAHO	WHO = -HQ	PAHO	
HIV/AIDS	\$13.42m	\$1.44 million	\$13.14 million	\$1.34 million	1 Sr Secondment
TB	\$344,018 (including \$176,367 for Stop TB Partnership)	\$30,600	\$43.4 million (including \$42.9 million for Stop TB Partnership)	\$13,900	
Malaria	\$957,855	\$£13,900	\$2.1 million (including \$1.6 million for RBM Partnership)	\$272	

* (estimated, pending closure of accounts).

Question 20: Do you wish to provide any other relevant information in addition to what you have said in answer to the above?

1 February 2008

Examination of Witnesses

Witnesses: DR DAVID HEYMANN, Assistant Director General, Health Security and Environment, DR PAUL GULLY, Senior Adviser to Dr Heymann, MR PAT DRURY, Department of Epidemic and Pandemic Alert and Response, GOARN, and DR MAX HARDIMAN, Coordinator of International Health Regulations Secretariat, World Health Organisation, examined.

Q505 Chairman: Welcome to the Intergovernmental Organisations Select Committee. We are very pleased to have you here and very grateful for the written evidence you have already given. The Clerk has already suggested to you that we are going to split this into two one-hour sessions. The bad news is that there is not a break in-between! We will go from organisational structure mode into the local outbreak alert issues. Perhaps I could start, as someone said to me last night, by wishing the World Health Organisation a happy birthday as of a week or two ago. It is a good time to review one's life's progress so far. I did the same at 60 and I am still here, so there must be something going for it! The purpose today is to look at the way in which, from the British perspective, the British Government uses its funds in intergovernmental organisations, in this case the World Health Organisation, in order to combat these diseases. As I indicated, for the first hour I am particularly interested in looking at the strategy, structure and organisation of the WHO, and in the second hour some of the application, if you like, although there will not be an absolute division. I would very much like to invite any of the witnesses to chip in when you feel you have something useful to say. At the end of this session in a few days' time, it might be longer than that, you will get a transcript of the evidence and will have an opportunity to look at that and correct it before it is published in its final form. Again, if you feel there is anything we have not covered that we should have covered, or anything that needs clarifying, then do not hesitate to write to the clerk. The whole purpose of this is to understand rather better than we do at the moment how the system is functioning, where the problems and the possibilities are, and to move forward. Perhaps I should start by asking each of you to very briefly introduce your roles within the organisation. I think that would help us, if you do not mind.

Dr Heymann: My name is David Heymann. I am the Assistant Director-General for Health Security in the Environment and the representative of the Director-General for Polio Eradication.

Dr Gully: My name is Paul Gully. I am a Senior Adviser to Dr Heymann in his office. I am actually seconded from the Public Health Agency of Canada and have been in WHO for the last two years.

Mr Drury: My name is Pat Drury. I work in the Department of Epidemic and Pandemic Alert Response, which is under David's *chapeau*. The Department is responsible for managing epidemic risks across the spectrum of all diseases, except for the big three. I work in a team called Alert and

Response Operations, in which I manage the Global Outbreak Alert and Response Network.

Dr Hardiman: My name is Max Hardiman. I work in the programme on the International Health Regulations, which is under David Heymann. My role is Coordinator of the International Health Regulations Secretariat, which is one of the teams within that programme.

Q506 Chairman: Thank you very much indeed. Perhaps I could start the questions with this overall strategy one and on the organisation of the WHO. I think everyone accepts that the diseases we face now are particularly serious, particularly difficult and on a global scale because of other changes that have happened in the world generally. I particularly want to know how you see your strategy. One of the areas of interest to us is this problem of our health structure within nations and within areas of the world, and it is often lacking particularly in areas of Africa, say, and the issue of vertical treatment of diseases. We are conscious that you have many organisations putting a lot of money into these diseases but often there are not the health structures within the country. My first question is very much on your strategy. What strategy do you have in view of the conflicting interests of these various groups, and there are a lot of them in our understanding?

Dr Heymann: Thank you. If I might start off by just thanking the United Kingdom for the strong support that it has given to WHO. We are all very grateful for that support in many different areas. To address what many people like to talk about as the vertical and the horizontal programmes, the strengthening of health systems versus the vertical programmes which concentrate on a specific disease, the easiest answer to give is that if a vertical programme is functioning properly, it will be horizontal in its nature and will permit other programmes to follow on. I will give you a good example: tuberculosis. Tuberculosis requires community action to provide supervised treatment to patients. If that can be accomplished for tuberculosis, that same system can be used for HIV treatment and a whole series of other interventions. Vertical programmes, if they are implemented properly, will end up in a strengthening of the health system to get the goods to the people. Vertical programmes can also strengthen disease surveillance or detection systems. The example of that is the Polio Eradication Initiative, which has a surveillance system which comprises over 3,000 health officers throughout the world who have real-time communications and at the same time have transport and fuel. They are

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constantly identifying foci of polio and reporting. This network is a vertical network supported by the Polio Eradication Initiative, but we have now begun to broaden it to include Yellow Fever in Africa, the haemorrhagic fevers in Africa, and to include measles, other immunisable diseases worldwide and a whole series of other interventions to make this vertical programme more horizontal. Both in surveillance and response, vertical programmes can lead to a horizontal strengthening of the infrastructure. In order that these systems can work properly there must be the correct health system environment in a country that develops the funding and other policies which will permit sustainability of that health system, and a whole series of other policies to make sure that what is occurring occurs in an integrated matter. No matter how vertical a programme is, either from the centre, the government, or from a region, when it gets to the peripheral areas it must be horizontal by necessity because there are only one or two people who can implement those programmes there. I will call on my colleagues if there are any other comments.

Mr Drury: In terms of explaining a bit of the operational glue that we are putting in place as well, the Alert Response Operations Team in Geneva runs a series of activities which are about using all sources of information to identify what we call “events”, that is a spike, and some news story or some incident of interest to us, and then puts that through a process of risk assessment, and out of that risk assessment we make recommendations for the country to take action and for WHO and its partners to take action. That is a system and a process which has been in place for ten or 15 years since David took over what was then the new Department of Emerging Diseases in WHO. It is now governed legally by the International Health Regulations and it is a major challenge for us to take it forward to the next step. We hook in on a daily basis to the Global Polio Network. So, if there is an incident in Angola, where we know there are polio people on the ground, we will be in touch with them for information about what is happening so that we can inform the risk assessment.

Q507 Chairman: The answers you have given suggest a slight blurring of the line between vertical and horizontal in a way that we have not quite heard from other people. What strikes me is that, in order to pull that together, you need a very strong central body. Is WHO that strong central body given that you are dealing with groups that are profoundly well-funded, better funded than you are in a sense? I am not quite sure that you are going to be able to manage this. Can you tell me a bit more about what you think about that?

Dr Heymann: Let me just give a brief reply and then I will call on Paul Gully. WHO is many times at the whim of its investors and funders, and many countries prefer to fund vertical programmes, others prefer horizontal programmes. We must do what those countries request us to do because they are our Member Countries and they decide how we will function. With a very small budget that comes in from our assessed contributions to countries we are required to take extra budgetary resources. For example, from the United States it is very seldom that they will invest in infrastructure or a system. What they will invest in is diseases because that is what their Congress is used to funding in a vertical manner. Paul may want to say something about this as well.

Dr Gully: What I was going to say in reference to your point was that there has now been reference to diagonal processes, a combination of vertical and horizontal. The promotion of health system strengthening, vertical, as opposed to polio, HIV, TB programmes, horizontal, and primary healthcare could be used as an example. The health system strengthening is there to ensure that, if there are vertical programmes and you want to promote them horizontally, then you have got an infrastructure in the health system which can then carry out those programmes and not just those vertical programmes. It has been described as something which pulls them together. The G8 meeting this year under the chair of Japan is promoting that concept of health system strengthening, and now in WHO there is an Assistant Director General with responsibility for health system strengthening to try and pull them both together. In terms of the other players, WHO is often on the frontline, and I will use the recent example of H5N1 in Pakistan, where we used the infrastructure which is in Pakistan for polio eradication in order to be able to investigate and respond there. The other main players, the funders and so on, are not there to do that, they are not there at the frontline and, in fact, I do not think they would regard it as being their responsibility. In order for those kinds of interventions to take place, which are going to be an inevitable reflection of new and emerging diseases, WHO has to be there, but that strengthened health system has to be there as well in order to be able to make it better, improve it and then make those responses more rapid on the ground.

Q508 Chairman: Before I bring my colleagues in, it is an interventionist role that you are describing in what we might call the horizontal health system. That requires funding and also raises questions about what happens to the government in the country that is also trying to structure it and presumably not always welcomes this intervention. What is your response to that?

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Dr Gully: WHO does not enter into a country without being invited by the government of that Member State. I think one could draw parallels to that in the way that an operation such as the Health Protection Agency in the UK or CDC in the US or the Public Health Agency in Canada work internally, that you do not go into a jurisdiction that has responsibility for health without being invited. However, having said that, the country representatives in those countries, such as Pakistan for example, will be there promoting working together with the government of the Member State to try and sell the advantages of that intervention. Often where it becomes difficult is if we want to encourage intervention not just in the health sector but perhaps in the agricultural sector and other sectors as well. Often that is not helped by a lack of intersectoral collaboration within the country itself. We do not go in without being invited but we can be there promoting that. Often health is more likely to be invited than perhaps other sectors, such as agriculture. On numerous occasions there have been illustrations of where those invitations have been extended. For example, the Government of Madagascar on Rift Valley fever, both from the health and agricultural side, has extended an invitation to investigate that as of Wednesday this week.

Q509 Lord Avebury: I was interested to hear what you said about the Assistant Director being responsible for health system strengthening, particularly in the light of what Dr Chan said about countries needing a primary healthcare basis to deliver relevant services. You said earlier that the organisation was constrained to a large extent by the voluntary funding. But would there not be very strong support in developing countries for assistance with the financing of their health services if that was something that WHO was prepared to provide?

Dr Gully: I think that is correct. The challenge is that countries often do not come forward and say generically, "We wish to support health system strengthening". This goes to the collaboration within countries too, because often there you have a development agency, a department of health, a department of foreign affairs or equivalent, and they do not necessarily reflect a unified policy within a country. So, whereas one might be in favour of that, another might not be. This comes down to how individual government policy is manifest. Often there is a wish to be much more precise and say health system strengthening. I think you are right, countries would welcome it, but it is not necessarily there. The other point I might make is that often countries do offer support in areas in which they are strong and often developed countries are strong in healthcare delivery as opposed to public health per se and,

therefore, what they might offer specifically might be less enabling for that health system strengthening across the board than perhaps might be needed.

Q510 Lord Howarth of Newport: I would like to ask you to talk about questions of synergy. If you look at an organogram of the different international intergovernmental organisations in the health field, you see a mass of organisations interlocking, overlapping, independent, and the world looks, fairly or unfairly, to the WHO to achieve a strategic vision to bring in some coherence, some coordination. It would be interesting to us if you could talk a little bit about how this works, where your successes are achieved, what the key has been to achieving success, and equally where the deficiencies are. You say in your excellent evidence to us that there is a strong level of synergy between the various organisations concerned with disease control but you also acknowledge that the synergy is not complete. Where it works well, why does it work well? Where it does not work well, why does it not work well?

Dr Heymann: I will start with that and pass it to others. The Polio Eradication Partnership is a very good example of a partnership that brings together four principal actors in polio eradication and it succeeds because each of those actors has found and adheres to its comparative advantage. In the Polio Eradication Initiative, the World Health Organisation is responsible for setting the norms and standards in global policy and providing technical support to governments to develop the appropriate responses to polio. UNICEF provides all the vaccines necessary and at the same time works on social mobilisation in countries and with countries. Rotary International advocates internationally, and if any of you are Rotarians you will know that it is a very important role. Not only do they advocate internationally, but they advocate in countries like the United States, where they ensure each year that there is a significant contribution to the Polio Eradication Initiative, as they do in the United Kingdom, in Sweden and in many other countries. The Polio Eradication partners are WHO, UNICEF and Rotary, they have each found their comparative advantage and stick to it, and CDC, the Center for Disease Control in Atlanta, where I come from, is a technical partner that provides technical support to countries through provision of staff to work on certain issues mainly involved in surveillance, monitoring and evaluation. Each partner sticks to its specific role and all four partners together mobilise resources, and to date have mobilised over US\$5.5 billion for polio eradication. The United Kingdom has been one of the very important partners in that financial partnership. Another partnership that has begun is the—

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Q511 Lord Howarth of Newport: Just before you move on to that, can I ask you how is that excellent orchestration achieved? And is the WHO the leader in coordination?

Dr Heymann: Yes, the WHO is the leader in that. This is achieved by weekly telephone calls with the four partners. There has never been a formal governance mechanism set up, it has been purely by the will of these four partners to talk together once a week or once every two weeks if it involves a specific area of work, and, in addition, working in concert at country level. For example, if I want to go and see a Head of State in a country, it is usually Rotary that is the most rapid in getting that visit, it is not the health sector, it is Rotary International. When the meeting occurs, it is Rotary, UNICEF and WHO who attend that meeting. CDC usually does not attend because they prefer to stay in the background. It works very well that each member uses its own comparative advantage, but it is a mechanism which is informally run, it is not formal governance. The other partnerships are partnerships that have formed around avian influenza. There are two major ones. There is GLEWS, which is a surveillance network, and Paul will speak more about that, which works with FAO, WHO and the OIE in Paris to be sure that we understand where avian influenza is occurring in animals and where the risk is greatest to humans. This is a partnership which is run with no formal governance, but it is run because one of our financial partners, Canada, insisted that we work together and provide the resources in such a way that it forces us to work together. Another initiative is the Tripartite Agreement of WHO, FAO and the World Organisation for Animals Health (OIE) in Paris: and UNICEF that has just begun to work with the partnership as well. Together we are working to set up a one health/one world programme, which will be a programme that operates at the country level and which provides programme capacity in both veterinary and human health making sure that together we are working to not let humans be the indicator of animal disease but animals themselves be the indicator. Today, in countries zoonotic infection, or an infection that comes from an animal to a human, is mostly found first in humans and then the infected animals are found and dealt with, but it needs to be the other way around, so that when BSE or other zoonotic diseases occur, the disease is dealt with so that the barrier that protects humans from being infected is strengthened early on.

Dr Gully: If I could just add a couple more examples. One is in relation to Yellow Fever, where there have been recent outbreaks in South America, particularly of note in Paraguay, where there had not been an outbreak for decades. Rapidly WHO, together with private industry, a vaccine manufacturer in Brazil but also one from the US and France, Sanofi, and

UNICEF, that has the logistics capability for delivery, worked together to deliver 1.6 million doses of vaccine to Paraguay in a very short space of time. That was also helped by a broader agreement about Yellow Fever vaccine, which was in collaboration with GAVI, the Global Alliance for Vaccines and Immunisation. That is one which does work between other UN countries but also with the private sector as well. The other relates to other intergovernmental organisations, such as the International Federation of the Red Cross, where WHO is working together with IFRC and the UN agencies involved in humanitarian response, and this relates to pandemic preparedness. IFRC has received a large amount of money from USAID to work on what they describe as Level Six pandemic preparedness. It has meant that the UN agencies, plus and including ones such as the World Food Programme, for example, which did provide a logistic response in the recent Ebola outbreak in Democratic Republic of Congo, together with other organisations do respond. They do relate to specific needs, specific initiatives, so there is not one big organisational structure that meets to say how they work together, but when it is necessary we believe that synergy does exist and I am sure it can be proved.

Q512 Lord Howarth of Newport: Those instances are admirable and encouraging but, on the less cheerful side, the world is an imperfect place; and, if we look at the tragic predicament of Africa, for example, you must be concerned at WHO that there are important problems where we are failing to get the coherence of effort that is needed to be properly effective. Will you talk to us about some of those as well?

Dr Heymann: An example in Africa is very important. Several years ago, maybe in the early 2000s, I cannot recall exactly the year, one country in Africa bought all the meningitis vaccine available on the open market because meningitis vaccine was required for pilgrims going to the Hajj, but that vaccine is also required to save the lives of children because each year there are major epidemics of meningitis. At that time, in order to deal with this issue, WHO formed a partnership and set up what is called the International Coordinating Group for Meningitis. We brought together all those competitors for vaccine internationally—Doctors without Borders (*MSF*), the International Federation of Red Cross and Red Crescent, Societies, UNICEF and WHO, the major partnerships for countries in meningitis. We got together and began to make forecasts on needs for meningitis vaccine, worked with industry to make sure that those needs were met, and mobilised resources which were made available to purchase vaccine in advance. That mechanism continues to function and each year provides vaccine to countries based on criteria that have been pre-established by

the four partners so that when there is an outbreak vaccine is immediately made available to those countries. Again, it is an informal mechanism, no formal governance, but there is intensive work by our staff to make sure that these activities occur. Another example in Africa is the Polio Surveillance Networks. When Nigeria developed avian influenza in humans, the only network that was able to respond was the Polio Eradication Network. That Network went to communities and began social mobilisation, explaining to people about influenza and how they should prevent themselves from becoming infected, a very important tool that we have called into action. Those are some of the successes in Africa. It is very difficult to work in Africa and very difficult for countries to understand all the issues that are going on, but we hope that with the International Health Regulations, and the requirement that all countries have accepted to establish core capacities in surveillance and response, these countries will be able to establish the capacity if the bilateral donors and international partnerships occur to deal with that. I could tell you, if you would like to hear about it, of a partnership that is just forming with the Commonwealth and Health Protection Agency on strengthening core capacities in countries.

Q513 Lord Howarth of Newport: Understandably enough, you are still talking about your successes. We would like you, if you will, to be candid with us about where your frustrations are, where your disappointments are, and whether these are systemic or what the explanation may be for the failures in progress that occur.

Dr Heymann: I will start just with an honest, open statement and then I think others will come in. As you know, our WHO system is such that the Director-General is an elected official and so are the six Regional Directors of WHO. At times this causes a great challenge in coordination and in making sure we work as a corporate World Health Organisation. Dr Brundtland, when she was here, worked very hard, and now Dr Chan is working even harder, much, much harder and more intensively, to make sure that we can work together and understand what each group can offer best, and promote that in working together. I must admit that many times there are delays in how WHO Headquarters responds to a situation and how our African Regional Office responds to that situation. On the other hand, there are very many successes in which Directors take the time to work closely with their regional counterparts at a technical level and succeed in accomplishing major events. There are some political issues because of the elected Director General and Regional Directors and responsibilities to countries that elected them, while at the same time as there are great successes working at a technical level within the

organisation and sometimes those two areas are not in synch.

Q514 Lord Howarth of Newport: You said synergy is not complete. Are you also frustrated from time to time by failure of synergy between the WHO and some of the other major organisations that have appeared on the scene, particularly in recent years, which command a lot of funding but which have their own terms of reference, their own impetus and may not dance to your tune?

Dr Heymann: We do not want people necessarily to dance to our tune. Our function for 194 Member Countries, is to set global policies, norms and standards and hope that others will work with them. The Global Fund came into Geneva several years ago and this was encouraged by WHO, WHO advocated with the G8 for the Global Fund. The Global Fund has come in, and it is not a technical agency whereas WHO is a technical agency. WHO has spent much time and energy, as you will hear from the tuberculosis people when you speak to them later on, in developing national proposals for the Global Fund so they can be effective in mobilising the resources from the Global Fund. Early on we approached the Global Fund for support to WHO in the endeavour to help countries develop their proposals and we were told that the Fund could not directly provide resources to WHO, those resources would go to countries and countries could engage WHO should they wish to have WHO work with them whilst developing their proposals. Of course, this is not the way countries work, countries do not pay WHO. If countries ask WHO for support we provide it to them at no cost.

Q515 Lord Jay of Ewelme: I just wanted to pick up one thing you said in your very interesting discussion about polio eradication and your handling of that. I think you said that the CDC's role in Atlanta in all of this, amongst other things, was that of monitoring and evaluation of progress on the ground?

Dr Heymann: Yes.

Q516 Lord Jay of Ewelme: I just wondered if you could enlarge a little bit on that and talk about how WHO ensures that there is proper monitoring and evaluation of its programmes more generally. Is that something which normally, as it were, you would outsource to something like the CDC? Or is it something you would do in-house? How do you ensure that there is that constant monitoring and evaluation so that you can learn the lessons and improve the programmes in the future?

Dr Heymann: Monitoring and evaluation are not outsourced, they are done by WHO in the partnership. What is outsourced is the provision of technical support to countries to do their national

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monitoring during campaigns. The monitoring system for polio eradication is a very strong monitoring system. Wednesday morning here in Geneva the entire polio team meets and at that meeting the indicators that have been established for surveillance are reviewed coming up from countries through Regional Offices into WHO, all the way from a district level. The indicators that have been set up concern the number of children with flaccid paralysis who are identified and the number of those children who are properly examined and provide the proper specimens of stool in the case of polio. The indicators have been established at one per 100,000 children under the age of 15 years must have been reported with flaccid paralysis because flaccid paralysis occurs for diseases other than polio and there is a background level of paralysis. This is reported and, if a country falls below that threshold, the next week the Regional Office, through its Country Office, contacts the government to find out what has happened and attempts are made to address the problem. We know, sitting here in Geneva, in which local government area in Nigeria there is not surveillance for polio because we receive that information once a week and we monitor it closely. If there is polio, the indicator goes up to two cases per 100,000 children required and that is how we continue to monitor polio surveillance. Polio response is monitored by the reports of countries of polio and those viruses that are isolated from countries are genetically sequenced so we can see where they come from. If a country has polio and it has not had polio in the last two years, we can see from the genetic sequence where that virus has come from and most times today it comes from Nigeria or India.

Q517 Lord Jay of Ewelme: Thank you very much for that. Just moving for a second on to evaluation, ex-post evaluation of programmes, is that done centrally, is that done here? Or would that be built into each programme so that there is a process for a year or two or three afterwards of checking how successful the programme has been and learning the lessons from that?

Dr Heymann: Each programme has a technical advisory group set up which consists of experts from each of our regions and headquarters. Through yearly or bi-yearly meetings they monitor progress and make broad recommendations. In the case of polio, each country has its own technical advisory group on which WHO sits and that advises in the countries. Also built into polio eradication and most other programmes are external assessments which are done by an external group which comes in and does those assessments to determine whether or not there is success. Right now one of those external assessments is being thought about for the Global

Outbreak Alert and Response Network and I wonder, Pat, if you could say a word about that.

Mr Drury: Maybe if I could take a step back to some of the earlier stuff and stick my neck out a little bit. It is natural for us to blow our own horn and be more comfortable talking about the successes, not least because any failure is a failure of a Member State, and as the Secretariat, we are protecting them. Our real success over the past seven or eight years has been in responding to events. The process that David spoke about, about meningitis vaccine, ensuring that the vaccine is there, is only useful because it can be transferred very rapidly and these groups come together to review the evidence and make a decision that the vaccine should be made available cheaply to the country within a matter of two or three days. The outbreaks in West Africa of Yellow Fever threatened all the major urban areas. In 2001 and 2002 there were outbreaks which threatened the populations of Dakar and Senegal, Abidjan and Cote d'Ivoire. Because WHO was able to deploy teams to investigate these cases, identify the outbreak and then call in the additional support, that created a powerful argument for the likes of GAVI and others who now have taken the example of the meningitis model and cloned it to apply to Yellow Fever. But we are in a constant struggle, and as soon as we think we have these two things in place and they are useful, the outbreaks happen in a different part of the world. This is to do with the meningitis belt in Africa and West Africa where the Yellow Fever outbreaks have taken place predominantly. The mosquitoes did not understand the rules, and this year outbreaks have taken place in Latin America. Up until the beginning of this year we felt we were comfortable and any evaluation would have said a six million dose vaccine stockpile available, support and money from GAVI and others, UNICEF and WHO and everybody is working together. But, as soon as one of the factors changes, the outbreaks happen in Latin America, the stockpile is not enough and what was an emergency stockpile is now being directed to Latin America to support a more programmatic approach. That is OK until the next crisis element comes in, which is that there are now outbreaks in Liberia and the Liberians should really have first claim on the emergency stockpile. But the emergency stockpile has been needed to support a more programmatic approach there. That is a bit long-winded. Where we have been successful is in our outbreak response and we measure that in terms of the time we got there, how many people died in the outbreak and how quickly it was brought under control. It may be that we are not measuring the right thing and, although these interventions and international missions are opportunities and the primary function is on controlling the outbreak, they should really be measured in terms of how they contribute to building

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national capacity and how these events are used to draw in the more programmatic approach to support the building of core capacities as envisaged under the IHR. The Global Outbreak Alert and Response Network is a network of about 140 technical institutions around the world that WHO coordinates with to ensure that there are experts available to support these types of activities.

Chairman: We will come back to the global outbreak a bit later. I am getting a bit worried that we are going to lose some of our areas. If I could leave it at this stage and ask Lord Desai to come in.

Lord Desai: My question has more or less been answered.

Q518 Chairman: We need to come back on the overlap.

Mr Drury: I was so long-winded I did not get a chance to answer Lord Jay's question about evaluation. There are two evaluations just about to kick off. One is the internal WHO audit group, which looks at performance, which during the month of April is going to begin an audit of performance in our group and in influenza and one or two others. That is an internal audit of performance. The partners in GOARN have asked that we bring together an external panel of experts to review the activities of the Network over the first seven or eight years and on the basis of that external evaluation provide guidance for the future development of the Network. We hope that will happen within the next six months with a view to having a meeting of the Network before the end of the year.

Q519 Lord Avebury: I was wondering, as you were talking about WHO's success in responding to outbreaks, whether you had any strategic scenarios over the years ahead which enable you to plan for the structures that will be needed to cope with what appear to be an enormous variety of unpredictable outbreaks occurring in different parts of the world. How do you develop scenarios within your own organisations to enable you to develop the structures that will cope with such a wide variety of possible outcomes?

Dr Heymann: Let me respond to that by giving you an example of how we cope. When the SARS outbreak was first identified in 2003, WHO, in order to notify countries about this disease, was obliged to put it in the press so that every country could read about it. Today, when an outbreak occurs, such as Rift Valley Fever in East Africa or many other diseases, we can have access immediately to an International Health Regulations Focal Point in each country so that information can be fed immediately to a country within its own system. These focal points are

nominations made by the country. This helps us greatly in our response to make sure that countries understand what is going on immediately. In order to test this new International Health Regulations system there will be a series of three different tabletop exercises. The first occurred last year, when the International Health Regulations came into force and WHO had an internal exercise to see how we would communicate about an outbreak should it occur. We found many difficulties, many weaknesses, which we have since remedied. This year on 11 and 12 June there will be another exercise within WHO and also involving our country Focal Points. These country Focal Points and WHO will have an exercise to see how they can best work together should there be a pandemic that occurs. I think this scenario will probably be an influenza outbreak. In addition, at the level of the United Nations we have an exercise coming up on 19 June, which will be an exercise to see how the United Nations systems work together in a pandemic; and in September there will be a further exercise which involves NGOs and the UN system to see how we can best respond internationally. We are working on several different scenarios and exercises which we hope will permit us to identify problems and solve those problems as we move ahead. This is all possible because we have this coordination with over 140 different networks and we have the International Health Regulations which penetrate countries.

Q520 Baroness Whitaker: A quick bit on the Alert Response, if I may. You receive reliable information regularly about vaccine delivery. Some vaccines still need to be kept cold, and in some countries the power supplies are really poor, say in Kenya, and the fridges go off. Do you receive information that the vaccines are no good any more? Is there some way you can tap into that? Also, what power can you exert on this different area, nothing to do with health, of the power supply?

Mr Drury: I will leave the power supply for my boss! We rely almost exclusively for our cold chain delivery of vaccine on the polio network. If this is in countries where there is not a big active polio infrastructure, it is a challenge. For any outbreak or any event where WHO is facilitating the delivery or the purchase of vaccine by a country, we encourage the country to engage in adverse event surveillance, so part of our support to the country is, "We can get you the vaccine, we can help you develop the plan for the delivery of the vaccine", but it is also important we are monitoring implementation of the immunisation campaign and any adverse events that are being picked up in it. It is a function of our operations in the field to monitor the efficacy and side-effects of the

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vaccine and our logisticians and operational infrastructure will be looking at issues of breakdown in the cold chain and how those might be addressed.

Q521 Baroness Whitaker: So you do what you can basically?

Mr Drury: We do, but in a very limited way. It is a big problem.

Dr Heymann: Just a couple of additional points on this. The comparative advantage is not with WHO but with UNICEF and the cold chain. UNICEF provides all of the purchase of the cold chain equipment and tailors that equipment to the possibilities in countries, either a petrol fridge, a solar fridge or an electric fridge. They do the assessment and provide the fridge based on that. In addition, vaccine vials each have a temperature indicator which will show if that vaccine has ever been exposed to temperatures above which it should be stored. The minute that happens the indicator turns colour and the vaccine is discarded.

Q522 Lord Desai: Is there too much specific investment, vertical investment, disease specific and not enough horizontal? Or are you satisfied with the way that these investments occur? Are there too many people who want not only to invest but to have their signature on what happens?

Dr Heymann: Vertical systems like the Global Fund, which provides directly for AIDS, TB or Malaria, and other partners who provide that funding, provide that with the understanding that health systems cannot function if there are not goods in those systems. If you only concentrate on strengthening a health system or strengthening the infrastructure, you risk having the equivalent of a school bus with no students. What the Global Fund and others who give vertically to disease control programmes provide is the students in that bus, or the goods in the health system. If there are goods in the health system, people will pull those goods out to the periphery because they know they are there, they will continue to go to the health facility to get those drugs. If the goods are not in the system, they will not go. Vaccines are very different because UNICEF, along with WHO, has worked very hard to make sure that those vaccines fit into a programme which can accommodate them and get them out safely to people through a good cold chain. The Global Fund and others do not have all the security mechanisms they need. In fact, one of the major needs in these vertical programmes which are pushing drugs out is a system to monitor the effectiveness of those drugs and to make sure that they do not lose effectiveness because of resistance developing, things that WHO and countries can do. The vertical programmes require a strengthening of systems to monitor effectiveness of

drugs and resistance in laboratories, and WHO tries to make sure that this occurs.

Q523 Lord Desai: You do not think there is overcrowding then, an overcrowding, overlapping of agencies?

Dr Gully: I think, inevitably, the world is such that people will invest in things which they understand, which are clear, precise and reflect their wishes, and an organisation such as WHO has to deal with that. Another way of looking at it is, if one can reduce the burden of an important disease—HIV, TB, Malaria, Meningitis, Yellow Fever—then, in fact, one is reducing the burden on a health system which then has a greater ability to deal with other things that are going to come along. Yes, I am sure that balance is not necessarily right, and it varies from country to country, but hopefully if one is able to build that capacity one can use it to deal with chronic diseases, for example. How do developing countries deal with diabetes, deal with renal disease, with cancer? Maybe they deal with them better if they do not have to fill their beds with acute disease which can be dealt with by the vertical programmes. There is always going to be a balance which, as I said, WHO will have to deal with. Our Director General has said that she recognises that, if you look at the budgets of the large programmes, GAVI, Global Fund, Gates and so on, some of them are larger than WHO but, therefore, WHO has to work with those and that is where she spends a huge amount of time and energy, so there can be some synergy, some collaboration.

Q524 Lord Desai: Can I just press this for one moment. The picture we have got so far is of an immensely complicated architecture, but what you are telling is there are very straight lines, it is very beautiful and it all works. I am trying to reconcile these statements.

Dr Heymann: Let me give you an example that the Director-General used just last week in our senior management meeting. The Secretary-General of the United Nations has appointed a special envoy on Malaria. Within three weeks that envoy had been to visit the major financial partners that he could identify, both in the private sector and in the government sector. He has mobilised approximately \$10 billion over the next five years. The special envoy, who was actually nominated by our Director-General, has done the job in three weeks and now WHO must respond in being able to help in strengthening the human resources and other infrastructure necessary to be sure that this money can be implemented within country. The Director General will lead us to change our way of working to work in a more rapid and responsive manner. She understands many of the issues that delay our

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response and she has indicated that she will try her best within the system to make it work better.

Q525 Chairman: Have you got the balance of investment right between treatment and prevention?

Dr Heymann: That is a very good question and it certainly depends on the disease. If you looked at what bilateral donors were giving, including the United Kingdom, back in 1990, they would not provide any resources at all for treatment or patient management, it was purely for prevention, purely for vaccines, vaccines were the investments we wanted to make. That is why David Nabarro and others in our Communicable Diseases Group back in the mid-1990s worked with Brundtland to increase the understanding of our financial partners through Jeffrey Sachs' Macroeconomics Commission and a whole series of activities that drugs were also a preventive mechanism. They are a preventive mechanism that help countries prevent themselves from falling deeper into poverty, using these drugs to cure diseases and let healthy people move their economies ahead. This is why the Global Fund and others have come along. Today we have investment in drugs as well. Is the balance correct? In some areas it is not; in others it is. It is probably not correct in HIV today, it has possibly gone a little bit further towards the treatment rather than towards the prevention, but that will come back eventually and WHO advocates for that, along with UNAIDS.

Dr Gully: If I could also talk about neglected tropical diseases, such as onchocerciasis, the treatment available with public-private partners has been hugely beneficial in terms of reducing the burden of disease and reducing the burden on the health system, where otherwise there was no applicable way of preventing that disease, apart from eliminating exposure to a certain insect which was not possible. Even in these situations treatment can be highly valuable, but it depends.

Q526 Lord Avebury: You mentioned that the balance will come back between prevention and treatment in the case of HIV, but what signs do you see of that? Are there not tremendous political restraints on the increase of preventive action in HIV, particularly on sexual and reproductive health? What are you doing to promote sexual and reproductive health in the face of some political opposition?

Dr Heymann: That is a very good question. It is true that there is a major financial partner in HIV, the United States Government, which has a bilateral series of programmes on HIV which has not permitted all of the prevention interventions from being used. WHO has advocated with the US Government, as have many, many others, and in the new allotment of funding prevention is now fully installed. It is a matter of education, continued work

with countries, and many times by other countries that can help better than WHO in some of the difficult situations. I know that the United Kingdom and Canada were very helpful with the US Government in helping them understand the importance of all forms of prevention in HIV. We work with others, we let others help us if they can, and together we work on solving these issues. These are very difficult issues and the more countries decide to go bilaterally with resources, the more difficult it is for the multilateral systems, like WHO and its major partners, to have a full impact. Everyone needs to work together on these issues.

Q527 Lord Jay of Ewelme: Can I, first of all, thank you very much indeed for your written response to the Call for Evidence, it is extremely helpful. Whoever put that together did a really good job. I just wanted to pick up on something which you said earlier on, Dr Heymann, when you talked about the problems that can arise because of the relationship between the elected Regional Offices and other parts of the organisation. It is a question about the internal structures of the WHO. Perhaps the best way to ask the question is this. Suppose you are a Country Director, you are sitting in Kinshasa, Kampala or Nairobi, and you have a relationship with the local government, a relationship with the Regional Office and with Geneva. When you are sitting there, who is your master? And how do you reconcile all of these conflicting pressures that may come upon you?

Dr Heymann: The organisation is very hierarchical, as you know. That WHO representative, although that representative is named by the Director-General, responds directly to the Regional Office mechanism and then to Headquarters. That does not stop direct contact from Headquarters with the WHO representative in a country or through the Regions. I must say the WHO system works on the ability of a Director or an Assistant Director-General to establish a working relationship with his or her counterparts in a region and in a country. In our area of communicable diseases there is a tendency for WHO representatives to be torn between a country's wish to hide a disease and WHO's need to have transparency. This is decreasing as time goes on, thanks to the boldness of the Director-General at the time of SARS in encouraging China to freely provide information. We are seeing that information does flow. If we have a problem the mechanism that we use in the communicable diseases area is to call a phone conference between the WHO Country Representative, the Regional Focal Point, if necessary the Regional Director, and the appropriate level in Geneva.

Q528 Lord Jay of Ewelme: The initiative in doing that would come from here?

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Dr Heymann: Yes.

Q529 Lord Jay of Ewelme: You would not find the Regional Office saying, "Sorry, that is our job, not yours"?

Dr Heymann: No, absolutely not. They would participate in the phone call if you have a established a decent working relationship. Some try to bypass the regions completely and those people would have difficulty, I believe. As I say, it depends on the Director's ability to work. In our communicable diseases area, the health security and environment area and polio, we have no difficulty in convening a telephone conference whenever we need it to solve a problem.

Q530 Lord Jay of Ewelme: On this question of the slight tension between the desire of the country to maybe hide a disease and the desire of Geneva to see it as transparent as possible, where along that spectrum would the Regional Director tend to sit?

Dr Heymann: It would depend on the issue, I think. The Regional Director would respond to any message sent to him saying, "This is necessary". In avian flu they would understand that this could be the beginning of a pandemic and it cannot happen. In polio they would understand the issue and in meningitis. I often like to say that WHO spends more time collaborating internally than it does with its external partners, which is many times true. Having said that, this is what our function is, to make things work. We are a multi-cultural, multi-language organisation and we must work hard at it, and we do work hard at it, and we succeed.

Dr Gully: If I could add to that. I think changes to the International Health Regulations in terms of being able to respond to rumours, as opposed, in the past to official notifications has made a huge difference. We are now able to go to a country through a region to ask specifically what is going on and that country realises that the world knows a particular country has a problem. Other sectors, such as agriculture, do not have that. For example, the OIE, the World Organisation for Animal Health, can only respond to a report from a country, an official report, and it does make a huge difference. The fact that everyone knows we are there asking puts pressure on a country. I did not work in WHO before, although I was aware of the old International Health Regulations, but I think there is a difference.

Chairman: That is a very important point actually about the OIE.

Q531 Lord Jay of Ewelme: The last point about the OIE was really interesting.

Dr Heymann: Let me add to that briefly. There was an outbreak of Rift Valley Fever in East Africa. Rift Valley Fever is caused by a virus that comes from

cattle to humans by way of a mosquito. This outbreak was occurring in East Africa in Sudan in October and November of last year at the same time that animals were being traded across the Red Sea to Saudi Arabia and Yemen for religious sacrifices. This was a formula for serious human disease in Saudi Arabia when infected animals were being transferred across the Red Sea from Sudan, where people were dying from the disease. FAO was frustrated because reports of animal disease were not as forthcoming as were reports of human infection and we worked together with FAO through the International Health Regulations and reported to Focal Points in every country in the world that there was a Rift Valley Fever outbreak in East Africa, that this was killing animals and animals were a very great danger to human populations. The FAO worked with WHO and WHO passed the message to countries through the IHR with the clear acknowledgment of FAO.

Q532 Chairman: That is very helpful. Before we move off this, could you say a little about how you would co-operate with other organisations, and I am thinking particularly of the World Trade Organisation and one or two other organisations. They have given written evidence to us but they are a bit reluctant to come forward. While you are on that, a very powerful operation in financial terms is the Gates Foundation. How do you relate to the World Trade Organisation and the Gates Foundation? If there are any other problems you can flag those up.

Dr Heymann: As you know, the World Trade Organisation responds differently from WHO. The World Trade Organisation response is after the event; our response is before the event. That gives an interface where we can and do work very well with the Phytosanitary Bureau. The Bureau and WTO were constant partners in the revision of our International Health Regulations to make sure that we were not overlapping in any way but were complementary. To give you an example: a few years ago there was a European embargo or ban on the importation of seafood from Tanzania, which was having a cholera outbreak. This was unnecessary based on the known epidemiology of cholera. The World Trade Organisation could do nothing and Tanzania continued to lose resources, so WHO sent a letter to the European Commission from the Director-General indicating that this was not a health problem that required a trade embargo and, therefore, the European Commission was able to work this through the system and was able to lift the trade ban. That is a very effective way of operating before the event and then after the event WTO will take over. We included WTO in all our deliberations on the International Health Regulations and we believe that will be beneficial. As you know, the Gates Foundation is a major funder of our activities. Our

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support from the Gates Foundation has been absolutely superb. I will give you one example. We needed a new polio vaccine three years ago, we went to the Gates Foundation and they provided the resources necessary to develop that vaccine within a very short period of time, the vaccine was developed and is now effectively used in programmes, and the Gates Foundation required nothing more than providing us with the resources and understanding that the resources were properly used. They do this periodically in the neglected tropical disease area. They do not usually provide resources to sustain interventions. Whereas they will provide for polio eradication and guinea worm because those disease have an endpoint, they will not presently provide major support to AIDS programmes or TB programmes at this point while they are beginning to provide more resources for malaria, which they have targeted for intensified control and eventual elimination or eradication.

Q533 Lord Avebury: We heard about the World Health Organisation's Intergovernmental Working Group on Public Health Innovation and Intellectual Property. Could you tell us who is on this group? Since it is to report to the World Health Authority in May, can you tell us anything about what it is likely to recommend?

Dr Heymann: The IGWG is a mechanism which was set up by a number of countries, and all Member Countries are a part of that mechanism, which is a series of meetings. Of course, the issue on this is to find other ways that will guarantee innovation which could complement or even replace intellectual property. The discussions are still at a very early level. The report to the World Health Assembly will be one of progress made but there have been no breakthroughs, it is just a discussion point and continued discussion. Many times there are very emotional inputs by certain Member Countries of WHO which have very strong beliefs and, therefore, at times that derails the discussions, which then come back on target. Much remains bracketed in that discussion at present, it is a discussion which continues.

Dr Gully: In relation to another organisation, the World Intellectual Property Organisation, which relates to the IGWG, we have also had discussions with them relating to the issue of influenza virus sharing which does involve them and we have got really very good advice from them in terms of the intellectual property aspects of that issue. That is another organisation we deal with.

Baroness Whitaker: When Dr Chan says health is not just for the health sector, but, for example, also depends on education; and we briefly touched on power supply—there are these non-health entities. Are you content that you have the right kind of

liaison with the international organisations which cover education, transport, et cetera?

Chairman: The other international bodies in a sense, whether they overlap with health is the question.

Q534 Baroness Whitaker: How would you like to see this changed or improved basically? What should be done for the future?

Dr Gully: I honestly cannot talk about education, but in terms of transport we have close collaboration with the organisations related to transport in particular to the International Health Regulations and the control of the spread of communicable disease. I do not know in which sense you are talking about education.

Baroness Whitaker: The education that is a part of communicable disease prevention itself.

Chairman: Are you thinking of prevention impacts?

Q535 Baroness Whitaker: Yes. These are all prevention measures.

Dr Gully: We have close contact with UNICEF which, quite apart from the logistical aspects we have talked about already, has a great deal of funding, in particular into avian influenza. I was in a meeting in Rome last week with FAO, OIE and UNICEF in relation to a five-year strategy for infectious diseases, particularly zoonotic diseases. UNICEF was there as a player with funds and with expertise in terms of social mobilisation, which is a fundamental part of communicable disease prevention and control.

Q536 Baroness Whitaker: So you are content that nothing more should be done?

Dr Gully: I am never content that nothing more should be done.

Q537 Baroness Whitaker: What would you like to be done?

Dr Gully: I think the challenge with social mobilisation on the ground is often the understanding at the local level of how social mobilisation works. For example, we have realised in Burkina Faso, looking at prevention of avian influenza, that it is the children who collect the eggs and have close contact with chickens, because the chicken hutches are built in such a way that they only allow children to go in, to protect from thieves. So it is the children who are exposed. Therefore, who is at greater risk depends on the particular social and cultural environment. It becomes very specific and we have to have that capacity on the ground, which is often what is missing.

Q538 Chairman: I am afraid we are quite well into our second hour, and we want to move on to the Global Outbreak and Alert area. If we are all terribly disciplined, I might allow some time if we have got it

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at the end for any mop-up, but I have got a horrible feeling we are not going to achieve it without coming back for another two hours, which perhaps indicates the importance of this session. We need to be very focused on this. Your written evidence refers to “gross under-investment” in the Global Outbreak Alert and Response system and it being dependent on “strong, capable and transparent national systems”, which was I think your phrase. Can you tell us how you think these problems can be met and the deficiencies can be addressed, if you like? Who is going to take that?

Mr Drury: It looks like me. There is a later question where it asks if this is a crisis or not, and in my mind gross under-investment and crisis is the equation we need to look at. In the work plan for the Alert and Response operations area, and WHO has some 32 million for the next biennium, we would have a fraction of that, maybe 25 per cent of the money available at this stage to fund the activities. That is still only the tip of the iceberg. The same thing is reflected in each of the Regional Offices of the organisation, there is fairly limited human resource capacity and fairly limited funding. If we had not had bird flu, I think it would be much more obvious because over the past four or five years there has been a large amount of money that has come in and been invested at a national level and in the international system because of the threat of a pandemic. Our role always is to cannibalise and feed off these opportunities to find the money to fund our activities and keep them going. If we had not had that investment, then the capacity of the organisation would be even further limited.

Chairman: I might come back to that later.

Q539 Lord Howarth of Newport: Alert and response are not going to work well where individual Member States lack the healthcare infrastructure to be able to perform that role. WHO is constructed on the principle that countries should assist each other across national boundaries to promote good health internationally, certainly to prevent the transmission of epidemics, and the International Health Regulations state that: “Member States have a responsibility not only to develop their own infrastructure but also to help less developed countries do the same”. How does that work in practice, or how should it work in practice? If an individual Member State does not have the capacity, what is the responsibility of other Member States? How is that responsibility allocated? And how can it be made to happen?

Dr Heymann: Let me start by giving you the example of a meeting we had with Pat Troop at the HPA just before she retired. We discussed with her an initiative which will be followed through this week with a meeting to the Commonwealth and in a few weeks

here in Geneva at the Health Ministers’ Meeting of the Commonwealth. The Health Protection Agency would like to partner or twin with agencies in developing countries within the Commonwealth and provide to them the technical guidance and resources necessary to strengthen their manpower to better implement the core capacity requirements of the International Health Regulations. This was the beginning of a series of meetings, the meeting with Pat, which will now continue with the Commonwealth to talk with them about this issue, and after that meeting we will meet here with specific donor countries—Australia, Canada, the UK and a fourth industrialised country—about assuming a broader role in partnering within the Commonwealth.

Q540 Lord Jay of Ewelme: New Zealand.

Dr Heymann: New Zealand, yes. We will discuss how we can move ahead with this partnering within the context of the Commonwealth, so that industrialised Commonwealth countries can partner with developing Commonwealth countries to strengthen core capacities in countries. We do not have the resources to do that, they will be bilateral resources, and hopefully DFID will be involved, as will AusAID, the New Zealand development agency, as will be Canadian CIDA, providing the bilateral resources so that this partnering and the technical transfer can occur.

Q541 Lord Howarth of Newport: You will be the broker in this?

Dr Heymann: We will be the broker in this. We have begun the same thing with the Institute Pasteur in Paris, we will do the brokering with them, and the Francophone agencies for strengthening the partnership. We will continue to build this partnership into a partnership which can eventually encompass the world, understanding that we do not have the financial resources to do this.

Mr Drury: Another example along those lines would be in 2005, when there was a major outbreak of Marburg in Angola, when Angola was coming out of 25 years of war and its health system was non-existent. Through the Global Network of Technical Institutions we were able to deploy a fairly significant Outbreak Response Team to effectively run the health system in the town of Uige for a period of three months, because there was not any national capacity. The outbreak eventually went away. One of the things that came out of that, and it was obvious, was that the country was not asking for world leaders in epidemiology or world leaders in communication; they were asking, “Whoever you send to us, please make sure they speak Portuguese”. This was the most important thing. Because there was not a government structure in place, being able to work with the local

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actors was going to be the key to it. These were local leaders of villages and stuff like this. Coming out of this, and partly because the Regional Director for Africa is from Angola also, is an emerging Lusophone network, a network of the Portuguese language countries of Southern America and Latin America. That is bringing the two Regional Offices together, PAHO for the Americas and AFRO for Africa, to try to develop this and take it forward. One of the areas they are working on is to come to the idea of twinning Portuguese-speaking laboratory experts in Latin America with epidemiologists and other experts in that area.

Dr Gully: Previously you referred to the complexity of the international environment and you have the example of the Commonwealth and the Lusophone, but all the other especially economic collaborations out there can be very valuable, APEC being another one which is an interesting collaboration between developed and developing economies, and has quite a strong health taskforce with collaboration between those economies in a very effective way and, again, therefore, WHO feeding into that. Of course, the European Union is a great example, but there are many others, Shanghai Corporation and Mercosur and so on and so forth, which we have to capitalise on because that is a reflection of what those States or economies wish to do and then WHO providing the expert technical advice and guidance in terms of where they might go.

Q542 Chairman: From what you have said on both of these questions so far, is it easier to see what you are describing as working for response rather than surveillance in the first instance?

Dr Heymann: The idea of the International Health Regulations is to strength country capacity so that they can detect and respond to diseases before they occur internationally. Our role in the International Health Regulations through the Global Outbreak Alert and Response Network is to provide a safety net in case they do get out of countries, and then we can respond. At the same time, the International Health Regulations permit us to stockpile vaccine for meningitis and other goods as we do but the goal is to have countries do the job themselves and for us not to respond.

Q543 Chairman: Having the ability to do the surveillance is probably more difficult than having the ability to do the response, is that not correct? I would have thought, and tell me if I am wrong, it requires quite a sophisticated medical surveillance structure in order to see something that is coming but has not yet arrived?

Dr Gully: You build what you can in a country. Africa, for example, does have an integrated surveillance system that is syndromic, it does not

relate to specific diagnosis but a collection of symptoms which may indicate a particular disease around gastrointestinal disease or haemorrhagic disease, for example. I was talking to someone from Afghanistan and I said, “How do you manage?” and they said, “We do have people in each village who do report to us what goes on, although it is a bit difficult in the southern part of the country”, the polio people. One would never want to transplant a surveillance system which you had in a sophisticated developed country into those countries but you have to design one, and this is where the Regions do come in and are very valuable, and give support which is then applicable to the Member States.

Q544 Chairman: Are you suggesting that this is a sort of informal structure in some developing countries because, in the Afghanistan example, someone knows and they pass that on? Is that what you are suggesting?

Dr Gully: No. It is a formal structure, although much less sophisticated than one would see in developed countries but still works well. You have to develop as formal a structure as you are able to do and you have to give people the tools. It may be a local health worker trained to identify certain collections of symptoms which they then report. We do hear reports of “mysterious illnesses” from all over the world, from the depths of Nepal and other countries as well, and we hear about what is going on in the depths of the Democratic Republic of the Congo, not a country which is well-organised.

Q545 Chairman: We will treat that as an understatement.

Dr Heymann: The goal in our strategy is to build on the Polio Network which is already there.

Mr Drury: If I could just come in on that. In Afghanistan it is a disease early warning system, which is very rudimentary. In Pakistan, I think it is also called a disease early warning system. In Kenya they had a disease early warning system and the government on its website has a commitment that they will publish information about any epidemic within two or three days (I cannot remember the details of it). That was fine until we had the election there and the crisis and the national surveillance system. It may still be working but it does not appear to be working to those of us outside, so we have to rely on the other bits of the global system that feed information to us, so the UN agencies in the field, NGOs that may be working with displaced populations, and we try to pool the structured national surveillance information with the information that is in the media and that which comes from NGOs and other partners.

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Q546 Baroness Whitaker: Through the Country Office? Through the people on the ground in Nairobi?
Mr Drury: Yes and no. At headquarters we have a global process that does this. In Kenya, WHO takes its position in the health cluster, so within the health cluster of the UN family they are working ferociously to work as one UN family on the ground there. We are working at the level of the headquarters and we might be talking to the HQ of *MSF* Holland or *MSF* France and then, during the teleconference that David alluded to, you put these two pieces of the puzzle together and you are able to move things forward.

Q547 Lord Avebury: My question follows neatly on from what Dr Gully said a few minutes ago, that you never want to transplant a system from a developed country into a developing state. And yet the US Centers for Disease Control are establishing these Global Disease Detection Centers in various parts of the world and they are effectively performing a regional surveillance and detection role for GOARN, as we understand it. How do you reconcile the development of all these various linguistic and regional detection response and surveillance systems with what the Americans are doing with the Centers for Disease Control?
Dr Heymann: I came from the Centers for Disease Control in the past, I spent my career there and then I retired. The US Government through CDC, which was a very strong partner in our Global Outbreak Alert and Response Network, is now setting up its own bilateral Global Disease Detection Network. This was a vision of the CDC back in the 1990s when we set up our WHO Emerging Infections Programme, but at that time they worked multilaterally within the Global Outbreak Alert and Response Network. Under the current Global Disease Detection Network, however, there has been a tendency towards more bilateral relationships, not only with disease detection and response but with influenza, with HIV and malaria, as well. Many times there is difficulty in knowing who is doing what in a country when there is an outbreak of disease, much different from a few years ago when response was being well-coordinated by GOARN, and which we believe will be well-coordinated again. Pat, maybe you can give some experiences we have recently had.
Mr Drury: The fact is that, in the Outbreak Response field, position is everything. We recognise this because within WHO we are trying to regionalise all the activities that have been historically headquarter-centred. We are trying to ensure that we have one system supported by software and standard operating procedures and a concept of operations which extends to the country office. It is no surprise that the US, with its concerns for health security, have taken a similar position. We have known about the development of the GDD centres and the

operational hub in Atlanta since before its inception. As David said, it goes back to the 1990s when there were various proposals to establish this type of system. On a day-to-day basis we try to maintain coordination between Atlanta and Geneva within the strict restrictions that are put on WHO with regard to sharing information about one country with another. In terms of sharing operational information, we have tried to get along as best we can, so between the two headquarters there is some degree of coordination. There may not be much coordination between the response centres on the ground and us here. We would not know what their activities are on a day-to-day basis; but, if there are events, they do provide a role. It is a difficult issue to coordinate and deal with but, at the same time, they provide a capacity that would not be there otherwise. If we are dealing with an outbreak in southern Sudan and we do not know what it is, the samples go to KEMRI, where the CDC in Kenya is located. When it comes to outbreak response, our activities centre on trying to coordinate between a multilateral intervention and the politics of bilateral intervention. From the technical and operational point of view we try to keep very focused on the technical and operational stuff, we develop the tools that are needed for epidemiology case contact tracing, counting and subtracting the living from the dead, this type of thing. But we constantly come up against this glass ceiling. Our colleagues in Atlanta are anxious, for whatever reason, to ensure that these response centres are seen as part of the international infrastructure supporting the IHR and that they continue to function within GOARN. We are taking that at face value and are trying to develop a set of procedures about how we will ensure that there is no compromise in the sovereignty of the countries in which they are located, that whatever international role they fulfil is done in accordance with the principles and the approach that has driven the IHR adoption and the guiding principles that we have established and run for the past seven or eight years for GOARN.

Q548 Lord Avebury: I wonder whether you have had any attempts at making the systems interoperable between Atlanta and Geneva?

Mr Drury: Interoperable is a very big word.

Q549 Lord Avebury: In the sense of interoperability with the software.

Mr Drury: Yes, to an extent, in that for the past ten years we have had an in-house piece of software we are developing called our Event Management System. That is an information management system that allows us to record all the key information about events that are happening around the world and to document our decisions. It is not something that would stand up to forensic examination but that is

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our main tool. We are involved in a big programme to develop a new tool which supports WHO globally. When GDD was being established, they asked the Secretariat of the World Health Organisation if they could see what we do, and as a Member State of the organisation we provided them with the details of how we had established in parallel the EMS software and how we worked. It is a close relationship between CDC and WHO, they have staff seconded to WHO headquarters here and provide key human resources, these are senior people and very knowledgeable and capable. There is a close level of cooperation there. It is true that not just for the GDD centres which are established in Thailand, Nairobi, Egypt and Guatemala, and there may be others, as these take on a life of their own they also generate opportunity on the US side to bring in other parts of the US Government overseas, so health attachés working in US embassies, USAID offices overseas, laboratories where there is a twinning between Atlanta and the NICD in Johannesburg, wherever. All of these things come together into this Global Disease Detection that, I think, is their response network. Of course, it causes problems for me because I run the Global Outbreak Alert and Response Network, so these things are very similar.

Q550 Chairman: Let me see if this summarises the situation, and tell me if it does. There is a political issue from the current US Administration being rather dubious about the international organisations and wanting to be separate from them to some degree, but what you have got with this organisation, which seems to me to be quite efficient in many respects, is in effect a shadow organisation, in the early stages if you like, of the WHO that people within those Disease Detection Centers and yourselves are trying to make work. Is that a fair summary of where it is at? Presumably you would like them to come right in rather than continue with their separate system, although the separate system does seem to work quite well? Is that right?

Dr Heymann: There is another dimension to that and that is the obtaining of specimens, viruses or bacteria that are occurring in these outbreaks. When these are obtained, WHO makes sure that they are distributed to the laboratories in the world that can do the research necessary to better understand, and this was done with SARS if you recall. If this falls into a bilateral system, the difficulty is that those viruses or bacteria are not studied in any other laboratories. There is thus another dimension in bilateralism—in specimens that might come from that outbreak.

Dr Gully: There is a document, I believe it is called *A Global Strategy*, from CDC which I might direct you to, because I think in that whole document there is one reference to WHO and it is more like a passing reference. Therefore, I think that is indicative of the

current situation, perhaps, in terms of the wish to collaborate with WHO and other UN organisations as well.

Q551 Lord Desai: I think most of what I wanted to ask has been dealt with already. You were just talking about the viruses, and in Indonesia there is an example of the refusal to share. You were also talking about Kenya, Tanzania and so on. Clearly, for infectious diseases you may have to impose restrictions on travel, trade and so on, and governments are reluctant to report therefore. It seems that the new International Health Regulations are giving you the power to override, but do you also use the power to name and shame?

Dr Heymann: When the Global Outbreak Detection activities of WHO were set up in the late 1990s one government, the Government of Canada, developed a mechanism to help WHO identify what was occurring in the world, and this is called the Global Public Health Intelligence Network. It is a web application, which crawls the web in seven languages looking for key words that might indicate an outbreak of infectious disease. That information is provided to WHO and every day there is a validation mechanism in WHO through our Country and Regional Offices to determine what is happening. This, plus other electronic discussion sites, increased dramatically the power of WHO. In fact, over 62 per cent of our information back in 1998 was coming from systems such as this rather than from countries. Fortunately, this has provided an environment where countries know that, if they do not report, then others are looking over their shoulders and will report and that ratio has completely turned around, so that now we get the majority of our reports from countries that are concerned. If a country does not report, as Paul said, we have a mechanism where in confidence we deal with the country, we provide them the information and ask them to verify it; and they are required to do that under the International Health Regulations, so progress is being made.

Dr Gully: I will talk about Indonesia because there was a statement at the Intergovernmental Meeting in November about International Health Regulations and the responsibilities of Indonesia to report. There had been an interpretation of the International Health Regulations in relation to a Member State's responsibility to report. WHO does not have any means of sanction, WHO is the Member States and we are just the Secretariat, so if the World Health Assembly wishes to do something then it could. The information that has been available to all Member States about what Indonesia has and has not done, and the WHO Secretariat has been quite clear as to the deleterious effects of that, I think means that most States would respond to that, but Indonesia for all

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sorts of very good reasons perhaps have not done that.

Dr Hardiman: I just want to say that, in addition to having this fallback mechanism if countries do not report, most of our effort is going into winning the argument that transparency and early reporting are not only good for the rest of the world but are good for the country that is suffering the problem. We do not have sanctions but we do have monitoring of compliance, if you like, with the International Health Regulations both through our own reporting of progress with implementation on the website but also a formal mechanism through the Assembly where both WHO and countries will report on the functioning and compliance with the regulations. The first Assembly to receive such reports is going to be in May.

Q552 Baroness Whitaker: We have touched on animals, so this is an opportunity to bring it all together. It was mentioned that we should deal first with the animals, so it would be helpful if you could tell us about your Global Early Warning System for Major Animal Diseases and how it operates. But also, in doing so, I have picked up a couple of other things which are about the whole international architecture. Dr Gully thought that the OIE does not seem to have a mechanism for early warning, am I right? Then again, I think Dr Heymann indicated that the FAO was virtually powerless over Rift Valley Fever. My question is not only a bit more about what happens now but really what ought to happen, not only in WHO but in any of the other organisations. And I am not quite clear. Is there a role here for the IHR? Or are they only about diseases that affect humans?

Dr Gully: If I could answer that. IHR do relate to a specific number of diseases which are human diseases, polio and SARS, for example. They relate to public health emergencies or events of international importance and that would be open to interpretation as to what situations the IHR applied to, but if it was just an animal disease then they would not apply.

Q553 Baroness Whitaker: There is no equivalent, then, for animals?

Dr Gully: There is no equivalent. The equivalent is in terms of the responsibilities of the Member States of OIE to report to OIE a certain number of diseases, but OIE can only respond to reports from governments.

Q554 Chairman: Should there be?

Dr Gully: Let us put it this way, I think there is interest certainly from OIE and FAO in terms of what WHO has in terms of the IHR. One can say it would be valuable, but the IHR have been in place ever since the beginning of—

Dr Hardiman: 1951.

Q555 Baroness Whitaker: The first ones, yes?

Dr Gully: Maybe Max would like to come in, and I will come in with a response to the other part of your question.

Q556 Lord Desai: Before you answer, if those animals have been traded, like you said in the case of Rift Valley Fever, that is a legal situation of having to report?

Dr Hardiman: Yes. If you assess the animal disease as posing a risk to human health, then it can be notified under the IHR or reported under the IHR if there is a public health risk associated with that outbreak among animals. Therefore, foot and mouth is generally not considered to be a risk to human health—it is a terrible agricultural problem—so that would never get reported through the International Health Regulations, whereas Rift Valley Fever, an outbreak which was threatening human health, could be.

Q557 Chairman: Could be or must be?

Dr Hardiman: It depends on the nature of the outbreak. The Regulations give you a series of questions, an algorithm to work through, to see if this event you are looking at is actually something that should be notified to WHO under these Regulations.

Q558 Lord Jay of Ewelme: Suppose you simply do not know but you think it might?

Dr Hardiman: Then the Regulations provide you with an option of consulting with WHO without formally notifying, so you can still consult and say, “Do you think this is a risk to public health?” and we can use our other forms of information and experts to help the country come to a decision on that.

Q559 Baroness Whitaker: Must consult or may consult?

Dr Hardiman: May consult. It is an option.

Q560 Baroness Whitaker: Is it an opportunity for us to explore whether it would be helpful to strengthen the IHR in this respect and also the OIE and FAO mechanisms?
Dr Hardiman: The Regulations are mandatory and notification is mandatory, so it is legally required of countries. The question we face is: can WHO enforce that requirement. Of course, we have no mandate to do that, either in our constitution or in the Regulations. When the Member States negotiated the Regulations, they had no appetite to give WHO such powers as to enforce the Regulations.

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Baroness Whitaker: I understand it would be a political act to do such a thing, and not for the Secretariat, but we are in a position to recommend what we like.

Chairman: Within reason!

Q561 Baroness Whitaker: So we would want to do something helpful.

Dr Heymann: To go back to the BSE issue in the United Kingdom in the early 1990s, with the UK Government we were consulting regularly on this disease and were looking in Europe to see if there was an increase in Creutzfeldt-Jakob disease anywhere in Europe. This was an activity that was going on between the United Kingdom and WHO, and WHO and other European countries and that way we were safeguarding health without the International Health Regulations. There are other mechanisms besides this. Max, is there not a special Article which does bring in other international organisations to the IHR?

Dr Hardiman: They have a requirement to collaborate with the appropriate international organisations, and we have mentioned most of them here. You mentioned transportation earlier and we also collaborate with the ICAO, the International Civil Aviation Organisation.

Q562 Baroness Whitaker: “We”, the IHR mechanism or WHO?

Dr Hardiman: No, WHO, but particularly on IHR issues, because there are rules about conveyances as well as people. Also with IMO, the Maritime Organisation. Yes, we do have a requirement to collaborate with other organisations during events as well.

Dr Gully: David mentioned earlier on the Global Early Warning System for Major Animal Diseases, which is WHO, FAO and OIE, which is a way the three organisations work together in terms of disease-tracking, information-sharing and multidisciplinary action. In fact, on two recent occasions, one related to contamination of baby corn from Thailand, WHO did disseminate that information to WHO Member States and it was related to a particular food product which in theory was under the mandate of the Food and Agricultural Organisation. It did disseminate information without direct permission from Thailand.

Q563 Baroness Whitaker: For contaminated corn?

Dr Gully: We have GLEWS, but we have another group called INFOSAN, which essentially is a collaboration of organisations within countries, such as the Food Protection Agency in the United Kingdom, that do share information because information such as that would come through a different route. Even though FAO and OIE do not

have the same powers as IHR, there are ways in which WHO, because of its assessment of a situation, can take some action which is as a result of that collaboration.

Q564 Baroness Whitaker: I get the impression that you make the maximum use of the powers, the networks, the relationships and the prestige that you have, but that is not quite the same as saying you have the most desirable structure.

Dr Heymann: Let me come back to an issue, because I think the jury is not yet in on whether coordinating mechanisms are the best way to move ahead. Back in the 1990s, UNAIDS was set up and it was set up as a coordinating mechanism. It is now an implementing agency with much more funding for AIDS than WHO. WHO has had a difficult time in finding its place within the UNAIDS partnership, but has finally succeeded. Another coordinating mechanism is UNSIC, which was set up as a coordinating mechanism for avian influenza. This was set up by the Secretary-General to coordinate activities. It is very valuable in letting all the partners provide their work plans to one central point and see how they fit together. The arrangements have been orchestrated within the UN system to support a response in a coordinated UN mechanism. It is my view that the jury is still out on whether any formal coordinating mechanisms are really necessary.

Q565 Baroness Whitaker: Would it not be helpful to you and to them if the OIE had a better mechanism for early warning and not just response?

Dr Gully: Absolutely.

Dr Heymann: Yes.

Dr Gully: They would say the same thing too.

Q566 Baroness Whitaker: More like your own position?

Dr Heymann: They run into the economic issues much more than we do. Human health is a little bit privileged.

Q567 Baroness Whitaker: The FAO was powerless over Rift Valley. What should the FAO have been in a position to do?

Dr Heymann: They should have been in a position to report this, based on reports from the ministry of agriculture through a press release. That press release did not clear through the system. It might have happened in WHO that a press release would not clear, either, but because there is a mechanism with the International Health Regulations we used that mechanism.

Q568 Baroness Whitaker: They have no such mechanism?

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Dr Heymann: No, and we did not before the IHR.

Q569 Chairman: So the summary of this bit is that the International Health Regulations are very important and very usable. They could possibly be considered for extension to other areas, such as animal health. You have an underlying problem at the end of the day that there is no enforcement mechanism, so you are relying on the cooperation of States and groups to make them work. Is that a fair summary of where we are at?

Dr Heymann: Yes. If our Member States required that they moved further into the animal area they might be able to be adapted to do that in collaboration FAO. It is the only international public health legislation that has all Member States of WHO agreeing to it. It is quite a powerful mechanism.

Dr Gully: It is binding as well under the constitution of WHO.

Lord Desai: My memory of BSE is that the UK Government dragged its feet for quite a long time and did not do what it should have done. I was getting up on my hind legs and telling them that. Is it that the WHO would sometimes prefer powerful rich countries to be better behaved, not just Indonesia but the UK as well? Was that your feeling at the time, that purely for trade reasons they were dragging their feet?

Q570 Chairman: We are allowed to criticise the Government!

Dr Heymann: I would certainly not criticise. It is the difference between a human health issue and an animal health issue. This cost the UK billions and billions of dollars and it had nothing to do with human health at the start, because we were looking to see if it did and it did not. It had not yet declared itself as a disease that transmitted to humans because of its nature. Once it did, our collaboration was very close with the United Kingdom and with Europe.

Dr Gully: I think other countries, such as Canada, were very sympathetic because they were very glad that the UK were having to deal with this as to the challenges that it presented.

Q571 Lord Desai: The Irish dealt better with BSE than the UK did.

Mr Drury: In terms of FAO, OIE and WHO coordination, below the legal framework there is a high degree of operational coordination between the three organisations on a daily basis, the GLEWS mechanism and also between the ARO and the operation centre and the FAO/OIE Centre for Crisis Management in Rome. We have agreed a set of standard operating procedures on information sharing, on how to plan missions to the field. In the same way that we shared our Event Management System software with the US and other Member

States, we have also shared that software and thought that went into it with FAO and OIE in an attempt to build up their capacity to do what we were doing illegally before the IHR were updated, but if they want to choose the outlaw route they can also do that.

Q572 Lord Jay of Ewelme: Drug resistance is clearly becoming a more and more important concern particularly, according to your written evidence, in TB and Malaria, although not yet, I am glad to see, in HIV/AIDS. Presumably, that is an area too where surveillance is necessary, so that you can find out what is going on and work out the appropriate responses. I wondered how far you thought there was adequate surveillance at the moment of drug resistance of the diseases we are talking about; and, if there is not, what role would WHO play, or could it play, in trying to increase the effectiveness of the surveillance of resistance to drugs?

Dr Heymann: To have an effective surveillance of drug resistance you must do surveillance in animals, plants and humans because the organisms of these three groups are all targeted by various agricultural and human health programmes for antibiotic use or antimicrobial use, so it is very useful that those come together. Back in the early 2000s WHO did develop a framework which included all the different groups involved in this, whether it be those who prescribe drugs or those who use them, growth promoters in animal food or anywhere along the way. That framework needs to be implemented and it has not yet been fully implemented. We have just moved it to a new level, however, by moving it to the Patient Safety Initiative which, as you know, has been supported by the United Kingdom and is the concept of Sir Liam Donaldson. That group will make a challenge to health facilities in the year 2010 on antimicrobial resistance in the hope that we can move this up in the political agenda because it is very important. We have drugs going out in massive quantities from the Global Fund and other organisations, and there are not systems in many countries that are monitoring resistance to these drugs. These are public goods, they must be preserved and we need to strengthen the surveillance activity. We are working to do that, but it is a job which has not yet been done. The framework fell into disuse after 2003 in WHO, it was not moved ahead as rapidly as it should have been but now it is being moved again. Whereas individual programmes have been monitoring very closely what is going on with their drugs, overall in antimicrobial resistance the framework has not been implemented.

Q573 Lord Jay of Ewelme: Presumably the Global Fund itself is concerned about this too if they are dishing out lots of funds?

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Dr Heymann: They will give countries resources for monitoring if countries ask. They will give resources if countries ask and, with a solid proposal for monitoring resistance, they will provide resources.

Q574 Lord Jay of Ewelme: But they would not be encouraging countries to do it?

Dr Heymann: Not proactively, no. That is a question you should ask but, as far as I know, they still do not promote this as one of the major issues.

Dr Gully: There are very few countries that have good surveillance of antimicrobial resistance, even in a lot of developed countries. Even if you had good surveillance, you would also have to ensure a good response ensuring close collaboration of the healthcare sector, physicians and nurses. I am talking of nurses particularly in terms of infection control. The second part is that, even in developing countries, or at least in a lot of developing countries, there is a huge private sector and, again, the question of getting information about antimicrobial use and then control in terms of utilisation in the private sector is a huge, huge challenge. I think the Patient Safety Initiative is a really good one but no-one has got a really good answer to this yet. Denmark has a good system.

Q575 Baroness Whitaker: Viral forecasting was something that we came across, a new project at the University of California that was in an article in *The Economist*. We asked a former colleague of Dr Heymann's, at the CDC about it when he gave us evidence and he said they had been discussing global viral forecasting as a future topic but that it is very early days. As I recall, this is analysing clusters of virus infection before the outbreak in animals so as to predict, with all sorts of interesting mathematics, where might be an animal pandemic of the sort which could jump across to humans. I wondered if WHO had any thoughts on this and whether it is an area of work for you at this time.

Dr Heymann: It is an area of work for us. We are working with several different laboratories that are developing multi-antigen diagnostic tests that can diagnose up to 30 or 40 known diseases and in some instances determine the sequences of unknown viruses that we do not yet understand. In fact, the Gates Foundation has just provided resources to WHO and a laboratory in New York, which are working together to develop a mechanism which can screen animal populations and understand what the different organisms are. That will not, however, tell us the risk factors associated with these animals and whether or not they could eventually infect humans and cause disease: unfortunately, that is something we do not yet know how to examine, so we will have to just continue good surveillance.

Q576 Baroness Whitaker: Thank you. Roughly what proportion of resource is it appropriate for WHO to put into this very future sort of work?

Dr Heymann: It will depend on what is going on outside WHO.

Q577 Baroness Whitaker: What are you putting in now?

Dr Heymann: The two million that will come from the Gates Foundation.

Q578 Baroness Whitaker: The Gates Foundation is quite useful?

Dr Heymann: Yes, it is very useful in new areas.

Q579 Baroness Whitaker: Would it have been the case that the national donors would have been a bit chary about it because it is all a bit speculative? Is that where the Gates Foundation is useful?

Dr Heymann: Yes, it is something that is speculative, and that is why what we have done is assessed the landscape outside and we know that there is activity, for example at UCLA and I think that is what you are referring to, Dr Wolf working at UCLA. Around the world there are groups working on this and, therefore, we are only trying to stimulate partnerships in this outside WHO with the money that comes from the Gates.

Q580 Chairman: Can I just ask you to step outside your current roles for a moment and take a look at the area in which you have been working and tell me and the Committee what you think are the main organisational changes you would like to see, looking at this whole area. There are many, many organisations involved. If you stood outside it and said what is the ideal structure, what would it be? What are the biggest problems at the moment?

Dr Heymann: If I were to step outside WHO and look at how could we make WHO function better, I would say it is an issue of the constitution.

Q581 Chairman: What would be the key issue?

Dr Heymann: The key issue is, of course, election of our Regional Directors. As I understand when the constitution was initially interpreted, it was interpreted based on the fact that one of our Regional Offices was the Pan American Health Organisation, which was already in existence and which had an elected Director. That elected Director was also to become the WHO American Office Director. The interpretation was therefore that the five remaining Regional Directors should also be elected. No Director-General would be mandated to work this through the system of change—this would need to be initiated by the Executive Board. A possible recommendation for the World Health Organisation would be to make the Director-General or Regional

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Director term one instead of two, one term after election, and during that term, which could possibly be longer than it is today, there would be no consideration of re-election. Those are two constitutional issues that in my personal view could possibly be examined by member countries.

Q582 Chairman: Would any of the other witnesses like to flag up anything new or comment on that?

Dr Gully: I have only been in WHO for two years and, therefore, I am not qualified to comment in the same way that David has. One thing I have discovered is that an understanding by Member States of the way WHO does operate and then inter-relates with other UN organisations, other international organisations, is only possible once you work within the organisation. It is very difficult to come to the Health Assembly or an Executive Board and really get a sense of how problematic it is from day-to-day and, therefore, what the possible solutions are. A close understanding from within the Department of Health and whoever represents the UK Government at the Assembly, I am not saying it is not good now but having people who have spent time perhaps in WHO who then can advise the Department of Health who come to the Assembly and work with the Assembly and WHO would be extremely valuable.

Q583 Lord Avebury: Do you get secondments from most States?

Dr Gully: There are many secondments from many countries. There will be a new policy about secondments, because one of the challenges is that developed countries can afford to second whereas developing countries cannot. In fact, in some ways it would be better for the developing countries often to spend some time. That is up in the air at the moment. Often there are secondments from countries like the US or Canada or the UK much more so than developing countries.

Q584 Lord Avebury: How about asking Gates to help with the funding of secondments from developing countries?

Dr Gully: That is an interesting point.

Mr Drury: There is a practical problem with that: they do not go back. Seeing as I have my boss's ear, if I could say a word. The single most significant structural change has already taken place, that is the establishment of the national Focal Points of the IHR. We are at a very early stage in how these Regulations eventually get legs and get up and walk

around, but we have a situation now where in the WHO firmament there is this new animal which is called the national Focal Point for the IHRs and it is how that gets developed, both as a focus for this systemic approach to risk management within strengthening health systems at a national level and the demands that they put on the Secretariat is how things might be driven as we take things forward.

Q585 Baroness Whitaker: Is the one UN country office helpful to you?

Mr Drury: It is helpful on a day-to-day basis, yes. There was an outbreak of Ebola in Uganda recently and they are a Country Office which was in a very strong position within the health cluster and was able to mobilise the UN system resources there quite effectively. There is an undercurrent of criticism of WHO in this because that position within the health cluster is something that is new and needs to be developed carefully, and in some countries, the Country Office, the WR as we call them, the representative is politically able to do that, but in others it is generating some criticism from other partners and big NGOs who have deliberately stayed outside the health cluster.

Q586 Baroness Whitaker: So it needs a little bit more?

Mr Drury: It needs more and we need to look at that and that is tied into the MDGs, the big UN agenda on delivering support to countries, while WHO has the International Health Regulations and a legal framework, and somehow as we go forward we have to look at how these two things dovetail so there is a real impact in countries.

Q587 Chairman: A lot of people are concerned about the multiplication of organisations, both intergovernmental and non-governmental organisations, involved in this whole area of disease. You seem to be slightly less worried about the confusion of the architecture and seem to feel that it can be coordinated. Is that a fair statement or not?

Mr Drury: There is an analogy somebody uses that if you throw a frog into boiling water it is a very explosive reaction; if you put him in cold water and turn up the heat under the water and gradually cook him the frog does not know what is going on.

Dr Heymann: No-one can top that!

Chairman: Thank you very much for your evidence, it has been very helpful. If you feel that anything has been left out, do let us know and feel free to send in any more information. Thank you very much.

MONDAY 21 APRIL 2008

Present	Avebury, L Desai, L Howarth of Newport, L	Jay of Ewelme, L Soley, L (Chairman) Whitaker, B
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Memorandum by the Swiss Federal Office of Public Health

Thank you for your invitation to provide evidence to your committee which I accept with pleasure. First of all I give a view word to my background for better interpretation of my views expressed in my personal capacity. I have a double background in medicine and international relations. After working as clinical physician for an international environment and health NGO I joined government service 5 years ago. During this time as head of international affairs of the Swiss Federal Office of Public Health (corresponding to the ministry of health) I have been leading the Swiss delegation to many WHO and OECD meetings and negotiations. I was and am lead negotiator during the negotiations of the International Health Regulations and the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property Rights. I chaired the drafting groups of the World Health Assembly leading to Resolutions WHA 58.3 on the Adoption of the International Health Regulations and WHA 59.24 on Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action.

INPUTS TO YOUR QUESTIONS

1. The globalized world has increased in vulnerability. People and therefore infectious agents travel faster and more often. Despite significant improvements in the fight against infectious diseases the threats are still present and will remain so. In addition the just in time production concept and other economic integration and globalisation tendency have increased the vulnerability of the economic system. Furthermore information travels faster in a way we know of epidemics around the world which were in earlier times simply ignored. Nevertheless I would not speak of a crisis since the control systems are also improving.

2. (no answer)

3. The Global Outbreak Alert and Response System GOARN of WHO is the key system functioning overall very well. Through the IHR this system has now an adequate legal backing.

4. (no answer)

5. We need to push further the horizontal strengthening of health systems and therein the strengthening of capacities for epidemic surveillance and response. Vertical disease specific efforts will remain necessary but have to be better integrated in the horizontal efforts to strengthen health systems.

Poverty remains the main risk factor for any disease. Economic development and poverty reduction is therefore also crucial in the fight against infectious diseases.

6. The Swiss Federal Office for Public Health plays in Switzerland a similar role to the Department of Health in the UK. In Switzerland we have together with the cantons the main responsibility for the surveillance and control of communicable diseases. The main responsibility within the Swiss administration for the support of developing countries lies with the Swiss development cooperation SDC. In order to strengthen policy coherence we have elaborated jointly with colleagues in foreign affairs and development cooperation the Swiss Health Foreign Policy signed by the ministers of health and foreign affairs:

(see <http://www.bag.admin.ch/org/01044/index.html?lang=en&download=M3wBPgDB/8ull6Du36WenojQ1NTTjaXZnqWfVp3Uhmfnapmmc7Zi6rZnqCkkIZ2fHh/bKbXrZ6lhuDZz8mMps2gpKfo>).

Several of the objectives are directly linked to the four diseases:

1. Strengthen the international monitoring networks for communicable diseases (e.g. pandemic influenza) through rapid implementation of the International Health Regulations (IHR).
7. Strengthen the normative role of WHO.
9. Improve international access to essential drugs—both recognized and newly developed.

14. Make appropriate contributions to eliminating the three significant poverty-related diseases—AIDS, tuberculosis and malaria (MDG 6)—paying particular attention to gender issues.

7. (no answer)

8. (no answer)

9. (no answer)

10. The question is asked in a dangerous way. Balancing short term health gains (through the use of DDT to fight malaria) and long term health threats (by the bioaccumulation of all POPs like DDT) need careful balancing and an active search for alternative solutions.

11. The coordination of WHO, FAO, OIE, the World Bank and the UN System coordinator (www.influenza.undg.org/) as key actors is working well compared with other cases of collaboration of intergovernmental organisations (or indeed inter-ministerial collaboration).

The particular challenge with the fight of H5N1 bird flu and the linked human pandemic threat is rather in the historically grown sector system in most governments. In industrialized countries usually health ministries, development ministries and defence ministries all have budgets in the billions. Health ministries are using the large budgets they have for domestic health issues. Development ministries are investing in their long term development priorities and in immediate humanitarian aid. Defence ministries spend their billions on the classical security issues. The animal epidemic of bird flu and the threat of a human influenza pandemic fall between these competences. Health ministries don't have the international budgets, development ministries see pandemic preparedness neither as immediate humanitarian emergency nor as long term development goal (why invest in a potential threat if we don't have enough money to fight the actual diseases . . .) Defence ministries don't have the appropriate toolbox nor mandates to invest heavily in this major human security threat. Through the intergovernmental organisations and the ad hoc series of meetings of the International Partnership on Avian and Pandemic Influenza IPAPI in Washington DC, Vienna, Delhi, Beijing, Bamako and next October in Cairo major efforts of international donors are undertaken. Much more will be needed.

Finally the media and political attention to the issue was probably exaggerated in autumn 2005 and risk to become too small currently.

12. (no answer)

13. (no answer)

14. The current patent system can be impeding the access to existing medicines in the short run, but is absolutely necessary as key incentive for research and development as a basis for access to new medicines in the long run. Much progress has been made in recent years in access to medicines through public private partnerships, bulk purchasing, differential pricing, the implementation of the Doha declaration, voluntary action by the researching pharmaceutical industry, the development of the generics industry, etc. More efforts will be needed. A comprehensive global strategy and plan of action is currently under negotiation by the WHO intergovernmental working group on public health, innovation and intellectual property rights. This process is important but constantly under danger from too simplistic positions of "patents are good" or "patents are bad". Major efforts will be needed by governments, intergovernmental organisations, industry, the private sector, civil society, academia, philanthropy, etc. for the implementation of this action plan. Access to medicines as a complex issues depending on a long chain of factors in the so-called innovation chain and by far not only on intellectual property: Basic & applied research on all diseases, drug development, production in the appropriate galenic form and good quality for an affordable price, a distribution chain, health systems sufficiently staffed capable of delivering treatments, etc.

15. (no answer)

16. IHR (2005) are a historic agreement bringing the global system to fight public health emergencies of international concern truly into the 21st century. The agreement does currently not need a revision but vigorous efforts for its implementation. The national capacity building in accordance with Annexe 1 of IHR will be key for implementation. One of the few weaknesses of the IHR is the fact that there is no assurance for countries in need to receive necessary support in building their capacity, especially when this task competes for resources with many other pressing needs.

17. The IHR apply to events irrespective of their origin and therefore also for deliberate use. Deliberate use of infectious agents might result in two simultaneous crisis: an epidemic and a security crisis. These two aspects should be dealt with separately but need nevertheless coordination. The lead of the international management of the health crisis should remain with WHO through the IHR mechanisms independently of the origin of an epidemic.

18. Over the last 20 years there was on average yearly a new or emerging infectious disease, many of which are of animal origin. Therefore we need to remain vigilant and prepared for new unknown diseases. The algorithm of annex 2 of IHR is an adequate instrument for the recognition of new diseases.

1 February 2008

Examination of Witness

Witness: DR GAUDENZ SILBERSCHMIDT, MD MA, Head International Affairs Division and Vice-Director, Swiss Federal Office of Public Health, examined.

Q588 Chairman: Good afternoon and thank you very much for attending today. Could I also offer a general thanks to the Swiss for being so involved in the health issue and also the World Health Organisation; we are very grateful for that. We have about an hour, we may or may not need all of that time. What we would like to do is hear your views on a number of issues related to the World Health Organisation and your own Health Foreign Policy. You will get a transcript of the remarks that you make here sent to you for corrections of a factual nature. After this session, if there are any things you feel we have missed out or you would like to bring to our attention, please do so through the Clerk. Could I, perhaps, start by asking you to say a little more about your Health Foreign Policy in Switzerland. The particular interest for us is how that has changed your approach or your policy, if you like, to international health issues and intergovernmental organisations, not just the World Health Organisation but other organisations to which it is relevant.

Dr Silberschmidt: Thank you very much. Good afternoon. I have brought you a print-out copy of the Health Foreign Policy. To go back a little into the history of why and how it came about, our Secretary of State, my direct boss, Thomas Zeltner, was a member of the WHO Executive Board from 2000-2002 and realised the growing importance of international affairs, not only for Ministries of Development but also for Ministries of Health. He created a senior management position reporting directly to him on international affairs. Between Health and Development Ministries we started to look into how to formalise. We more or less got stuck on that process but the Government Cabinet decided they did not want to have only country-wise foreign policy strategy papers and annual strategies, but they also wanted to have sector-wise strategies, which was a window of opportunity where we managed to become the pilot of sectoral foreign policy, which is defined as an agreement on objectives. Now they are working on energy, environment, trade and culture, so other sectors are following. This meant we had the Ministry of Foreign Affairs as the neutral broker between the Ministry of Health and the Swiss Development Cooperation, which is formerly part of Foreign Affairs but very independent, as it often is in many countries. This triangle is quite crucial. I have had exchanges with many colleagues from other

industrialised countries and the tension we most often have is that the Minister of Health is in the lead in the WHO, whereas the Ministry of Development has most resources and is paying most money to WHO. All the time there is the question as to who is really the decision-maker. With the brokering of the Ministry of Foreign Affairs this allowed us to come to an agreement of objectives and, to my knowledge, we are still the only country that has one which is jointly signed by the Ministers of Foreign Affairs and Health. This was signed by both and submitted for information to the Government Cabinet, but they wanted to keep it as an agreement of objectives between the two Ministries. I have to specify that we are a system without a Prime Minister, so it is the whole Cabinet which fulfils the function of Prime Minister. I know that a few other countries are working on the same model, Sweden for example, whereas the UK has probably gone into it much deeper in the thinking but, as far as I know from the Department of Health, it is still a document of the Department of Health, it is not a joint document of the three main partners, Health, Foreign Affairs and Development, independent of Development and Foreign Affairs being the same ministry or not. What we are currently doing is trying to deepen strategy topic-by-topic. We have started with two documents, one on food safety issues where we are currently negotiating a bilateral agreement with the EU, and then we have to see what resources we are putting into the EU, into Codex Alimentarius and other organisations. A second such paper will be on the migration of health personnel, where so far the office responsible for migration, the Development Corporation, and the cantons responsible for the hiring of personnel and other relevant actors sometimes do not even know each other. We have tried to take stock of what we are doing. Unlike the UK, we are not such a big importer of personnel from developing countries, but we hire in France and Germany and the Germans hire in Poland, the Polish hire in Belorussia, so there is a domino effect where we are a main actor in the migration question. Health Foreign Policy provides us with a decision-making platform where we have one level which I co-chair with the ambassador responsible for sectoral policy in foreign affairs and at the ministerial, the Secretary of State level, we have a once-a-year platform where we can bring all the issues together and draw attention to them. Last summer I was invited at the

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Ambassadors' Conference of all Swiss ambassadors to present the Health Foreign Policy and it was useful to put it in the picture of diplomacy where health has traditionally been absent. This summer for the first time I will be teaching junior diplomats on health. Whilst trade, environment, human rights etc. are in the diplomatic training, health has been missing so far. It gives that visibility but also gives a coordination mechanism. As next step we will go deeper into the intellectual property and public health question. There we have established a specific coordination mechanism. We are currently setting up an electronic platform where we are in a trial phase, but afterwards all government actors of the Swiss Health Foreign Policy will save their key documentation in the same place. That means that an embassy, wherever it is, can put information into the health platform and we can put what we do to the WHO or bilateral meeting when the Swiss and UK ministers meet. We have a joint platform there and we hope for quite a lot of synergies.

Q589 Chairman: Thank you very much. That is a very helpful description. Could I ask you something that, perhaps, I should have clarified at the beginning. I understand that your title is Head of International Affairs, but you are also Vice-Director of the Federal Office of Public Health. Does the Vice-Director mean that you are second-in-command of the public health system in Switzerland?

Dr Silberschmidt: There is the Director. A Vice-Director is what is often called in other countries Director-General. That means I am one of five of the second-in-line. There is one formal deputy and I am one of the four others. It is a sign that international affairs has been upgraded. I am in the hierarchical position that David Harper has in the UK, while I have the function of Sarah Hendry. I report directly to the top official.

Q590 Chairman: In other words, the aim of the structure in Switzerland has been to put the international affairs bit at the second tier of the Ministry, if you like. Is that a fair understanding?

Dr Silberschmidt: Yes.

Q591 Baroness Whitaker: This is only a very small clarification. Is that because international health matters affect the health of Swiss citizens? Or is it because of a recognition of the importance of international health to the rest of the world? Are you able to separate those two?

Dr Silberschmidt: That is a key question and the answer is clearly both. What we have tried to do with the Health Foreign Policy is to move beyond the domestic/others question. We had a lot of discussion on how to translate *Gesundheitsaussenpolitik*, which was the original title, into English, whether it should

be "Foreign Health Policy" or "Health Foreign Policy". We wanted to avoid giving the impression of speaking of the foreigners. It is a continuum of how international policy affects us, the Framework Convention on Tobacco Control, what the EU is doing, the obesity work which is directly affecting us. We are probably not that far, but in ten or 20 years it will start to affect our healthcare system as well, to what we do on trans-border issues, planning with France for a pandemic and how is International Geneva working where we have a project with the WHO to be able to handle the trans-border issue, to our EU relations, to global health security issues, to pro-poor health service. It is important to get out of the division between industrialized and developing countries into a continuum, especially as most countries are emerging economies and do not fit into either of them any more.

Q592 Lord Howarth of Newport: In the document you have just given us, whatever its title should be, it is mentioned among your medium-term goals, on Page 15 under "Improve international collaboration on health issues," that you seek to "strengthen the normative role of WHO". I wondered what, more precisely, you had in mind by "normative role" and in what regard you think it needs strengthening.

Dr Silberschmidt: Especially in the drafting period about two or three years ago there was some tendency in WHO to see first and foremost the operative role which means its development function. It was also linked to the fact that much more money is involved in the operative role than in the normative role. I would not question the amount of money that has to be involved in the operative role, but at that time a large proportion of senior management brainpower was going into the operative and not into the normative role. In the operative role, WHO is one of many players. It can be the World Bank, the WHO, an NGO, there are many players. While in the normative health function, and I am speaking of the International Health Regulations, the Framework Convention of Tobacco Control, the Global Strategy of Diet, Physical Activity and Health, the currently negotiated Global Strategy and Plan of Action of Public Health Innovation and Intellectual Property, the Strategy on Alcohol and so on, be it soft law or hard law, there was not sufficient attention. We were firmly convinced that WHO should really work on both legs, on the normative and the operative.

Q593 Lord Howarth of Newport: So it is about the development of a global vision, a strategy and standard setting?

Dr Silberschmidt: Yes. At the global but also the regional level.

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Q594 Lord Howarth of Newport: Yes. Do you consider that the WHO has improved its performance in that respect in the period since this document was drafted?

Dr Silberschmidt: I would say on leadership it looks quite balanced. We can take the example of the Intergovernmental Working Group on Public Health Innovation, where initially the D.G. might have underestimated its importance, although now and it has top leadership attention and the Secretariat has been moved into her own office. She realised that IHR implementation and the Global Strategy on Public Health Innovation and Intellectual Property, are absolute core issues.

Q595 Lord Howarth of Newport: The international scene has been changing very much in terms of the arrival of major new players, the Global Fund, the Gates Foundation, PEPFAR, all sorts of organisations powerfully resourced. Do you think that the WHO has known how to adapt to these new developments and turn them to best account?

Dr Silberschmidt: I am in the process of publishing an article on that question in *The Lancet*,¹ where we propose a Committee C for the World Health Assembly. One of the key challenges is the fact that WHO is not the biggest player any more and you have intergovernmental players. The Global Fund is somehow mixed, the current chair is from the private sector, which is a good thing. The Bill & Melinda Gates Foundation, has more resources than the WHO; and, while efforts like the Downing Street meeting last September are very welcome, we think it should be complemented by more transparent and sustainable action, so the proposal is to have a committee where engagement with the other organisations could be annexed to World Health Assembly resolutions. We have deliberately put it out as an article, an opinion piece, in *The Lancet* and not as a formal government position because we want to stimulate debate. You are absolutely right, one of the challenges of the coming years is to find a governance mechanism which keeps the momentum, keeps the independence of the different organisations, but assures coordination between all the global health players.

Q596 Lord Desai: Your medium-term goal Number Ten is to “improve the efficiency of multilateral players”, et cetera, and one can do that in different ways. You are either looking at players that have a variety of objectives, like Development and Trade and Education, trying to coordinate NGOs’ ideas on that, or you are thinking in the Health field between

the WHO and all the other coordinating bodies. Which way do you read your objectives?

Dr Silberschmidt: First of all, as you see in the lead agency, that are colleagues from the (SDC) Development Cooperation. One of the strengths is that we have both in the same document and one of the weaknesses is I cannot fully defend that, although I will try my best. We need both. We need the global governance mechanism, where the top key players start to get into mechanisms of coordinating what they are doing at the global level and at the same time colleagues from the Swiss Development Corporation have been co-hosting and co-sponsoring initiatives with the UK towards the “One UN” approach towards real coordination in the developing countries where action on the ground is going on. I think both approaches are fully complementary.

Q597 Baroness Whitaker: I would like to narrow that down to the IGOs which look into monitoring human and animal health. I think you give them a fairly good press in your written evidence, where you say: “the coordination of WHO, FAO, OIE, the World Bank and the UN System Coordinator as key actors is working well”. I am sure people have learnt quite a lot from pandemic flu outbreaks, and coordination is probably much better than it was; but I have to say we have heard from other people that it could work better, particularly with the OIE and FAO. I just wondered what your views were, not only on how it works now—and there are good points and bad points—but what should be done if it should need to be improved in the future.

Dr Silberschmidt: First of all, my statement was not an absolute but a relative statement. Overall, to make intergovernmental organisations work together is extremely difficult. We are well-advanced in the field of pandemic preparedness and they co-organise meetings and at the rome meeting you do not know who is actually in the lead. Often it is easier for a single meeting than it is in the implementation. It is probably useful if I give you an example which I have been working on. We have asked for a review of the Swiss health system done by OECD and WHO jointly. I can tell you it was a real fight to get them to do it jointly. From my point of view, politically it was absolutely crucial because the political right wing would say, “WHO, that is not that serious” and the political left wing would say, “OECD is about economics, health is different”. This document has become the standard reference on the Swiss health system for actors in Switzerland since it was published. Because we managed to get both organisations to work jointly it was not possible to say it was biased one way or the other, but it was difficult. On the migration of healthcare personnel we also had a joint project. I would say the difficulty within the organisation, within the Secretariat of the

¹ *Note by Witness:* Creating a committee C of the World Health Assembly; Gaudenz Silberschmidt, Don Matheson, Ilona Kickbusch; *The Lancet*—Vol. 371, Issue 9623, 3 May 2008, Pages 1483-1486.

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organisation, was more often in the middle management. It is not too difficult to make desk officers work together and with top officials you usually manage to get them at the table, but with middle management there is a tendency to drive it apart. On the other side, we should also blame ourselves as governments, and there I think policy coherence is absolutely crucial because the mandate we governments give to the organisation often drives them apart. What we are trying, and we are far from reaching the ideal point, is when we defend something in WTO. To take an example, we asked for a waiver on tariff and taxes on essential medicine. That was something within the competence of WTO because it has to be raised in trade negotiations. But since trade colleagues have been defending that in WTO we are defending the same thing in WHO. On the other hand, when it comes to access to medicine questions from them, they have started to consult us on what our view is. Yes, we have to blame the secretariats of the international organisations and continue to put pressure, but we also have to blame governments because we give different views, and even from the same government department or ministry there are different people and the coordination is not sufficient. So one project comes up at one point and in another organisation a similar project comes up. It needs consistency within the positions to say, "Stop, we do not want to work there any more". I can give another example. We tried to stop the Council of Europe doing whatever niche they can pick on health, and I have been fighting for five years to have them focus on the human rights question because material in the context of foodstuffs is technically important but I just cannot see the relevance to the human rights question. The Council of Europe had a committee on materials in the context of foodstuffs.

Q598 Baroness Whitaker: What you are describing is surely an inherent tension which is part of the dynamics of organisations and you can never completely do away with it. I think what I would like to hear about is things that we can and should do away with. There are always going to be different mandates because there are perfectly legitimate interests that happen to conflict with each other at various points. Particularly in the animal health organisations, the FAO and the OIE, perhaps there are structural aspects of coordination which could be improved so that health is better protected?

Dr Silberschmidt: I think we have achieved improvements in WHO which is in my responsibility. What I hear from FAO and less from OIE is less promising. Yes, I think sound governance is something we can do systematically in whichever organisation we are in. We can really insist on sound governance, on coordination. I often ask the

question, "Have you spoken to them?" and there I think we can make a difference. Sound governance of each of the organisations, policy coherence within governments and systematically asking on projects, "Have you consulted the others? Why are those not at the table at this conference?" the more governments ask, the better the response will be.

Q599 Baroness Whitaker: Finally, would you see that most room for improvement would be in the conduct of national governments or through their own representatives on FAO and OIE?

Dr Silberschmidt: It needs both. The Secretary-General has to make policy coherence efforts within the UN family but, on the other hand, we from governments should do our part and insist on that at the lower level because it is not only a top-down effort.

Baroness Whitaker: That is a very important point. Thank you very much.

Q600 Chairman: You talked about the struggle to get that document produced because of disagreement, but you also talked about it being very successful. Do you think people have learnt from that that the cooperation was worth it?

Dr Silberschmidt: The cooperation with foreign affairs has significantly improved. The attention has improved especially. My colleagues in the Development Cooperation are currently at an interregnum, where the head of the Swiss Agency for Development and Cooperation has just retired and has not been replaced. Health is not well-placed, you do not even see it on the organigram. In recent discussions with colleagues in the Development Cooperation I was asked why I was in favour of a coordination unit within the Ministry of Foreign Affairs. My answer was that, while I am in favour of one coordination person for Health, I would be against five or seven people, which is what they have in Environment and Culture, where it has led to conflict between the foreign affairs and sectoral ministries. In the Development Cooperation they have one or two half posts currently and I would be in favour of seven posts. A lot of the conflict there is due to the fact that they are overwhelmed by the task and there are too few staff; they did not manage to get the funding increase where other countries, notably the UK, have been heavily increasing health funding. There I would be in favour of having a strengthening of Health and also having an interlocutor at senior level, which currently I do not have.

Q601 Unallocated

Q602 Lord Jay of Ewelme: Thank you very much. I just wanted to focus for a moment on the WHO's Global Outbreak Alert and Response System, which

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is clearly a crucial element in responding to present and future pandemics. You said in your written evidence, for which many thanks, that you thought that was working quite well—I think you actually said very well—under the International Health Regulations. But the WHO in their evidence to us said that there was “gross under-investment” in the system and that it depended on “strong, capable and transparent national systems”, which are again subject to under-investment. One point that has struck us rather is their sense that there is a need for more investment in it. The point that I would be quite interested in your views on is that clearly the system is only going to work if there are effective national systems of surveillance and reporting so that the people who are at the centre know what is going on; and clearly in a number of developing countries those systems are very basic indeed, in some cases absent. I wondered if you had any comments on that aspect of it—the importance of effective national systems if the reporting system is really going to be effective.

Dr Silberschmidt: I was commenting on the global infrastructure, that means WHO headquarters in the structure of GOARN, which is working excellently. I do not know if you have had the chance to see the Emergency Room in WHO, but it is really impressive and is working well. The IHR have really brought us into the 21st Century on what infectious disease control is. The strengths of the IHR are the fact that they are binding, they are universal around the world, it has an algorithm which does not bind them to known diseases any more but makes them relevant to all diseases independent of their origin. Personally, I was involved in mediating between the US and Iran on how to handle bioterrorism. We do not name it but it is covered. It is really broad for chemical, biological, nuclear, natural origin, deliberate origin, and we call it occurring naturally or otherwise, a diplomatic way of saying it is all covered. That is a strength. Another strength, which is quite significant for an international treaty, is it explicitly allows the use of non-state information. That means the health intelligence efforts of WHO have the legal backing and, when they find information from other sources, they can go back to the country and ask what is going on. Probably the biggest weakness is the fact that there are no resources attached to the national capacity building. That was a point you were making, which is absolutely true. It was tricky enough to have a package for the 193 Member Countries of WHO in a legally-binding instrument, so we were not able to put the capacity building and finances in the same instrument: that was too much. We have another fundamental problem there and I have tried to explain it in my evidence. Take the example of financing of pandemic influenza preparedness. A colleague from Australia has told me the same story. The Ministry of Health has a budget of billions for

domestic purposes; the Ministry of Development Cooperation have their own priorities and, say, it is either a humanitarian crisis nor long-term development. But, wait a moment; we have things killing people, so we do not look at a threat that might kill people, we have enough other things. The Ministry of Defence should be about security but has a different concept of security. The sector-wise budgeting of our government means that there even it would be a win-win investment in fighting avian flu but the prevention of a flu pandemic never gets the same large resources. I would say we have the same dilemma in the capacity strengthening for the IHR/GOARN system, because it is a joint interest and it is not clearly in our Minister of Health’s competence—“I do not have a mandate nor sufficient resources to invest in that”. The Development Corporation sees other priorities, so why should they invest in that. One positive aspect is the fact that the international community, WHO leadership, is starting to re-focus on the health system, and the health system instead of a vertical disease-wise approach is about strengthening capacities. If you have a vertical IHR implementation approach, you plan the laboratory; but, if you do not have the health system to provide the samples, the laboratory does not help much.

Q603 Lord Jay of Ewelme: That is a very interesting analysis. I suppose an answer is for Development Ministries to see capacity building as an essential part of their work. If they were to do that, then presumably capacity building here and the development of health systems would be as central as other aspects.

Dr Silberschmidt: I would go deeper than that. Do you think that is feasible with the development mindset? We do not have a large ministry in our government with a global public good mindset yet. With a development logic which is appropriate for an African developing country, bottom-up approaches and working in the country, working strongly with NGOs, it is appropriate, but our governments lacks the mindset of providing global public good.

Q604 Chairman: You mentioned the International Health Regulations, and it was suggested to us earlier that there could be a case for extending them to cover some of the animal health issues because of the tipping-over between animal health and human health. Do you have a view on that?

Dr Silberschmidt: I think they are too young and rather need further strengthening and implementation then have a formal revision at this point. We now have to focus on implementing the International Health Regulations. It is already a record that we adopted them in 2005 and they entered into force on 16 June 2007 and are applied universally to each and every human being on the earth. That

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was extremely quick. I would be careful to enlarge, we should deepen. If you look down the road, we are relatively clear on who is the responsible secretariat and organisation for IHR; but, before going strongly into animal health, you would need an in-depth analysis to see if your gain in synergies is bigger or if you lose by creating new interfaces with in the functioning of IHR which will not be as important. For the time being I would be careful with opening it up.

Q605 Lord Desai: I want to make an observation on what Lord Jay said. Even though people think of capacity building in developing countries, they do not think of health necessarily. Health for ministries in capacity building is not as high a priority, there are other things to develop, so there is a conflict there.

Dr Silberschmidt: I would go further. I have recently had the Vice-Governor of a Chinese province coming to visit the Swiss health system and he was not asking development questions, he asked; what kind of public-private mix do we have? How do we make universal coverage of health insurance by using the private sector to make it work? I then went to my colleagues in the WHO, the World Bank and elsewhere, asking who in the world has significant capacity, an analytical capacity of emerging country health systems, and the answer is nobody. Nobody can tell you what the Indians, Chinese, Brazilians, Egyptians, Indonesians, South Africans can learn from each other's health systems. WHO and many other institutions know from developing countries' health systems. In the OECD the European Observatory on Health Systems and in academic institutions, think-tanks, we have started to create knowledge on industrialised countries, but we are still in the duel system, which is not a reality nowadays.

Q606 Lord Howarth of Newport: The consequence of investing which is very real—there should be such investment in the generation of more trained personnel, doctors, nurses and other people who are needed in this field in the developing world—is that there will be a large haemorrhage of those very people coming back into the developed world.

Dr Silberschmidt: The migration question will be the next big issue we are going to negotiate in WHO. In anticipation of that we have been asking the WHO and OECD jointly to do a project, which they have concluded now. One finding is the different domino effects. As I was saying earlier, Switzerland, although it does not import from developing countries, is still a player because we still import indirectly. On the other hand, there was a very clear finding that migration is not the main cause nor would its resolution be the solution to the workforce crisis in developing countries. While it is true for some specific countries

that losing more than 50 per cent of their personnel is a key factor, for many other countries if we take India, the biggest exporter of doctors worldwide, it is less than ten per cent of Indian doctors going abroad, which means it is not a danger to the Indian health system. If we take the Philippines, the largest exporter of nurses, they deliberately train nurses for this situation. We are in a complex situation. Yes, there are instances where migration is crucial, but you have to look at all the push and pull factors, and basically all of our countries train too few health personnel.

Chairman: Can we now move on to Intellectual Property Rights.

Q607 Lord Avebury: In Paragraphs 17 and 18 of the document that you gave us to draw attention to Geneva's position as the health capital in the world, both as a centre of excellence for public and humanitarian health and as a generator of huge amounts of intellectual property from the existence of the pharmaceutical companies that are based in this country, you say that a balance has to be struck between protecting the intellectual property of those who fund and pioneer new drugs and getting those medicines that they generate to the people who need them as readily and cheaply as possible. I would like to ask you, first of all, if you have any specific suggestions as to how that balance of interest can be struck.

Dr Silberschmidt: We have a mathematician as a Secretary of Foreign Affairs, and therefore the intellectual rigour of our drafting here was such that we deliberately did not put the balance of interests within the same objective. But Objective Nine is to improve access to essential drugs and Objective 18, where it does not say to maximise protection of intellectual property, it says "appropriate" protection.

Q608 Lord Avebury: What does that mean?

Dr Silberschmidt: I just comment on that because I am quoting somebody I want to introduce. Currently I am co-chairing an Expert Group together with the Deputy Director of the Swiss Office for Intellectual Property, where we have Health, Intellectual Property, Trade, Research, Development Corporation, Foreign Affairs, Human Rights, at the table to draw up a position on this issue. I learned from him that he is clearly saying, and industry hates to hear this, that even for us the maximising of protection of intellectual property is not maximising innovation, because you have too many patents hindering the collaboration that is needed for innovation. There is an optimal protection of intellectual property which gives you the most innovative output. The same applies to the big challenge of developing countries. The least

developed countries are relatively easy, because there is hardly any industry claiming patents in least developed countries and there is not much of a conflict. The big challenge is, once again, in emerging economies because it starts to be a relevant market and it is the fastest growing market for the pharmaceutical industry, when you speak of the 20 per cent rich or middle class people within these countries, but at the same time you have poor people; and we have not found a system yet which accommodates both legitimate concerns. It is absolutely legitimate that the pharmaceutical industry wants to make profit if somebody is as rich as we are in India, China, Indonesia, Thailand or Brazil. On the other hand, it is unacceptable that the drugs are totally unaffordable for the poor in these countries. This is where we have a dilemma. You are asking for concrete examples, and I would be very cautious in the sense that we are in the process of moving out of the “patents are good” or “patents are bad” discussion. If you look at the draft Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property, and the negotiations are going on next Monday and should conclude within the next week, it gives about 80 actions. The answer is that there is no silver bullet as to the action we have to do. It goes from basic research to strengthening health systems but over traditional medicine recognition, over capacity building for research and development in developing countries, over strengthening of regulatory capacity, fighting counterfeit drugs (in many countries more than half of the medicines are counterfeit), and over the intellectual property question. Switzerland has implemented the Doha amendments to the TRIPS Agreement on compulsory licence. It is the whole forest and, whichever tree you pick out, you have to look at individually; but you should not think that is the solution to the problem.

Q609 Lord Avebury: There is not an algorithm that you could write which would tell you how to strike this balance? It is a qualitative process of looking at the various factors you mention, one of the most important of which obviously is the prevalence of counterfeit drugs, which I believe are spreading massively at the moment, which means that pharmaceutical companies are content to give way, for example, on the recent amendment to the TRIPS Agreement which allows for non-manufacturing countries to import under generic licences.

Dr Silberschmidt: I would say that access to medicine is a challenge for the pharmaceutical industry as much as climate change is a challenge for the energy industry. Within the industry you find a similar kind of split, with some companies being fully aware of

that being the biggest challenge for their industry and some others being closed or wanting to totally ignore the challenge. The tendency in both sectors is that the European countries are more on the progressive side than the US-based companies. There are always exceptions but that is the case. As Switzerland we are not fundamentally against compulsory licensing but that is a last resort. We are not happy with all of the compulsory licensing going on. Sometimes it attracts attention away from all the other parts of the game. What I am saying should not be understood the other way around, as attracting attention away from IP, because IP is one of the trees in that forest.

Q610 Chairman: I have heard it argued that the pharmaceutical industry overstates the case for the amount of new drugs that come from their work alone but, in fact, a lot of the work is done by science-based hospitals and academic institutions on the public side. Would you agree with that? Or do you not think that is correct?

Dr Silberschmidt: Overall, the system is not running perfectly in the sense that real innovative output is not as it should be, especially in view of the growing investment. Investment has been growing fast while the output has not been growing that fast or not at all. On the basic research side, you are absolutely right, basic research is much more government funded than it is pharmaceutical-industry-funded. We want to re-orient towards developing country needs but a sound basic research policy of a government is curiosity-driven, not objective-driven. You want to have the best research you can fund, we have to look for mechanisms which accommodate both aspects. An example is that colleagues from the Research Ministry, amongst others, as a consequence of that collaboration, have helped to set up the Research Centre of Global Health at the EPFL, the Technical University in Lausanne. On basic research you are right; and on applied research the very first results are now coming out of public-private partnerships, but otherwise can you tell me of any government that has ever developed a drug?

Q611 Lord Howarth of Newport: The financial strength of the pharmaceutical companies in the West derives from long-term relationships with publicly-funded clients, publicly-funded purchasers, health services constructed in one way or another in these various countries, and that is another reason why I think the public interest has a very strong claim. I think it is a false argument for the pharmaceutical industries to say that their accountability is solely to their shareholders.

Dr Silberschmidt: I would be careful with that argument, because they would immediately answer, “So take the US system, we earn more from private

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prices". They are against the government-set prices. We would not agree to abolish the European model, we have to rethink it. In the OECD we are starting to compare our systems better because, when you have a comparison basket with other countries, they know where they have to feed in the drug first to get the best price out. The private model would not be better in the sense that drug prices would tend to be higher, especially as in the US where you allow direct-to-consumer advertising, which I think we are right not to allow. I would not go down the line of argument that it is because of the government-set price or government purchasing, I would rather go down the line of corporate social responsibility, because even if energy companies do not have government purchasers they bear a responsibility on climate change and climate mitigation; and, if the food companies do not have government purchasers, they have a responsibility on obesity and have to work on it.

Q612 Lord Howarth of Newport: But the notion of corporate social responsibility recognised by the pharmaceutical industry does not seem to extend to the needs of the developing world. There is a market failure. They are not willing to invest in research to find drugs and treatments that are required distinctively in the developing world. Their interest is in supplying more affluent markets in the advanced countries?

Dr Silberschmidt: I would say that in the last five or ten years the picture has changed. The Novartis Institute in Singapore, which is specifically on tuberculosis, is one example, GSK is another, and so on. It has started to change. On the other hand, we have to acknowledge that they can put one or two per cent of their research into pure corporate social responsibility and that means no return on their investment. Their argument is that it is a market failure, so they need government intervention; and, if we provide the market, they will do the research. We need to find mixed solutions, you cannot just say, "Do your job". Business is business, but it has to do it responsibly.

Q613 Chairman: Does your Government or your Department put pressure on the drug industry in Switzerland? Or would you not describe it as putting pressure but would you describe it as discussing common problems?

Dr Silberschmidt: On this issue we are discussing common problems. On the Swiss prices we put quite a lot of pressure and they do not like this, since my boss is the one setting the drug prices in Switzerland, and they do not like it when it starts to go down. We are discussing issues but it does not mean we just follow their view.

Q614 Baroness Whitaker: This is another of these tensions which you have identified very clearly on Page 13 of your Swiss Health Foreign Policy—that trade can bring prosperity which leads to improved healthcare, but also it makes it much easier for infections to travel around the world, and you say that the WHO has made an exception in this case. We wondered if you had any other ideas. One suggestion we have heard is for international trade initiatives to have health impact assessments attached to them. Do you think there is any mileage in that? Or is there anything else we can do to bring trade into corporate social responsibility?

Dr Silberschmidt: The quantitative health impact assessment is an interesting but very, very complex exercise. We need to learn more from health in all policy initiatives like that brought by the Finnish Presidency of the EU into our own policy. My approach would be slightly different. If you ask me what is best done with £1 million to improve health in Africa, I would train African health diplomats. There are very, few very good negotiators both in the bilateral and multilateral fields or on the recipient's side. The next step would be to link it to trade and bring them also to the table.

Q615 Baroness Whitaker: So you would have health advocates as well as trade advocates coming from, say, Nigeria or Kenya?

Dr Silberschmidt: If there is a free trade agreement negotiation and Nigeria, Kenya or whoever has a competent health diplomat from the Ministry of Health involved in the negotiation, the outcome will be significantly better for health.

Q616 Baroness Whitaker: That is very interesting.

Dr Silberschmidt: If you look at the WHO negotiations, there are very few individuals from all over the world, who have really mastered the game of health negotiations.

Q617 Baroness Whitaker: Who should train these people? Should it be bilateral people, DFID, CIDA, that sort of thing? Is it an international responsibility?

Dr Silberschmidt: In another objective for implementation, we have been helping the establishment of the Global Health Programme at the Graduate School of International and Development Studies here in Geneva, where we are running a summer course for the second time and are overbooked. Brazil has started a Masters programme in Health Diplomacy in the Fiocruz Foundation. There are other institutions starting. In the long run it should probably be the top diplomatic training institutions in industrialised countries plus local

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training. We are already discussing with a Kenyan colleague setting up in Kenya such courses locally to train people in negotiating skills. The interface between technical health work and diplomacy is tricky and then the international interface. It is tricky, but if you can train people that is the best return on investment.

Q618 Baroness Whitaker: I know DFID does train people in negotiations at the WHO, but I do not know about this health diplomacy. Is health diplomacy for trade negotiations a new concept?

Dr Silberschmidt: Overall it is a new concept. The course we had last summer, I think, was the first overall, and now they are starting in the US, and they have one starting in Brazil. There should be more of this.

Chairman: If there is anything you feel you have not covered that you think we ought to hear about, please say so. If not, you can send it in later. If you are happy with that, thank you very much indeed, it has been very useful. We wish your new Department luck and good progress with the way it is heading. Thank you very much.

MONDAY 21 APRIL 2008

Present	Avebury, L Desai, L Howarth of Newport, L	Jay of Ewelme, L Soley, L (Chairman) Whitaker, B
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Memorandum by the Global Fund to Fight AIDS, Tuberculosis and Malaria

1. *A recent report on Communicable Diseases by the UK Department of Health stated that “post-war optimism that their conquest was near has proved dramatically unfounded”. What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis?*

In the second half of the 20th Century, the combined result of improved nutrition and hygienic conditions with the availability of effective antimicrobials and protective vaccines brought a dramatic reduction in the burden of infectious diseases in the most industrialized countries and many believed that infectious diseases could be eliminated as a public health problem. As a result research and investment in developing new diagnostic and therapeutic tools dropped. Only the few interested in Tropical Medicine or in health development of poor countries kept being interested in the subject. This period culminated with the eradication of smallpox in 1979 and with plans for eradication of other diseases, including polio and malaria.

The reporting of the first AIDS cases in 1981 marked the end of the optimistic view that infectious diseases can be controlled and eliminated. Since 1981, more than 20 new human pathogens have been discovered, including Ebola, SA RS and H5N1. In addition, many infectious agents are becoming resistant to the available antimicrobials and relatively few new antimicrobial agents are in the research pipeline. Old diseases like TB and malaria that had never disappeared stage an important comeback driven in part by drug resistance and in part by HIV.

The 20th Century has witnessed major achievements in the fight against infectious diseases. However, the increased awareness and media coverage that accompanied the AIDS epidemic (and more recently SAO and Avian Flu) have resulted in the recent increased attention to infectious disease threats. Epidemics have accompanied the history of the human race and new pathogens have probably emerged undetected in the past. There is no hard evidence of an actual deterioration of the situation or the acceleration of the emergence of new diseases. However, recent social and economic trends may contribute to increasing the spread of infectious diseases. For example, the massive urbanization in poor countries which forces millions of people to live in close proximity and poor hygienic conditions create a fertile ground for the spread of diseases. Or the changes in the way animals are raised and fed can contribute to the emergence of new diseases (usually of zoonotic origin) or the development or antibiotic resistance.

While we cannot simply eradicate all infectious diseases, prevent new ones from emerging or stop the development of drug resistance, we do have the capacities, resources, technical tools to control them and dramatically reduce the disease and death burden. Too many people die every day for infectious diseases that can be prevented or cured with available tools. They die because they live in unhealthy conditions and because they do not have access to basic vaccines, drugs or basic health services. This can and must change.

Driven in particular by the recognition of the dramatic impact of the AIDS pandemic, towards the end of the 90s world leaders and decision makers finally realized that tackling major global disease problems was not only possible but also necessary on both humanitarian, social and economic grounds. This led to the launching of several major global initiatives, including the Global Fund to Fight AIDS, TB and malaria, PEPFAR and the more recent US President Malaria Initiative, that aim at ensuring that sufficient resources are made available to poor countries to scale up all the necessary prevention and treatment activities and finally reduce the burden of these diseases. After the MRS outbreak and the epidemic of Avian Flu, a similar global effort has led to the approval of the revised International Health Regulations and the development of improved surveillance tools to respond effectively to emerging epidemics threats. It might be too early to say if these

global initiatives are achieving the stated goals, but initial successes are being documented in access to HIV treatment, detection and cure rate for TB and prevention of malaria in children. This shows that we are probably on the right track.

2. What reliable data exist regarding the numbers of people infected globally with the four diseases on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?

AIDS: Starting in 1986 with the WHO Global Programme on AIDS, major investments have been made in the collection and analysis of HIV/AIDS data. This has allowed WHO and MAIDS to provide regular updates of disease burden and the response to the epidemic for most countries in the world. Yearly estimates of HIV prevalence, incidence, mortality and other key indicators are published yearly by MAIDS and WHO just before World AIDS Day. Global estimates were reduced recently thanks to better data collected through population-based studies. Trends differ considerably in different countries and among different population groups but overall HIV incidence appears to have peaked and prevalence, in spite of the increasing number of patient being treated, has started to decline. Still, in 2007 UNAIDS estimated that 2.5 million people became newly infected and 2.1 million people died of AIDS.

TB: Since the establishment of the STB Partnership, important efforts have been made in improving availability and quality of TB data (DOTS coverage, burden of disease, detection rate, and drug resistance patterns). Key TB indicators are published regularly and the latest global report with TB estimates was released in 2007. However, good data is only available from few selected countries it would be essential to improve on data collection and analysis at country, level to allow for better monitoring of TB burden and trends.

Malaria: Our appreciation is that malaria data is of insufficient quantity and quality, to allow for the necessary monitoring of disease trends, prevention and treatment coverage, and drug resistance patterns. We believe that a major effort is required to improve the quality and availability of malaria data, particularly if we are to embark in efforts towards elimination or eradication of the disease in selected countries. The latest World Malaria Report was published in 2005.

3. What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? And what improvements might be made?

4. Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years?

Predicting future trends is never particularly easy. Based on the current observations (reduction in HIV incidence, initial reduction of TB prevalence and reports of reduce malaria incidence and mortality where sufficient coverage with long-lasting bednets and other preventive tools is achieved) we would expect that if the level of investments in HIV, TB and malaria is sustained or increased, we will achieve major reduction in the disease burden and mortality due to these three diseases, though we might not be able to fully achieve the ambitious targets set by UNGASS, RBM and STB or the health MDGs. However, a reduction in financial support and national commitment could easily reverse these trends, particularly for malaria.

5. What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?

The establishment of the Global Fund to fight AIDS, TB and malaria and other bilateral initiative like PEPFAR and PMI aimed at removing one of the major barriers in the prevention or control of HIV, TB and malaria: the lack of financial resources. While we are still far from covering all needs, substantial funds are now being made available to national programmes in many countries.

Weaknesses in the health system of many developing countries, and in particular the lack of trained health workers, have been identified as major barriers for the scaling up of disease prevention and control activities.

WHO estimates that it will take an additional 2.4 million physicians, nurses, and midwives to meet the needs, along with an additional 1.9 million pharmacists, health aides, technicians, and other auxiliary personnel.

Several international initiatives have been launched to address system weaknesses and remove obstacles to scaling up of interventions, including the GA VI HSS initiative the International Health Partnership. The Global Fund has also revised recently its policy to better support health system strengthening activities aimed at removing bottlenecks to achieving wide coverage of HIV, TB and malaria interventions.

Inadequate financing of research and development for new diagnostics, drugs and vaccines is also a major barrier. Simpler, cheaper and more effective tools, including simple rapid diagnostics and vaccines could greatly facilitate access to prevention and treatment, particularly in remote and poor areas. Malaria or TB elimination will be unlikely without an effective vaccine.

6. What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?

The Global Fund was created to finance a dramatic turn-around in the fight against AIDS, tuberculosis and malaria. The Global Fund currently provides two-thirds of the international resources for the fight against malaria and tuberculosis, and 20% of the international funding to fight AIDS. As a partnership between governments, civil society, the private sector and affected communities, the Global Fund represents an innovative approach to international health financing, enshrined in the principles of additionality, performance, national ownership and participation.

To date, the Global Fund has committed up to date US\$ 10 billion in 136 countries to support aggressive interventions against all three diseases. During the second replenishment meeting of the Global Fund in September 2007, additional pledges have been received for 9.7 billion dollars for the years 2008-2010, with the perspective of increasing further, if convincing levels of demand are expressed by countries through the submission of good quality proposals to the Global Fund. Donors, partners and civil society advocates consider that funding for up to 8 billion annually by 2010 can become a realistic target, if demand is sustained. Sustaining demand, in line with the existing needs in countries, will be indeed a major challenge for the future for the partnership of the Global Fund with implementing countries, technical partners, the private sector and the civil society.

The Global Fund's purpose is to attract, manage and disburse resources to fight AIDS, TB and malaria. We do not implement programs directly, relying instead on the knowledge of local experts. The Global Fund is committed to relying on existing financial management, monitoring and reporting systems, where possible.

As a financing mechanism, the Global Fund works closely with other multilateral and bilateral organizations involved in health and development issues to ensure that newly funded programs are coordinated with existing ones. Intergovernmental organizations like WHO, the WB and UNAIDS are also members of the Board of the Global Fund and representatives of the intergovernmental organizations are members of many Country Coordinating Mechanism (CCMs) that lead the application process and oversee Global Fund grant implementation at country level. In many cases, these partners participate in local Country Coordinating Mechanisms, providing important technical assistance during the development of proposals and implementation of programs. The Global Fund has been advocating for increased, predictable and sustainable resources to countries to scale up their interventions. Therefore the Global Fund acknowledges the UK commitment to ensuring long-term financing for health as a way to increase predictability, sustainability and effectiveness in the health and development architecture. The Global Fund is a signatory of the Global Health Partnership "Working together for better health: Evidence for Action" launched by the UK and aimed, inter alia to improving the effectiveness of international funding for health. The Global Fund is also a signatory of the Rome and Paris declarations on aid effectiveness and has taken the responsibility of monitoring indicators of progress as part of its performance assessment system and of facilitating the work of the global partnerships around the Paris approach.

7. *What are the main non-health causes (e.g. global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient 'joined-up' thinking in approaching the problem?*

8. *Cases of Tuberculosis fell progressively in the UK until the mid-1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of Tuberculosis infections in Britain? And how could intergovernmental action help to reverse the trend?*

9. *Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions—eg HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?*

WHO estimates that TB prevalence and death rates have probably been falling globally for several years. In 2005, the TB incidence rate was stable or in decline in all six WHO regions, and had reached a peak worldwide. However, the total number of new TB cases was still rising slowly due to both population growth and the impact of HIV. In Africa, case rates have stabilized after rapid increases over more than a decade, due principally to the HIV epidemic in Africa. TB case detection rate globally is approaching the 70% target and has reached the 85% cure rate target set by the WHO for 2005 thanks to an acceleration since 2001 supported, among others, by the Global Fund.

Each year, nearly 2 million people die of TB, despite the availability of inexpensive treatments that are effective in up to 95% of cases. However, increasingly patients are receiving the appropriate treatment though access is not universal, particularly in poor rural areas, and the emergence of drug resistance is threatening to reverse the positive trend of the recent years.

Global Fund grants are helping to increase access to TB treatment. With Global Fund support 5 million additional cases of infectious tuberculosis are being detected, 3 million people are being cured through the internationally approved DOTS treatment strategy and treatment is being provided to 24,000 new cases of multi-drug resistant tuberculosis.

The STB Partnership has proven an effective mechanism for coordinating international action by different stakeholders including Governments, technical agencies, academics and civil society organizations in support to the Global Plan to Stop TB, 2006-2015. Partners are expanding coordination in support of national scale-up proven effective control policies, harmonize approaches and align them with national health sector plans and initiatives, ensure coordinated technical assistance that meets the demands of recipients, and to increase powerful surveillance and urgently needed research.

10. *To what extent do you believe that the 2004 Stockholm Convention limiting the use of DDT against Malaria-carrying mosquitoes has been a factor of increases in the spread of the disease? Has any risk analysis been carried out comparing the relative dangers to human health posed by DDT and Malaria?*

Under the 2004 Stockholm Convention DDT may be produced and used only for disease vector control and according to the recommendations and guidelines of the World Health Organization. DDT can be used when safe, effective and affordable alternatives are not locally available in a country. The World Health Organization considers the use of DDT as an effective prevention method but recommends only indoor residual spraying (spraying only on the inside walls of buildings) of DDT for disease vector control. The Global Fund will therefore support the use of DDT for indoor residual spraying where accepted by the national malaria programme and the WHO.

However, only a limited number of countries have included indoor residual spraying with DDT as part of their national strategy, in part due to the Stockholm Convention. WHO has recently released a position paper summarizing the findings about efficacy and toxicity of DDT for vector control.

11. *What intergovernmental action is planned or in hand for early detection of the transmission of Avian Flu from birds to humans and of human-to-human transmission in potential source countries? Is this proving sufficiently effective to prevent an Influenza pandemic? What more could be done?*

12. *To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?*

The major impact of increased antimicrobial resistance is on malaria control. HIV drug resistance, though an important problem for the management of the individual patient, is still low at population level and has limited or no impact on transmission of HIV MDR and XDR dramatically increase the cost of treating the individual TB patient but are not more transmissible than regular TB and the impact on incidence and prevalence of TB is probably limited or none.

In malaria, the rapid spread of resistance to cheap and widely available drugs (CO and SP) has contributed to the high death burden, especially in young children, and the high transmission rates due to the endemicity of the infection. Vector resistance to common insecticides has also probably contributed to the malaria burden.

Global schemes for surveillance of HIV TB and malaria drug resistance have been established but coverage is still limited and data is patchy. Additional action is indeed necessary to ensure that resistance is detected at early stage and remedial actions can be put in place in order to preserve the efficacy of available drugs for as long as possible.

13. *In a number of countries, including the UK, there is a problem with hospital-acquired infections. What intergovernmental sharing of knowledge is taking place to help bring this problem under control?*

14. *Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?*

15. *What interchange exists between States in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?*

Several international conferences and technical fora exist for the exchange of scientific and programmatic knowledge and information on best practices for the prevention and treatment of NIT/, B and malaria. In addition, global and regional partnerships (eg, STB and Roll Back Malaria Partnerships) have been established to allow for the participation of all stakeholders, including academia and civil society, in the sharing of information and development of global policies and strategies.

16. *The International Health Regulations 2005 are intended to provide a global framework for the rapid identification and containment of public health emergencies. How effective do you consider this response system to be? Do improvements need to be made?*

17. *What intergovernmental planning has been undertaken to cope with the impact of an outbreak of infectious disease caused by deliberate release of micro-organisms into the environment? Is there adequate liaison between the various agencies involved, including intelligence, law enforcement and health care professionals? How could action by intergovernmental bodies help further?*

18. *Though our remit is focused specifically on known infectious diseases, we would be interested to know how you view the global threat from new or previously unrecognized ones and from the transmission of infections from animals to humans.*

19. *What resources (subscriptions, staff, training, medicines etc) does the UK Government commit to intergovernmental bodies to help in the fight against the four diseases listed?*

Concerning the Global Fund the UK has regularly and substantially increased its financial support over the years. The UK is currently the second largest donor to the Global Fund, taking into account cumulative pledges and contributions made since 2002. To date, the UK has contributed an amount of USD 668.6 million to the Global Fund. For the next replenishment period 2008-2010, the UK pledge is GBP 360 million. In line with its approach to multi-year funding, the UK has also pledged up to GBP 640 million for the Global Fund over the five years from 2011 to 2015, conditional to evidence of demand, performance and impact.

20. Do you wish to provide any other relevant information in addition to what you have said in answer to the above?

February 2008

Examination of Witnesses

Witnesses: Ms DIANE STEWART, Head of Board and Donor Relations, and DR STEFANO LAZARRI, Senior Health Adviser, The Global Fund, examined.

Q619 Chairman: Good afternoon. Thank you very much for your time. Thank you very much also for your written evidence, it was very helpful. We have got about an hour now and we want to go through some questions with you. These proceedings are being recorded and you will see a transcript of them before they are published to enable you to correct any factual errors. Also, if you feel after the event that there are issues you would like to bring to our attention or to clarify points which you did not bring up in the hearing itself, please feel free to contact the Clerk and do so. Perhaps I could start by asking you to introduce what you do. I know, Ms Stewart, that you are the Head of Board and Donor Relations, but perhaps you could briefly say what your two job descriptions are.

Ms Stewart: Thank you very much. I am the Head of the Board and Donor Relations Service at the Global Fund, which means that I am principally responsible for all the governance mechanisms, which includes the Board, its committees and all the operations of the Board as well as the Partnership Forum, which is our broader stakeholder grouping and representative group. The other section of my team is responsible for public donors, so governmental donors of whatever nature, and that is 98 per cent of the funding of the Global Fund.

Dr Lazarri: Thank you. I am the Senior Health Adviser in the office of the Executive Director. I am in charge of keeping the technical dialogue and collaboration ongoing with our technical partners, WHO, UNAIDS in particular but also the World Bank and others, and in keeping the Global Fund updated on scientific and medical developments, what is new and what is happening, so that our policies and strategies are in line with the most recent approaches, discoveries, developments in the medical field. I also represent the Fund in a number of technical forums and events, including some of the boards of our Partners—Roll Back Malaria, Stop TB Partnership and others.

Chairman: Thank you very much.

Q620 Lord Desai: Good afternoon. In your evidence you refer to the fact that there are many health infrastructures in developing countries that have some weaknesses, especially the shortage of health workers. Previous people who have given evidence to us have suggested that one of the reasons is that, since a lot of money goes into something like HIV, that drains the health systems of health workers who

would be useful otherwise. You are one of the big, big donors. How do you reconcile the conflict between having disease-specific programmes and at the same shoring up the health worker capacity in developing countries?

Dr Lazarri: Thank you, Lord Desai, this is a very important question. We try to reconcile that by trying to do both because one is linked to the other. Vertical programmes are not external to the health system, they are part of the health system. The Global Fund was based in the Framework Document from the beginning to provide resources to achieve results for the three diseases but in ways to strengthen the system. What we are trying to achieve is this diagonal approach; it is not vertical, it is not horizontal; it achieves results for the three diseases, but at the same time it reinforces and strengthens the system, or at least tries not to undermine and avoid some of the potential risks or unintended consequences you have referred to. It is not easy. The system would require a larger investment than the Global Fund itself has. There are many systems which are terribly weak. The weakness of the system is, in fact, often the main bottleneck, the main problem, in achieving results for the three diseases. It is in the interests of the Global Fund, in reaching our objectives, to address this bottleneck. You referred to human resources, which is probably the largest, the most difficult one to address. There are very few qualified health workers in many poor countries and those who are good and qualified often migrate to better places, including the UK, and it is difficult to replace or keep them there. Quite a large amount of resources from the Global Fund goes into training or providing, where it is feasible and in line with national policies, incentives, benefits or whatever way a country can design to try to retain their health workers, to better qualify them and ensure they are there to do the job. That is not something we can do alone, but it is something we have tried very hard to address. You might be aware that recently, after a long discussion at Board level, the Fund has agreed to a new approach to health system strengthening that allows a country to apply not just for health system strengthening activity as a separate component—it is still an integral component of the diseases that we are addressing—but they can come with more ambitious and more focused system-strengthening proposals that try to address these bottlenecks where they are identified. The new approach allows countries to make ambitious proposals that will not undermine the

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disease support; they will be addressed, evaluated and approved separately from the disease component. We hope that this will bring more proposals that include a greater element of health system strengthening, including human resource development, and in that way we will accelerate both the fight against the disease and improve the overall health system in the country.

Ms Stewart: If I may add, perhaps, some examples of how that can work in a country. In Ethiopia, for example, part of the AIDS funding that goes to that country is for the support of the health extension worker programme, which is trying to reach out into rural areas and really extend the reach of primarily very first-line interventions, getting people to get tested and so on. When they discussed that at the country level, they realised it was impossible to do that only for AIDS because there was nobody dealing with anything else. So the health extension worker now does all sorts of primary healthcare interventions. I have seen them in very rural areas giving vaccinations, et cetera, and they also discuss how to do bednet distribution and encourage people to be tested, about safe sex, distribute condoms and so on. In many ways what we are trying to do is fund additional resources that will be there for all sorts of health interventions, not just for AIDS. Part of that is also the whole task-shifting discussion, and these extension workers are sometimes doing the work of nurses and other healthcare professionals who are in short supply and where we could not get the coverage that we now have with those extension workers if we waited for all the nurses to be trained. We are trying to support that whole approach of broadening the base. Similarly, in many of the countries, especially in southern Africa, it is the health workers themselves who are most affected by AIDS, TB and Malaria in our case, but primarily AIDS. Treatment for AIDS is significantly benefiting the health service, and particularly health workers because they are the first to be treated. In Malawi, we have seen a significant increase in capacity within healthcare workers simply because they are staying alive, which is obviously the basic point. Also, in places like Zambia and Rwanda, where antiretroviral therapy programmes are quite well-advanced, we are seeing a reduction in the use of beds and so on in hospitals, freeing up resources throughout the health system to treat other diseases, whereas normally those hospitals are full of people dying of AIDS. There are direct effects and, as Stefano was saying, there are knock-on effects within the health system.

Q621 Lord Desai: I just want to add the frivolous comment that earlier today we heard the term “diagonal”, not vertical and not horizontal. It is like Pythagoras’s theorem that the diagonal is more important than the two sides. That is an interesting

concept of having both vertical and horizontal, so there is complementarity between those two things.

Dr Lazarri: If I may, what you want to avoid are the two extremes, programmes which are too vertical, too focused, that are not sustainable in the long-term or very hard to sustain, and we have had plenty of experience of those, as well as programmes that are so broad, but lacking focus and concrete results, that become difficult to sustain in the sense that you do not get the required investment. The attempt to make it diagonal and make the best use of the resources for the disease to strengthen the system and making strengthening the system contributing to the fight against the disease is the concept. Of course, it is an image but it does provide an idea.

Q622 Baroness Whitaker: Do not your private donors particularly want to have something that is narrowly focused so there is a very measurable outcome? Is that a tendency you have to educate people out of?

Ms Stewart: Yes and no. What we are experiencing with the private donors is that we have been able to isolate stories that we can tell, because we had no earmarking for our public or private. What we do with our private funding is that sometimes for their purposes they need to concentrate on a particular cause, because the whole way in which fund-raising works is completely different for public and private. For example, with the Red Campaign they are focusing on AIDS in Africa and they tell stories to their big consumers who are buying Red products about AIDS in Africa, but we do not channel that funding directly in any way. They use those particular stories, children on ARVs in Rwanda and so on, because it is helpful for them to tell their stories, but it is also important that they are in this bigger context of other things that are going on; and, when they do their visits with the Red advocates, they go and see the full programme. The extent to which consumers especially are quite willing to process quite complex development issues has been interesting and it is not just the “keep one child alive for a year” kind of concept that is possible not with quite a sophisticated set of consumers. They are aware that there are much broader situations in the country that have to be addressed. So far it has not been a huge challenge for us in that way.

Q623 Chairman: Dr Lazarri, you said the trick is to avoid the two extremes, the extreme vertical and extreme horizontal. Whether or not you name names, can you think of examples where there are these extremes that are not going to continue to function? Are there examples like that that trouble you?

Dr Lazarri: We have some examples of successful vertical programmes. The best one is smallpox eradication. Eradication programmes are very

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amenable to verticality because they are focused, they have a limited time, they want to eliminate the problem so you do not deal with it any more, and that is a good example. There have been other examples where similar attempts have been made that were not based on strong systems. Malaria eradication is a good example. You cannot verticalise Malaria because it is everywhere, transmission is broad because there is a vector, so you really have to work in a more horizontal way to be able to address that problem.

Q624 *Chairman:* But overall at the present time you are not acutely concerned that there is too much focus on either the vertical or the horizontal by too many organisations?

Dr Lazarri: I think organisations are converging anyway. It comes out of the opportunity of saying there are large new resources for health driven mainly by disease programmes or immunisation for polio or others and we should try to make the best use of these resources and use them in a way that does not just address the specific disease but has additional positive spins on the system and develops the overall system. As I said, there is a second reason why they are converging and that is that, if you do not address the basic system weaknesses, you cannot achieve the objectives of the disease programmes or you cannot sustain them in the long-term. If the health workers are not there and the infrastructure is not there, you will not be able to achieve this. There is a win-win situation in becoming diagonal and seeing how best you can merge these. I would not wish to say everybody is on line with the diagonal approaches, there are still differences, but the debate is on and I think the positions are converging on that, and that is a positive.

Q625 *Lord Avebury:* To pursue this analogy, I am wondering how you draw this hypotenuse if you have to have this balance between the vertical and the horizontal. You have already told us that you have a new approach, which I take to mean your Framework Document, which I understand does include allowing you to fund strengthening health systems. But your answer just now seemed to imply that was so only when the strengthening of health systems was directly related to the main objectives of the Global Fund. I take it, for example, you would fund sexual and reproductive health where you want to achieve the twin objectives of reducing AIDS but at the same time improving general health of the population, as in the case of Malawi for instance. My first question is how you do decide what the balance is between the two sides of the triangle in terms of your overall budget. Do you decide that by means of a financial mechanism? Or is there a set of criteria which you apply to all proposals whether they are

concentrated on specific diseases or on the strengthening of the general health systems? Do they all go into the pot and, as it were, the proportion comes out at the end of the day according to the choices that you have made individually in each case?

Ms Stewart: Firstly, the important aspect is that we do not decide centrally any of those things. Because we are a country-driven process, we very much rely on the country's national strategy and what they decide to apply for funding to the Global Fund for, so there is no central management of that. There are two important points. Firstly, we do not see ourselves as isolated. We are not assuming that we are the only funder, as you know it is a crowded landscape. We rely very much on our Partners to fund supporting interventions, particularly around health systems. GAVI, for example, has a whole health systems component that they are currently funding. We are trying very hard not to overlap, which is one of the reasons why we are focusing very much on health system strengthening directly related to TB, AIDS and Malaria outcomes. The other important factor is, of course, that at the country level they need to decide on what the national strategy is and what other funders are funding for them. In the context of the horizontal-versus-vertical debate, I was going to mention a conversation we are in with the European Union about direct budget support and vertical programming. They are doing a lot of budget support and giving a small amount to us for our vertical programme. We see those things as complementary. A lot of that funding has to go into the country to support these other things and our funding will fund a specific aspect of that. We rely on the country actors and the Partnership at the country level to decide who might fund which piece and which is the piece that they apply to the Global Fund for funding. You might want to explain more about how that works.

Dr Lazarri: The distribution of the Global Fund portfolio, whether it is across the diseases or by intervention or geographical areas, is really decided by a process that starts with a needs assessment at the country level, where the countries themselves, through the Country Coordinating Mechanisms, based on the epidemiological situation, on their understanding and their resources, identify their programmatic and financial gaps. That is the first part. We try to make it in as transparent and open a way as possible. The Country Coordinating Mechanism then comes up with a proposal, which is what they agree is their priority for funding. That is the first thing that drives what we support in countries.

Q626 *Lord Avebury:* Whose Country Coordinating Mechanism? Is that yours? Or is it the property of the country?

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Ms Stewart: It is the country's.

Q627 Lord Avebury: It belongs to the state?

Ms Stewart: Not the State, the Partners in the country.

Q628 Lord Jay of Ewelme: Who puts it together?

Ms Stewart: It could be convened by the government, it often is, but often by the National AIDS Council, which is often a partnership in-country between civil society, government and other actors. In some countries they were first initiated by the World Health Organisation and UNAIDS. UNAIDS, in fact, supported the establishment of many of the Country Coordinating Mechanisms. Increasingly, that is supposed to be part of UNAIDS' "Three Ones" concept, so one coordinating body for AIDS, and in many countries that acts as a coordinating body for AIDS, TB and Malaria, and sometimes other things. Wherever there are players that go beyond government, and it is important that it is beyond government, especially for HIV/AIDS, the Coordinating Mechanism then takes all of those stakeholders at the country level and they discuss what the priorities will be. It is very much a joint process. Yes, often it is chaired by the State, the Minister of Health, or in some cases the Deputy President. It is often quite a high level organisation but it is not owned by the State and it is certainly not supposed to be, it is supposed to be a partnership. Many donors are on those Country Coordinating Mechanisms. There is the voice of all the players.

Dr Lazarri: It includes donors, representatives of technical agencies present in the country, and definitely should include representatives of civil society, the non-government sector, and representatives of the people living with the disease. We try to have around the table all the key stakeholders involved in or affected by addressing the disease. They are the ones who in a sense are giving the first cut to the portfolio and the Fund. The second one is done by our independent Technical Review Panel that looks at the proposals and assesses them based on the soundness of approach—is it technically sound? Does it have all the elements we would like to see in a good technical proposal eg feasibility? Do we see they have all the conditions to achieve the results that they have indicated? And the potential for impact and sustainability? These are the main criteria that the Technical Review Panel, independently from the Secretariat, looks at and they make a recommendation to the Board for the funding decision. That is how it is shaped. In a sense, in that way the Fund does not have its own priorities beyond the collective priorities of our Partners in the country. That is the best way I can describe it.

Q629 Baroness Whitaker: When you say potential for impact, do you mean impact on the diseases concerned? This is measured in a particular way, I suppose.

Dr Lazarri: Yes. It is measured overall by ten core indicators of the impact of Global Fund resources which we monitor for all countries. Each individual proposal has its own indicators of performance, achievement and targets, which are defined and set by the country themselves. We negotiate how that is measured. Disbursement is based on achievement of results against those agreed targets.

Q630 Lord Avebury: Can I ask you specifically, I did mention it *en passant*, about sexual and reproductive health. Are you aware of the campaign for universal access to reproductive health being waged by Countdown 2015 Europe?

Dr Lazarri: Yes.

Lord Avebury: Does that have any impact on the applications that are coming to you from Country Coordinating Mechanisms? And can we be assured that there is not any political inhibition on Country Coordinating Mechanisms applying for grants in the field of SRH?

Q631 Chairman: I like the idea that there will not be any political considerations, but you had better give your answer.

Ms Stewart: I am project managing our Gender Strategy at the moment, so it has been a big push over the last year, firstly to get our strategic position publicised and in place—and we are still working on that—and also to push for this round for programmes that generally benefit particularly women and girls but more gender specific and appropriate programming, and in the case of AIDS, sexual and reproductive health rights. What we are hoping for with the advocacy around the gender issue, plus the new arrangements that are in place for health system strengthening, is the combination of those two things will produce a lot of integrated sexual and reproductive health programmes. That is what we are hoping. Certainly we know there are obstacles at the country level, but by integrating more of these statements directly into our guidance to say, "We are expecting you to look at X, Y and Z issues. We are expecting to receive programmes that address sexual and reproductive health", we are hoping that those obstacles will be overcome. To be specific, for example, there is hesitancy at the country level, particularly on behalf of the government, to apply for those things because they are not sure that they would be funded, they are not sure they would be perceived as being appropriate. So we have made sure those questions are answered in the guidelines this time and no-one can say we are not accepting proposals of that nature. Obviously they have to be

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technically sound. The Technical Review Panel will look at them and make sure that they are technically sound. It has been challenging to integrate sexual and reproductive health and HIV/AIDS programming, it has not always been successful. We have had technical problems with previous proposals that have come to us. We are optimistic because there has been a huge push of technical assistance in this period. Stefano has been working very hard with the World Health Organisation, UNAIDS and many of our civil society partners and lots of coalitions and mobilisation networks around the issue. We are hoping that Round 8 will bring results on that. At the global level there is no political obstacle to that. We have never had a technically sound proposal that has been recommended to the Board that has been refused—never.

Q632 Lord Avebury: Are you hinting that many Country Coordinating Mechanisms need technical help in formulating SRH proposals? How would that be accomplished? Are you able to go a stage earlier and help the Country Coordinating Mechanisms to formulate applications?

Ms Stewart: We would see that as a conflict of interest. We would not think it would be appropriate for us to fund the country to produce the proposal that comes to us, but that is a huge challenge in our model.

Q633 Lord Avebury: Is it a gap?

Ms Stewart: Is it a gap? Stefano, you work on that all the time.

Dr Lazarri: My colleagues at the World Health Organisation would say that it is a gap, because they have not been provided with the financial resources to be able to play a technical advisory role in the development of the proposal. It is an unfunded mandate, it comes on top of their responsibilities, but it is their responsibility to help countries develop policy and develop proposals. It is definitely part of their responsibility.

Q634 Lord Howarth of Newport: We would be grateful to have your take on the World Health Organisation. You just now pointed to a problem that changes in the international scene have posed for them. The world has been changing a lot and your arrival on the scene in 2002, bursting on the scene as a very important and very big player, is among those significant changes. Do you feel that the WHO is reacting constructively and appropriately to this changing international geography and architecture, of healthcare and health policy? How are they as collaborators, as partners? I know they are on your Board, they are a Board and Development Partner. But can you tell us more about how you work with them, the complementarity?

Dr Lazarri: I need to declare a conflict of interest because, in fact, I am WHO staff seconded to the Global Fund.

Ms Stewart: Great collaboration!

Q635 Lord Howarth of Newport: Clearly a very beautiful relationship!

Dr Lazarri: It is an example of how the collaboration is increasingly positive in defining the roles and collaborating together. There has been lots of development that has resulted, for example, in much higher approval of the Malaria grants and better performance of the role of the grant portfolio. I will say that is definitely increasing and I see that in two ways. We rely on the WHO, UNAIDS and other technical partners for the policy/strategy guidance, where the resources should go and what are the most appropriate interventions, what provides the best results in different conditions—because the Fund is not a technical agency, it cannot decide on that. It cannot even decide on the priorities. We rely on their work in providing the global guidance, and this is through UNAIDS, the Stop TB Partnership, the Roll Back Malaria Partnership and the work of the technical departments of WHO. We are increasingly collaborating with the health system and services cluster and with the making-pregnancy-safer reproductive health groups in aligning all these policies.

Q636 Lord Howarth of Newport: In your perception, your WHO colleagues are indeed providing the kind of strategic vision and context that you need in order to know how to take your place most usefully in the array of efforts that are being made?

Dr Lazarri: I really think they are doing their best under some of the limitations that WHO has. I could put my WHO hat on and answer that, but as the Global Fund I do not think we can comment on that. It is improving and we are seeing the results of that. The second part, which is what may be linked to the availability of resources in WHO, is the technical assistance at country level. That has also improved greatly, both in the development of the proposals, where there are training workshops organised with countries to explain the forms and guidelines, in which the Global Fund also participates in part, not on the technical content but how to fill in the form and what are the new developments parts. We do that in collaboration and it has become a routine activity when the grants are launched. We have just finished a series of these workshops around the world. Then there is also providing consultants to countries to write the specific proposal and this is something that, as the Global Fund, we do not intervene in. Later on there is implementation, which is also important because, once the proposal is approved, you have to negotiate a grant and that requires definitional and

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technical elements. It is important the performance of the grant is up to speed and that requires technical assistance. That is where WHO and other agencies have made an effort, but it does not cover all the needs because of a lack of resources. It depends a lot on the Regional Offices and what their attitude is. This could cause some regions to be much more proactive in working with the countries and others to sit back and just respond to requests. We can see these differences across some regions. There is still progress that can be made.

Ms Stewart: An important element of our relationship with WHO has been our hosting agreement and, from the Global Fund's perspective, that has been a challenge, certainly in the early days when we were both hosted by WHO administratively but they were also a collaborating technical partner. The fact that we are moving out of that hosting arrangement at the end of this year and will become fully independent will assist in the clarification of roles and responsibilities and improve our technical relationship. As Stefano said, it is going in the right direction, it is incredibly positive, and certainly on things like preparing for the rounds the collaboration is enormous, daily and invaluable. Once the administrative arrangements are clarified, it will take the pressure off some of that relationship in a way. I do agree that there is definitely a difference between our global collaboration and our reliance on them for even coming in and briefing our Technical Review Panel, keeping them up to speed with all the latest technical developments and so on, and collaboration at the local country level, where it is totally dependent on individuals and particular regions for what actually happens.

Q637 Lord Howarth of Newport: If they do not have enough resources to do what you would hope they could do, should do, in future funding rounds, would it be preferable that they should receive more resources and you slightly less?

Dr Lazarri: You are the fund-raiser!

Q638 Chairman: You can do a Yes or No answer if you like.

Ms Stewart: Our position has always been that it is much more important to increase the whole pie than to play one group off against another: we do not see that as helpful. Our money is channelled entirely to countries for countries to spend, our overheads are incredibly low compared to anyone you want to compare us to. The funding that is being provided to the Global Fund is going directly for implementation. WHO's challenge, of course, is that they are a normative agency, not an implementer, so it is very hard for them to mobilise in the same way that we can. There is also some debate about the extent to which technical assistance should be

provided directly from WHO itself. They are setting the norms, the standards, the appropriate interventions, and educating people on what is appropriate in terms of response. Should they be going out there and funding proposal preparation and so on? I think that is a conversation that they also have to have. I do not think there is even agreement everywhere in WHO about exactly how far they should be going down that very hands-on route. Certainly there needs to be more support at the country level all round. Particularly on the work around gender and sexual and reproductive health, a large part of that is being done by civil society, foundations and other funders, not necessarily WHO. WHO is setting very important guidelines, and so is UNAIDS, in that area. There is no other comparable agency who can do that, that is absolutely what they have to do. Whether they need to be down there helping the countries to interpret that into a viable proposal for the Global Fund is maybe a complex issue.

Q639 Chairman: I am interested in these two hats that you wear, Dr Lazarri. If you take Lord Avebury's question on sexual and reproductive health, could you go into a situation and put on your World Health Organisation hat and say, "Actually we cannot fund that whatever, but we, as the Global Fund, can help you set up the structure that would enable it to be funded"? Does that happen?

Dr Lazarri: The Global Fund cannot support WHO directly, it is not part of our mandate. The resources of the Global Fund go to country programmes for implementation. What we can do, and definitely do, is collaborate with them, so that in a sense they can mobilise their resources where needed. It is not only WHO. At least for the three diseases we are talking of, a broad range of partners rotates around a partnership for Stop TB, Roll Back Malaria and around UNAIDS and their co-sponsors. It is not just the World Health Organisation that can provide and does provide support. When it comes to reproductive health or health systems, we have less developed partnerships globally. The number of partners that it can support is limited, even the number of technical experts available is limited. They start from a more difficult position when requested to provide support to countries for proposal development. I would see a need for investment there definitely. I do not know what hat I am wearing, but maybe with both hats I could say that, if we want them to be able to respond to these requests from countries in areas which are outside HIV, TB and Malaria, they would require additional resources. Also, it is better co-ordination, recruiting partners who can fill in the gaps and provide support, and there is quite a number. It is moving. We have started to see a movement in reproductive health and in health systems and I think

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it will expand even more. Maybe I should mention that, if this is true for proposal development where we see a conflict of interest, when it comes to implementation of the grants, then the Global Fund can provide support to technical assistance, it can and it is included in the proposal. I cannot remember the figure exactly—I can provide it to you—but we tracked this for Round 7 and I think we had four or five per cent of the resources that were for technical assistance. There is funding available within the grants that can be used to provide technical assistance and implementation, including, if countries so wish, from WHO, so that is an area where the Fund can indirectly support international organisations through the grant and the country.

Q640 Lord Jay of Ewelme: Since we are all declaring an interest, perhaps I should declare an interest as the Chairman of the Trustees of the British medical charity Merlin, which does indeed work with the Global Fund in a number of countries. I just wanted to go back for a moment to this question, because I think it is a really interesting one, of the funding for project preparation. We seem to be in a situation in which we all recognise that there is a real need here and, indeed, the success of all the various actors in this rather complicated scene depends on there being properly prepared proposals and projects. Yet we do not seem to have a mechanism, as I understand it, for ensuring there are funds available for preparing the projects. You say there is a conflict of interest for the Global Fund and WHO are not quite clear whether it would be right or they should be able to do it. Let me ask you: who do you think should be doing this? Is it something for the World Bank? Should Gates be doing it? Should bilateral donors be doing it? Is it something DFID and others should be spending more money on ensuring that the projects are prepared for others to finance? If there is more and more money available for really well-prepared projects but there are not the projects that have been properly prepared, it is actually quite a gap in the system?

Dr Lazarri: External technical assistance is only one element in the development of a sound proposal. What is even more important than that is the function of the Country Coordinating Mechanism, the participation of all partners in the development of the proposal. There are already quite a number of technical advisers in countries through WHO, through bilaterals, universities, that can participate in this. In my view, the most critical element for the development of a sound proposal is the country's consultative process and the way they analyse the problem and can express it.

Q641 Lord Jay of Ewelme: What you are saying is that, if the Country Coordinating Mechanism works well, then it will have within it what is needed to prepare a project?

Dr Lazarri: Most of the expertise that is needed. However, the Global Fund has a number of specific requirements that require an understanding of the Global Fund mechanisms, their monitoring and evaluation, the performance-based funding, which might not be present in the country, and they might need some technical assistance in this respect as they might need some technical assistance in the actual writing of the proposal. There are skills involved in translating the needs assessment into a well-articulated proposal and sometimes language problems, because all the proposals are assessed in English. These are all elements that a technical adviser can facilitate. We would not wish to see the opposite, having technical advisers going to countries with ready-made proposals in their pockets. That would look good on paper but become terrible in implementation because they would not take into consideration the needs, the resources, or the complexity of the country. It is mixing the two that works best.

Ms Stewart: If I may come in on that issue. There are two things that we are trying to do on that. One is that in the future we are trying to move towards the approval of national strategies for funding, so countries will be able to develop their national strategy, say which piece of it they do not have funds for, what is the gap, and submit that to the Global Fund for funding. You know a lot more about that than me, Stefano. Essentially, in a way that completely circumvents the need to develop a large proposal because that national strategy would be it. Whether you have the capacity to develop your national strategy is a different question. Essentially all countries should be doing that anyway. We are in an interesting discussion about how you would validate those strategies and so on, but essentially that is the idea. Secondly, we have also started funding what we are calling community assistance strengthening, which is a way of pre-funding because you are going to strengthen civil society, you are going to strengthen those actors that do not have the capacity currently to play at the national level to be able to accept funds, to understand what it is that they mean, and that is really important especially for marginalised groups and people who need to access funding for specific things and cannot. We are trying to address that.

Dr Lazarri: We are also funding Country Coordinating Mechanism functioning to a certain limit. The CCM can request the Secretariat to provide resources for their own functioning, so that we facilitate this dialogue and collaboration that is required at country level. In some ways we are trying to address that.

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Q642 Lord Jay of Ewelme: Thank you very much for that. I am sorry to have gone back to that point but I thought it was an important one. Just to move on for a moment to drugs and vaccines. In a sense, this is another of the barriers that we have been looking at, and you say in your evidence, for which many thanks, that there is “inadequate financing of research and development for new diagnostics, drugs and vaccines”, and that “simpler, cheaper and more effective tools, including simple rapid diagnostics and vaccines, could greatly facilitate access”, which indeed is a conclusion we have come to ourselves. Here again, whose job would you see it as being to try to take this forward? I might just say on vaccines that it is not just a question of getting the cheap vaccines and so on but also ensuring the delivery mechanisms, that they are delivered in the right kind of condition and are cold when they need to be cold, even when they have been taking them 12 miles down a rural lane.

Ms Stewart: On a bicycle!

Q643 Lord Jay of Ewelme: Yes, on the back of a bicycle, exactly, which I have seen. I would be interested in your comments on that.

Dr Lazarri: There are only two limitations really, two items that the Global Fund will not support in principle. These are large infrastructure projects, large hospitals, large schools of medicine, because we think this is for other agencies to take care of, and the basic research and development of new tools, vaccines and drugs. However, when it comes to operational research, looking at how best they can be deployed and we can increase coverage, scale up access in specific situations, that is something the Fund would definitely consider and, in fact, I think the TRP has commented several times that—

Q644 Lord Jay of Ewelme: Sorry, the what?

Dr Lazarri: The Technical Review Panel. It has commented several times that the proposals are not coming forward sufficiently with operational research requests that they think appropriate, so you study the best way to do it in your situation before you launch a major effort. The Fund cannot do everything and there are definitely other international institutions that do finance basic research. What the Fund does do is create markets for drugs, for diagnostics, for vaccines, where markets did not exist before, because people did not have the capacity to buy. The Fund can be a pull factor in saying, “If you develop a vaccine for Malaria, we would definitely be interested in making sure this is purchased and distributed”. We can create that market. A lot of the incentive in private research has not been in tropical diseases or diseases of the poor because the market forces were not there and there was no specific interest. That can be created. At

least for AIDS the research has not been neglected, there has been quite a bit of support. It is more on TB and Malaria where it is picking up just now. There are several global initiatives now that are trying to address drugs, diagnostics and vaccines for TB and Malaria. In a sense, that is a result of the renewed interest and availability of funds around those diseases. It is being addressed indirectly but the Fund does not have that mandate.

Ms Stewart: Maybe just an example, the Artemisinin experience was very interesting in terms of going from a sort of very elite drug, if I might say that, something very small and available to only a few to suddenly being a mass production product, and that was entirely because the Global Fund had the money to buy it. We were right there at the beginning of it and manufacturers were in discussions with us saying, “If we produce, will you help” and there was an agreement between countries, WHO and so on that, yes, this was a drug that was useful, could be recommended, could be produced, et cetera, and the money was there. That is a good example of how, if something new becomes available, we can make it available very, very quickly compared to how it would have happened historically.

Dr Lazarri: It is in some way an advance market commitment that we can make because the Fund has resources, at least around these three diseases.

Q645 Lord Jay of Ewelme: Just one final partly related question which is about drug resistance. You say in your evidence that: “global schemes for resistance monitoring are limited and data are patchy”. There again, I wondered—is that something that you would see as something for you to do either yourselves or encourage the recipient countries, developing countries, perhaps with the CCM mechanisms, to ensure they are monitoring drug resistance? How would you see that filling that gap?

Dr Lazarri: Now I have to declare another conflict of interest because I have been heading the WHO Antimicrobial Resistance Programme for a year and a half.

Q646 Lord Jay of Ewelme: We should have had you at our session this morning!

Dr Lazarri: I think that, from the very beginning, the Fund has addressed the issue of resistance. For all three diseases this is a major issue, but even beyond those diseases it is a broader issue. We are encouraging countries to put money both in the surveillance and monitoring of resistance and in containment strategies. Again, I do not think it is accessed as much as it could be, and this might be because of some of the technical complexity of doing it and maybe weaknesses of our technical partners sometimes in making this a priority for countries and convincing countries technically that this is

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important. There is definitely a benefit in setting up regional and global networks that collect it. There is definitely a need to have supranational laboratories that can perform drug resistance testing that is of such complexity that it is difficult to see every single country having its own capacity. The Fund has some limitations in its structure in supporting supranational activities. We can and do support regional initiatives coming together across borders on this sort of issue. The only real way of doing that is if the countries agree to include resources in their own grants and then pull it together, but this requires a certain level of negotiation and I do not think we have seen that yet. There is a gap there. In our response we have tried to highlight where there is a gap. When it comes to country activity on resistance, the Fund can and is happy to support more, but when it comes to a supranational or global level then there are other mechanisms and they should probably look at alternative sources of funding and negotiating and networking is required. I will stop there otherwise I will get—

Chairman: Into trouble.

Q647 Baroness Whitaker: On that gap, say one of the members of WHO recognised that gap and thought it was in their national interest to try and do something about it, what would be the most helpful pressure they could bring to bear—as national ambassador, minister or whoever?

Dr Lazzari: WHO is a technical advisory agency at country level, so the pressure comes from the WHO representative, from opportunities they have to influence decisions at country level on what are the priorities. There are at least two ways of doing that, there may be more. One is to have a global movement that is approved by the World Health Assembly and becomes a global priority and everybody is committed to participate in that. To my surprise, antimicrobial resistance is not a global priority yet, because I think it should be.

Q648 Chairman: Could it be led by some of the science-based hospitals around the world? Or is that not a role for them?

Dr Lazzari: One of the issues is that it is seen as a clinical problem and not as much of a public health problem as it should be, so it is dealt with as an individual problem in a hospital or for a specific disease.

Q649 Chairman: It is the link between science and medicine that you are looking for, is it not?

Dr Lazzari: Yes.

Q650 Lord Avebury: It is not on the agenda for the World Health Assembly?

Dr Lazzari: It has been on the agenda and there have been resolutions at the World Health Assembly but backed by global movement, as I think it should be. That is my personal opinion.

Q651 Baroness Whitaker: First, it should be reclassified perhaps as a public health issue so that it comes out of the laboratory and into the political arena?

Dr Lazzari: It is one of the issues, absolutely. The other one is to demonstrate that it is a real problem for the country and there you need to have a good surveillance system in place. You have to have evidence and data which show this is what is happening, because if you do not know you cannot address the problem. That is the weakness of the drug resistance surveillance systems in-country. We have evidence, especially from northern Europe, that if you realise there is a problem and you intervene you can contain the problem and achieve results. Yes, there is a lot that WHO and other technical agencies could and should do on this. We do encourage it. We cannot require but we do recommend and encourage countries to address different problems that might arise.

Q652 Baroness Whitaker: Still with the Country Coordinating Mechanisms: this is a technical point in a way. Many countries, for instance Tanzania, say that they have got so many donors, so many accountability mechanisms for monitoring, that they have hardly got time to govern their country. How do the CCMs manage not to add to this or avoid it? Is there some special way in which they need to interface with other donors in their country?

Ms Stewart: We have been working very hard on this. Firstly, the idea of the Country Coordinating Mechanism is exactly to try and reduce some of the overlap of different requests and so on. Because our proposals are supposed to be country-owned it is not something that we impose on a country. It is not like getting bilateral funds from another donor where that donor says, “These are the five things I am going to fund” and so on, it is very much owned and governed by that country. Depending, of course, on the strength and political leadership within that country is the extent to which that is easier or more difficult. In countries where there are a lot of donors and minimum national capacity, of course, it gets more and more challenging. The idea is that the Country Coordinating Mechanism brings together many, if not most, if not all of those players and, certainly in countries like Mozambique, Malawi, Tanzania and Zambia, where there are a lot of donors, most of them are on those Coordinating Committees. The idea is that they manage Global

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Fund money, yes, but also see how all these other funds are complementing that. For example, in many of the countries where we work with PEPFAR, it is worked out at the CCM, “PEPFAR will do this, the Global Fund will do this, the government will do this and civil society will do that,” and they try and coordinate at that level. From our perspective, we have been trying very hard through working very closely with the implementation of the Paris Declaration to harmonise and align our processes with national processes as much as possible. I would not say we have got as far as we would like to be. For example, the very process we have been talking about a lot, which is the rounds-based process, is somewhat arbitrary; it does not fit in at all with the national planning cycle, et cetera, but we are trying to get closer and closer to meeting with that national cycle. We also try as much as possible to involve those other donors in those conversations in the country so they can try and fit their funding profiles into a supportive environment. We have participated in SWAps, for example, in a number of countries if that is what the country wants to do.

Q653 Baroness Whitaker: SWAps?

Ms Stewart: It is a Sector-Wide Approach, where everybody pools their funding. In Mozambique, for example, all the donors pool their funding to do a specific number of things. Because we have a performance-based funding approach that we do not compromise on, the Mozambique negotiation was quite difficult, because we needed to get the agreement of all the donors that we would produce X, Y and Z results with the money when it went in. It was quite difficult to set up, but many of those donors are now delighted because they are getting much more concrete results out of that SWAp for their own reporting; and from the perspective of the Minister of Health, he was very pleased because it was one conversation with one group of donors. I would not say we have had that amount of success everywhere, it depends very much on the country. I know the Rwandan situation reasonably well and the Rwandan Government is just very, very firm, shall we say, with the donors and says, “You will do this, you will do that and, sorry, if you want to do that you are not doing it because that is not part of our national plan and our national strategy”. Unfortunately, that is not really possible in all countries.

Q654 Chairman: Could I just pursue that for a little bit. Is it your view that there are not necessarily too many organisations involved in the field, it is just a matter of coordination? Or are there too many organisations and would some rationalisation help, or make it easier?

Ms Stewart: I think in the best case scenarios there are not too many and everybody is working in complementarity. We have identified a number of things here today where Global Fund funding does not cover X and does not cover Y. If you are talking about just from our perspective, we are putting a lot of money in-country but we are not there—there is no Global Fund representative in Lusaka or any other country, we are nowhere. We very much rely on the people from DFID, the people from Swedish CIDA, or whoever it is on the ground, to help make our money work. They are providing a lot of technical assistance to make that money work in many cases or they are providing parallel funding for maternal health, things that are complementary. Coordination is an easy thing to say and a hard thing to do, it is not that simple. We have tried to contribute to that by also saying that our CCM does not need to be some sort of special Global Fund body that sits in a corner, it could and should do other things.

Q655 Baroness Whitaker: What happens when the CCM’s, or the Fund’s perception of priorities differs from the host country’s perception? For Uganda, say, in their AIDS strategy, they have decided that abstinence is the big thing and condoms has really dropped off the bottom of the list, for all sorts of reasons. Presumably that might not be the view of the Global Fund. How do you manage in that kind of situation?

Ms Stewart: In some ways this is the beauty of our independent Technical Review Panel because they are a group of recognised international experts and they would make the call on whether the Ugandan programme was appropriate across the board for a response to a disease. Perhaps all we would be asked to fund is an abstinence programme but then they would look at the totality of that programme and make sure that that programme is holistic and balanced. That is a big and complex programme but for other programmes, for example on some small island states that I am familiar with, where they have come in with HIV programming that has not addressed at all the issue of sexual minorities, marginal groups and IDUs, where it is a small concentrated epidemic driven exactly by those behaviours and those groups, the Technical Review Panel has said, “Sorry, this is not going to address your epidemic. You have not taken the appropriate action”.

Q656 Baroness Whitaker: So they do not get the money?

Ms Stewart: So they do not get the money. If Uganda came in with a programme that the Technical Review Panel thought was skewed entirely to interventions that were not going to address their epidemic, it would not be considered technically sound.

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Dr Lazarri: One of the things they look at is the balance of the intervention, the balance between prevention and treatment, balance of different kinds of intervention that together make up a technically sound programme.

Q657 Baroness Whitaker: So what happened with Uganda, because I thought that was the case, they had dropped condoms off their list of solutions?

Ms Stewart: I do not think for what we are funding.

Dr Lazarri: As far as I know, no. Going back to your question on many donors and many coordinating mechanisms, the national strategy application that Diane referred to is meant to address that problem. In fact, the Board called for this possibility, but as a possibility to share it with the other Partners. We would like to have a system whereby, once a national strategy is developed and validated as being technically sound and correct, then all Partners would agree to finance as it is, and that is the coordinating tool. A coordinating tool around which everybody can work is a sound, strong national strategy with a government that can enforce the rules. In some countries it works, and works quite well, and most of the Partners go by the rules, but in other countries it does not. We are trying to go in a direction where this coordination becomes stronger, but it is based on national institutions and a national strategic plan, it is not plans, strategies or mechanisms imposed from outside.

Q658 Baroness Whitaker: One of your great strengths is obviously your performance-based granting. I just want to check the elements of performance. To what extent they are outcomes. They are, presumably, things which will happen in the future as well as pre-conditions they have now. Would they be related to prevalence of the disease? Or is it things like the number of personnel in place and the delivery mechanisms? What I am trying to get at is how you can tell that it is actually the person not getting ill which is the end outcome, not all the machinery to create that?

Dr Lazarri: There are different levels of performance that we monitor. There is a level which is specific to the grant, and it helps us monitor the performance and the achievement of the grant and is linked to disbursements. So, if certain targets or milestones are not reached, then the disbursement can be questioned and the amount of money can also be reduced. It is the internal mechanism in monitoring the performance of the grant. Then you can monitor the achievement of the grant, and these are the outcomes that were set out in the proposal that you want to achieve at the end of five years, the coverage of interventions, the number of people under treatment, whatever that is. That is set by the countries and

agreed by the TRP and agreed at the moment of grant negotiation.

Q659 Baroness Whitaker: Is prevalence among them?

Dr Lazarri: Yes. Then you have the true outcome indicators.

Q660 Lord Howarth of Newport: This is a slightly different question. You are a very important grant-giver, you have been clear about what you will and will not fund, and I imagine other people understand what your parameters are. Among the things you will not fund is technical support to people making bids to you and more broadly, I think, the development of infrastructure in countries, building hospitals or the international laboratories that Dr Lazarri mentioned. As you stand back and review the overall pattern of the availability of funding for the needs that there are, are there significant gaps? Where you will not fund, are there always going to be others who in principle are available to fund? There is a lot of money, all in all, being channelled and disbursed through this hugely complex international system of health organisations, intergovernmental and NGOs. But are there needs that cannot in principle be met through this system?

Ms Stewart: Maybe just a few words, and then I am sure Stefano will have more. One of the reasons that we have been so successful in only six years has been because of our very narrowly and clearly-defined mandate. There was also a reason behind why the Global Fund was set up for those three diseases. I think there are always going to be gaps, it is a question of prioritisation and maybe process. What we have said all along is that we want to be one of many, and what we are trying to do is give an example of a model that might be a more effective development model that could be used for other things. We have certainly been talking about that a lot in relation to education, and we are talking about much broader development issues. Even within the health arena we are also saying that there may indeed be other areas, neglected diseases et cetera, that could benefit from using our model. What we are hoping for is to be able to say, "This is a good way to go about it". It does not necessarily mean that you expand our organisation to do all of those things, but it may be you use that model to do that. There is also the question of the MDGs and their priorities. One of the things we are already seeing with our impact indicators—and I have some leaflets that might be helpful—is our outcomes and impact can have an effect that makes it possible for other things to be addressed. Yes, there may be gaps right now today,

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but by dealing with some of these things you make it possible for people to address other things. The example I gave you about the health workers in Malawi is a good one, where if you do not immediately deal with the fact that those nurses are dying today of HIV/AIDS you cannot deal with the fact that they need to be better carers for maternity wings tomorrow. That is a Global Fund view of the world, but that would be our immediate response to say that, yes, there are most definitely gaps but it is a question of how you target your money today most effectively.

Dr Lazarri: I would see at least three major gaps. One is that we really have not achieved the coverage of interventions nor sufficient funds for the three diseases; there are still gaps in the three diseases. We would not wish to see the Global Fund being the only funder, so there is definitely room for others to come in. We have to be clear that we are not there yet, we do not have all the resources required to properly address the problems of HIV, TB and Malaria. The second one, and we have touched on it, is the system problems, the weaknesses that make achieving these objectives difficult, but also prevent the achievement of better health as such. There again, the Fund can play a role and we have described how we are trying to play that role, but we cannot do that alone; we need major contributions by many Partners, countries and governments. The third one is on the research issue, coming up with new, appropriate and easier-to-use tools. The TB people will tell you that they are using drugs which are 40 years old and diagnostics which are 100 years old, and we have technologies now to do better than that. So there is definitely room to fill the gaps and come up with more

appropriate tools. This is an area where we need to make a greater effort.

Q661 Lord Avebury: You mentioned earlier on the national strategies and said you were funding these now, but could you give us an example? Not now, but could you send us an example?

Ms Stewart: We will be funding them. We are hoping to be able to fund them in Round 9. That is the short answer.

Dr Lazarri: We are already funding national strategies but through a project proposal approach. We want to use the strategy as the funding request, that is the difference. So countries will develop the strategy, present it to the Global Fund and we will fund it as it is; they will not have to come every year with a grant proposal to be assessed every time. That is the difference. What we are contributing in countries we expect to be supporting the national strategies, that is the whole principle of national ownership and being demand-driven.

Ms Stewart: We do have some if you want, for example a national AIDS strategy, but there are disappointingly few.

Dr Lazarri: A few countries have presented a strategy as such for funding, so we could provide some examples.

Chairman: The fact that we have eaten into our own time by ten minutes indicates that what you have been saying has been very useful and helpful. Thank you very much. If you do have any further thoughts or, indeed, want to give us examples, as was indicated in the last question, do not hesitate to send them to us. Once again, thank you very much for your attendance and help today.

MONDAY 21 APRIL 2008

Present:	Avebury, L Desai, L Howarth of Newport, L	Jay of Ewelme, L Soley, L (Chairman) Whitaker, B
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Memorandum by UNITAID

UNITAID is pleased to answer the UK Parliamentary Inquiry into the “Control of Infectious Diseases” by the House of Lords, Ad Hoc Committee on Intergovernmental Organisations. Taking into account UNITAID specific missions, we are only in a position to answer the questions that are relevant to UNITAID activities (questions 5, 6, 9, 14, 19). Additionally, it is relevant to clarify that UNITAID has no specific activities related to Avian or Human Pandemic Influenza.

5. What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated inter-governmental action?

Despite progress made in the recent years in the fight against HIV/AIDS, tuberculosis and malaria, the mechanisms currently in place are still outweighed by the challenge that the major pandemic diseases pose.

UNITAID, an intergovernmental initiative hosted by the World Health Organization, was created in response to some of the remaining challenges:

- The drug market is typically structured around solvent demand in the North and therefore does not provide the quantity of drugs required at a price that developing country patients can afford. If the goal of universal access to treatment for the three target diseases by 2010 is to be achieved, global production must increase tenfold in the next five years. This massive increase poses many practical problems both for brand name drug producers and generics manufacturers.
- Prices are still too high, both for drugs (especially second-line antiretrovirals—ARVs, which currently cost 10 to 20 times more than first-line treatments and anti-malarial drugs that are effective against new resistant strains) and for tests, diagnostic kits and patient monitoring tools.
- Many treatments require adaptation (special formulas for children, combined set doses) in order to ensure the most appropriate treatment and optimum patient comfort, which play a role in patients’ adherence to treatment. For example, ready-made formulations, appropriate for children are not available for these diseases, as there is no market for specific paediatric ARV in the North where preventive treatment have almost eradicated transmission from mother to child; therefore incorrect dosages are more likely as a result.
- Insufficient funding, as well as a dearth of predictable long-term funding so as to ensure a sustainable supply of treatments, remains a problem.

UNITAID fills a critical gap in the global health financing landscape. By guaranteeing sustainable predictable revenues for the purchase of drugs, UNITAID plays an important role in influencing manufacturers to drive price reductions and increase drug quality by:

- Broadening the funding supply and help centre it on recurrent and sustainable revenue.
- Improving the security and the solvency of demand in the medium-term using its financial resources. With stable financial resources provided, developing countries are able to obtain drugs and other healthcare products on the basis of purchasing programmes that are guaranteed in the medium- to long-term.
- Increasing production capacity, which is currently limited by poor visibility on long-term solvent demand.
- Encouraging price reductions and diversification of supply through greater market efficiency.

- Fostering a more diverse and competitive supply for all the products poorly served by the market, such as second-line HIV drugs or the new artemisinin-based malaria treatments, by promoting the participation of new suppliers.
- Ensuring the quality of drugs and diagnostic products.

6. *What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?*

MEDICINES ARE IN THE NORTH, PATIENTS IN THE SOUTH

We live in an unequal world. The less developed countries represent 84% of the world population and suffer more than 93% of disease, and yet benefit from less than 11% of global health expenditure.

Each year nearly 11 million children die worldwide from the three big killers: HIV/AIDS, malaria and tuberculosis. More than half of these deaths are avoidable if we can just scale up access to the care, medicines and vaccines that already exist. UNITAID has been created to take action to help save those lives. We are dedicated to providing better ways of identifying HIV/AIDS, malaria and tuberculosis in poor and vulnerable populations, and providing access to the drugs and treatments that can help give those people back their health.

The challenge of combating the world's three major pandemics—HIV/AIDS, malaria and tuberculosis—is enormous. With the mandate UNITAID is part of the global response to meet the challenge of the three big pandemics. Everyone affected by HIV/AIDS, malaria and tuberculosis no matter where they live on the planet should have access to the drugs and treatments, which can mean the difference between life and death. UNITAID's mission is to provide lower-cost life saving medicines for HIV/AIDS, tuberculosis and malaria for people in developing countries.

UNITAID was established in September 2006, during the World Assembly of the U.N. in New York, by 5 founder countries: Brazil, France, the United Kingdom, Chile and Norway. It counts now 27 participating countries plus the Bill and Melinda Gates foundation. After its first year of existence, UNITAID funds programmes for the three diseases in more than 80 countries.

UNITAID eligibility criteria mandate that 85% of UNITAID funds must be allocated to low-income countries.

AN ORIGINAL FUNDING: THE SOLIDARITY CONTRIBUTION ON AIRLINE TICKETS

One of the most innovative proposals designed to bring fresh funding for the achievement of the Millennium Development Goals was the implementation of a solidarity contribution on airline tickets, more commonly called "air ticket tax". This was chosen as an economically neutral tool, easy to implement at the national level and well-suited to mobilizing predictable resources to provide sustainable access to medicines. Each country decides freely what rate to introduce and what it will apply to, for example all flights or only international flights; all classes or only business class etc. Countries are invited to confirm their intention to allocate the proceeds of the levy to UNITAID. Chile, France, Guinea, Mauritius, Niger and the Republic of Korea have implemented such a contribution, and other countries are preparing its implementation in 2008. Norway affects part of its existing tax on kerosene (CO₂) to UNITAID. When countries don't want to raise a tax, they can contribute through long-term commitments to UNITAID, in order to ensure a sustainable funding, such as the United Kingdom, which has accepted a 20 years budget commitment.

The solidarity contribution on airline tickets is a simple and effective mechanism that has no negative economic impact. For example, in spite of the implementation of a tax on air tickets in France on the 1st July 2006, Air France passenger's traffic has increased in 2006 and 2007 by more than 5%, as stated in the latest budget report from the French Parliament.

The contribution of African countries deserves a special recognition, since it demonstrates that UNITAID can bring together countries from the North and the South and overcome the obsolete notions of "donor" and "beneficiary" countries.

For 2006–07¹, UNITAID's budget was US\$383.2 million.

¹ Period November 2006–December 2007.

UNITAID ADDED VALUE

UNITAID uses its funding to make a difference in four specific ways:

- To reduce prices which means more drugs can be made available for the same budget.
- To have drugs manufactured that are better adapted to patient needs—for example fixed dose combinations.
- To contribute to the manufacture of better quality drugs through the drug pre-qualification programme which encourages manufacturers to invest.
- To rapidly deliver drugs to places where they are needed most.

UNITAID is also committed to evaluating other innovative solutions that may emerge that can overcome limitations to market diversification in developing countries; these options will also be pursued.

UNITAID UNIQUE BUSINESS MODEL

Currently, international drugs procurement is fragmented and large differences in price may occur for a given drug between regions in the world. The UNITAID intention rests on the following assumptions: the existence of large transaction and marketing costs that can be reduced by centrally pooled purchasing; the use of monopolistic buying power removes excessive rents earned by pharmaceutical companies; and increased overall demand leads to decreased prices.

UNITAID uses its purchasing power and understanding of market dynamics to help generate a steady demand for drugs and diagnostics and significantly impact market dynamics through innovative activities. UNITAID concentrates its efforts on markets where the reduction in the cost of drugs and improvement in supply of high-quality products will have most impact.

For each target market UNITAID conducts continuous analysis of market dynamics in order to identify and address key market bottlenecks. Based on such analysis, by using purchasing power and an understanding of the market, we can drive long-term reductions in the price of medicines and diagnostics. As these lower prices become available to all our stakeholders, they will also expand access to quality products globally. As well as the wide range of tools we use to help us meet our objectives, our core concept of working in partnership to supply poor countries with lower-cost life-saving medicines has now been solidly established.

This market-specific orientation is unique to UNITAID and we anticipate that the resulting price reduction will benefit other funding organizations, and in turn, dramatically scale up access to treatment. When sufficient price reductions will be achieved within a particular market, UNITAID will phase out of drug niches and identify new markets where its resources may be better utilized.

UNITAID relies largely on existing organisations who become collaborative partners (organisations that have experience in procurement, price negotiation, shipment and handling), rather than be involved directly in procurement activities themselves. For each programme, UNITAID sets up an ad hoc partnership with recognized partner organizations, such as the Clinton Foundation, the Global Fund, UNICEF, WHO, the Global Drug Facility. UNITAID funded projects are implemented through these collaborative partnerships.

UNITAID funds are restricted exclusively to financing the purchase and supply of high quality drugs, diagnostics and related commodities, not to finance operating costs or administrative expenses. UNITAID eligibility criteria mandate that 85% of UNITAID funds must be allocated to low-income countries.

UNITAID OUTCOMES

In the first year of UNITAID existence, there have been many successes of which just a few are outlined: increased supply of drugs and treatments, lower prices, better quality drugs and faster delivery to where they are needed.

Making drugs more affordable

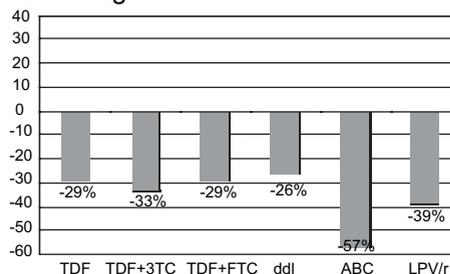
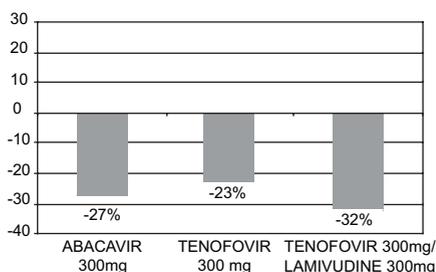
One of the biggest areas where UNITAID has made an impact in its first year is in making more drugs available for the same budget. We have achieved a reduction in the price of anti-retroviral (ARV) drugs used to combat HIV/AIDS in children by an average of 40%. Our efforts have also lead to a price reduction of second line ARVs, used against HIV/AIDS, of between 25% and 50% when measured by the income level of the country concerned.

With the financial support of UNITAID, the Global Drug Facility (GDF) has been able to use bulk orders and streamlined purchasing procedures to generate significant price reductions for anti-tuberculosis drugs for children. By offering this financial support UNITAID has contributed to the expansion of supply of anti-TB drugs to approximately 600,000 children in an estimated 40 countries over a three years period.

UNITAID added value on price

Reduced prices: more drugs available for the same budget

30 November 2006
on antiretroviral
for HIV positive children
(with the Clinton
foundation)



8 May 2007
on second-line
antiretroviral
(with the Clinton
foundation)

Making medicines better adapted for patients

UNITAID has in its first year been at the forefront of the manufacture of medicines better adapted to patient needs, such as fixed dose combinations of ARV for children, where 3 pills a day now replace 16 daily doses of syrup. Such formulations did not exist as there was not solvent demand for them before. This will make sure more treatments are completed and limit the development of resistance to first line treatments.

UNITAID also provided financial support to the Global Drug Facility (GDF) of the Stop TB Partnership to provide appropriate-strength drugs for children under the age of 15, and to ensure the development of new child-friendly formulations for infants under five years old. A total supply of 180,000 anti-Tuberculosis treatments for children in 20 countries was provided.

UNITAID added value on quality



UNITAID use of funds allows to have manufactured drugs better adapted to patient needs (fix dose combinations)



Better quality medicines

One of the key areas for UNITAID is to improve the quality of drugs and diagnostics through supporting the World Health Organization's (WHO) drug Prequalification Programme. UNITAID is a major funder of the WHO Prequalification Programme; this resulted in 21 new prequalified drugs in 2007 and maintenance of the current list of 180 prequalified products.

The Prequalification Programme increases access to medicines that meet unified standards of acceptable quality, safety and efficacy for HIV/AIDS, malaria and tuberculosis. Manufacturers wishing their products to be included in the WHO list must present extensive information and open their manufacturing sites to an inspection team that assesses working procedures for compliance with WHO Good Manufacturing Practices (GMP).

Delivering medicines when and where they are needed

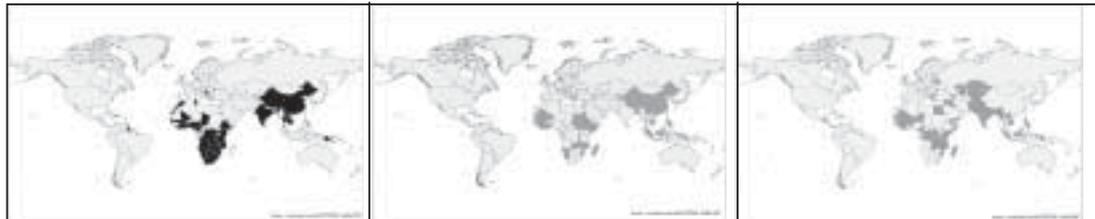
When illness strikes a community speed of reaction is often critical. UNITAID has provided financial support for its partners to prevent stocks of key drugs running out, and through the development of Strategic Rotating Stockpile(s), lead times for delivering drugs when they are needed have been reduced and the emergency cost of providing those drugs has been cut.

UNITAID now delivers medicines and diagnoses in over 80 countries worldwide.

UNITAID added value



More than 80 countries already receive UNITAID support ...



HIV / AIDS
53 recipient countries

- Pediatric ARV
- Second line ARV
- PMTCT

Malaria
22 recipient countries

- ACT

Tuberculosis
58 recipient countries

- First line TB
- Pediatric TB
- MDR-TB

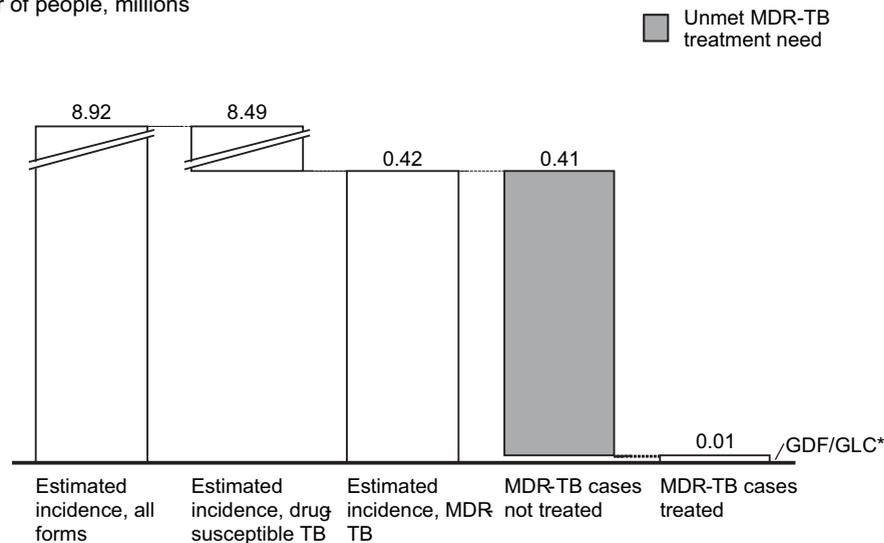
9. *Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions—eg HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?*

9 Million people develop active tuberculosis (TB) each year. Regarding tuberculosis, several concerns can be mentioned:

- The number of multi-drug resistant tuberculosis (MDR-TB) is increasing, due to resistance to first line treatments. It is estimated that at least 450,000 individuals worldwide have contracted a multi drug resistant form of tuberculosis (MDR-TB). A very small percentage receives appropriate treatment, the cost of which is very high (approximately \$4,000 at the high end of the range). There is also a shortage of quality-certified suppliers in this market.
- Although it is estimated that about 10% of TB cases are in children, paediatric TB has been largely neglected, with little focus on the specific treatment needs of children. As a result, no paediatric tuberculosis products are currently pre-qualified. Nor have child-friendly formulations yet been approved. These needs were not being funded by other existing programmes.
- In terms of quality, there is a lack of prequalified drugs.

INCIDENCE OF MDR-TB

Number of people, millions



* Number of treatments funded in 2004

Source: World Health Organisation Global Control Report 2006, Global Drug Facility/Green Light Committee

UNITAID funds anti-tuberculosis drugs, which are procured through the Global drug Facility (GDF) and the Global Fund:

— First line treatments against tuberculosis

UNITAID has made a commitment to the Stop TB Partnership's Global Drug Facility (GDF) to:

- finance the purchase of 866,000 first-line anti-TB treatments for 19 low and low middle income countries (these countries being at risk of no or interrupted treatment without UNITAID intervention); and
- fund the creation of a strategic rotating stockpile of first line anti-TB drugs.

These actions will have a strong impact in helping to achieve cost containment of anti-TB drugs in the short-term, achieve price stabilization and potential price reductions in the medium term, minimize the risk of stock-outs and therefore drug resistance, improve delivery lead times and reduce overall treatment costs for drug deliveries.

— Pediatric formulations against tuberculosis

UNITAID is funding pediatric therapies for approximately 180,000 children in 30 countries at a cost of \$5.6 million. UNITAID plans to continue to finance this program until 2010 with the aim of providing treatment to the 900,000 children who need it.

The long-term funding provided by UNITAID will help encourage manufacturers to develop fixed-dose combination formulations that are pre-qualified and suitable for children, especially those under five years of age. In addition, UNITAID's large procurement volumes will enable price reductions to be obtained for more pediatric drugs. Prices already secured will allow treating more children until 2010 within the allocated budget. By July, 180,000 treatments had been approved. Their delivery started in September 2007.

— Treatment against multidrug-resistant tuberculosis

UNITAID made a commitment of \$20.8 m to finance the purchase of 4700 second-line MDR-TB treatments for 17 countries from 2007—2011. The finances will also be used to establish a strategic rotating stockpile of priority second-line drugs. This commitment means that UNITAID will be able to play a role as catalyst for manufacturers, enabling them to increase their production capacity and develop pre-qualified products. Price reductions of the order of 20% for second-line drugs are expected during the course of the commitment. Deliveries of second-line drugs will begin in 2008. In addition, UNITAID is providing funding of \$7.3 million to combat MDR-TB through the Global Fund (Round 6).

14. *Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?*

Despite the Doha declaration in 2001 and the possibility for developing countries to make use of the TRIPS Agreement flexibilities and especially to be able to issue compulsory licensing, its use has been very limited so far. Bilateral or Regional free trade agreements are superseding Global Agreements in many countries.

In term of patents for essential drugs, where a drug would need the use of several patents, for example for ARV, there are many issues including blocking patents, where a large number of companies can block or limit the use of the technology. For essential drugs, as ARV for example, it is necessary to combine 3 or 4 different drugs to have an efficient result on the virus.

UNITAID Constitution states in Section 1 (Mission, objectives and principle of UNITAID), textually: “. . . Where intellectual property barriers hamper competition and price reductions, it will support the use by countries of compulsory licensing or other flexibilities under the framework of the Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health, when applicable”.

Following a memo submitted to the consideration of the French Ministry of Foreign Affairs and UNITAID Board by Médecins sans Frontières in June 2006, UNITAID Secretariat conducted a feasibility study with McGill University on the implications of setting a patent pool for medicines and which would potentially be UNITAID’s involvement in such. A preliminary report on the legal aspects of patent pools considered feasible the establishment of patent pools, under international laws. Its organization would require special arrangements and several issues still need to be cleared and will be discussed by UNITAID Board. The use of patent pools could also contribute to price reductions, as fees for new manufacturers would be reduced. In intellectual property laws, a patent pool is a consortium of companies agreeing to cross-license patents relating to a particular technology. The creation of a patent pool can save patentees and licensees time and money, and, in case of blocking patents, it may also be the only reasonable method for making the invention available to the public.

UNITAID also works on this issue jointly with the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property.

19. *What resources (subscriptions, staff, training, medicines etc) does the UK Government commit to intergovernmental bodies to help in the fight against the four diseases listed?*

The UK is one of the five founding countries of UNITAID. The UK has committed €20m to UNITAID for 2007, and has agreed that, subject to the outcome of a joint assessment of the performance of UNITAID, the UK commitment will gradually rise to €60 million per year by 2010 up to 2027.²

DFID’s continued support to UNITAID is based on regular assessments of UNITAID’s performance. Targets and key performance indicators have been developed and approved by the UNITAID Executive Board in advance of each three year period of funding and UNITAID’s performance assessed against them.

UK is a member of the Board of UNITAID. DFID has been consulted from an early stage of this initiative.

DFID will decide on its 2008–10 commitments in the light of an assessment made at the end of 2007 that, inter alia, will derive new targets through to 2010. It will undertake a similar process in 2010 for the following three

² For its part, la France fully supports IFFIm (International Finance Facility for Immunization), the initiative for vaccines development, with a contribution of 1,3 billion € on 20 years, (25% of the total).

years period, and so on for the duration of its 20 year commitment. Thus DFID funding for the next four years, subject to the results of the joint assessments, will provisionally be as follows:

<i>Calendar year</i>	<i>2007</i>		<i>2008</i>	<i>2009</i>	<i>2010</i>
<i>DFID Financial year</i>	<i>2006–07</i>	<i>2007–08</i>	<i>2008–09</i>	<i>2009–10</i>	<i>2010–11</i>
Amount (£)	15	nil	20	35	45
Amount(€)	20	n/a	30	40	60

A table setting out the relative position of donors is below (indicative—figures need to be refined)

Contributions to UNITAID in € millions

Estimated future contributions in italics

	<i>2006</i>	<i>2007</i>	<i>2008</i>	<i>2009</i>	<i>2010</i>
Brazil	5	12	12	12	12
Chile	2	5	5	5	5
Cyprus	0	1	1	1	1
France	45	230	230	230	230
Norway		20	20	20	20
Spain		15	15	15	15
UK		20	30	40	60
Mauritius		tba	—	—	—
South Korea		—	5	tba	tba
Gates Foundation		10	10	10	10
Others		2	2	2	2

12 February 2008

Annex A

<i>UNITAID Project Support</i>	<i>Title</i>	<i>Partners</i>	<i>UNITAID contribution disbursed in 2007 in US\$ (millions)</i>	<i>Key Objective(s) for 2007</i>	<i>Key Achievements</i>
HIV/AIDS	HIV/AIDS Paediatric ARV project (2006–08)	Clinton Foundation HIV/AIDS initiative (CHAI)	26.5	New paediatric ARV formulations Provision of treatment to children Price reduction on paediatric ARVs	19 paediatric formulations including new fixed dose combinations (FDC). 62,000 additional children treated; 40,000 continued on treatment. Average price reduction of 40% on paediatric ARVs.
	2nd line HIV/AIDS Programme (2007–08)	Clinton Foundation HIV/AIDS initiative (CHAI)	35.9	Price reduction in 2nd line ARVs Provision of ARV treatments supplied	Average price reduction of 23% in low income countries and a 49% price reduction in middle income countries. 29,000 2nd line treatments and 25,000 Tenofovir 1st line treatments supplied.
	Acceleration of Prevention of Mother-to-Child Transmission (PMTCT) and Scale-Up (2007–09)	UNICEF, WHO	6.47	Provision of more efficacious ARV regimens to women and their new born. Provision of co-trimoxazole prophylaxis for the prevention of opportunistic infections	Following signature of Agreement in December 2007, 1st disbursement made December 2007: orders for commodities placed.

<i>UNITAID Project Support</i>	<i>Title</i>	<i>Partners</i>	<i>UNITAID contribution disbursed in 2007 in US\$ (millions)</i>	<i>Key Objective(s) for 2007</i>	<i>Key Achievements</i>
				Accelerate the scale-up of HIV testing and counselling in antenatal, maternity and postpartum services	Implementation Letters sent out to the 8 countries and UNITAID-funded PMTCT activities incorporated into country plans for PMTCT interventions in countries.
Malaria	ACT Scale-up Initiative 2007–11	Global Fund, UNICEF	15.6	To support scale up ACT treatment for malaria control through Global Fund grants in 8 countries	Following signature of MOU in December 2007, 1st disbursement made in the same month. Letters of implementation dispatched. Revisions to GF Grant Agreements made to reflect increase in target treatments attributable to UNITAID funding. Tendering and Long Term Agreements under way. Prequalification of two ACTs and approximately 16 ACT-combination products submitted for Prequalification. Arrangements with suppliers regarding buffer stocks at their premises in place.
	UNITAID Project Support for Emergency ACTs for Liberia and Burundi, 2007	UNICEF, WHO	1.3	To fill the gaps in ACT treatment courses in Burundi and Liberia and to prevent disruptions in ACT treatments in these countries	722 953 ACT treatments delivered in Burundi in August 2007. 678 858 ACT treatments delivered in Liberia in June 2007.
TB	First Line anti-TB drugs-add to reflect purpose (to avoid stock outs until alternative funding sources become available) (2007–09)	Stop TB Partnership, Global Drug Facility	22.5	Timely provision to 19 countries of 1st line TB drugs.	Orders for the 19 countries for 1st Line Drugs in accordance with schedule developed.
				Creation of strategic rotating stockpile for 1st line drugs to (i) reduce delivery lead times, (ii) reduce overall treatment costs for drug deliveries and (iii) prevent stock outs	Competitive tender for stockpile launched and selection in process.
	MDR-TB Scale-Up (2007–11)	Green Light Committee, Global Drug Facility, and the Global Fund	7.1	Cost containment at below 20 USD for a 6 month treatment with WHO standard FDC Price reduction	Cost containment at below 20 USD for a 6 month treatment with WHO standard FDC secured. Competitive prices secured via direct negotiation.
				Provision of 2nd line anti-TB drugs for 17 beneficiary countries Rotating stockpile production	2nd line anti-TB drugs orders placed for 2 out of 17 beneficiary countries Procurement agent contracted and stockpiling production initiated.

<i>UNITAID Project Support</i>	<i>Title</i>	<i>Partners</i>	<i>UNITAID contribution disbursed in 2007 in US\$ (millions)</i>	<i>Key Objective(s) for 2007</i>	<i>Key Achievements</i>
	Support to Paediatric TB (2006-07)	Global Drug Facility	5.7	Identification of paediatric TB suppliers Supply of 150,000 paediatric anti-Tuberculosis (TB) treatments for children in 20 countries. Agreement amended scale-up supply of an additional 450'000 paediatric anti-Tuberculosis (TB) treatments in an additional 20 countries Price containment	4 paediatric TB suppliers under contract 150'000 treatments being supplied. Impact of pooled procurement has generated significant price reductions for paediatric anti-TB drugs. As a consequence, of cost savings, scale-up process initiated. Competitive prices secured via direct negotiation
Transversal Projects	Support to WHO Prequalification Programme (2007)	WHO	6	Prequalification of UNITAID priority medicines Field sampling and quality testing	21 drugs pre-qualified in 2007 for TB, HIV/AIDS and Malaria. Laboratories identified in 4 pilot Products and protocols being finalized in view of implementation.
	UNITAID Support for Global Fund Round 6, Phase 1	Global Fund, WHO	0	To support the Round 6 through a contribution of 52.5 million for the provision of ACTs, 2nd Line and Paediatric ARVs and MDR-TB treatments.	Memorandum of Understanding signed December 2007 and implementation according to Global Fund country grants commenced.

Annex B**BRIEFING ON UNITAID****BACKGROUND**

UNITAID, initiated by Brazil, Chile, France, Norway and the United Kingdom, now has 27 member countries, 19 of which are in Africa. UNITAID is an innovative funding facility, benefiting particularly from contributions on air tickets levies. Its Secretariat and Trust Fund are hosted by WHO.

UNITAID's mission is to contribute to scaling up access to treatment for HIV/AIDS, malaria and tuberculosis for people primarily in low income countries by leveraging quality drug- and diagnostic- price reductions and accelerating the pace at which these are made available. UNITAID achieves impact by applying its market dynamics toolkit comprising of pool procurement, volume price negotiation (including cost plus negotiation) and supporting the pre-qualification of drugs.

UNITAID works strategically with partners who can contribute and add value to achieving UNITAID's goals and objectives. Current partners include the Clinton Foundation, a not-for-profit corporation engaged in humanitarian efforts, the Global Fund, Stop TB Partnership, UNICEF and WHO Joint Prequalification Programme.

Hitherto, UNITAID has focused its interventions in the following niche areas: Paediatric and Second Line ARVs, Acceleration of Prevention of Mother to Child Transmission (PMTCT) and scale up of linkages to paediatric HIV/AIDS care and treatment; Scaling-up of ACT drugs for malaria treatments, and treatments for tuberculosis (First Line TB: Transitional Grants & Strategic Rotating Stockpile; UNITAID Support to Paediatric TB and; MDR-TB Scale-up Initiative).

For 2006–07, UNITAID’s budget was US\$383.2 million. As stipulated in UNITAID’s Constitution, 85% UNITAID’s funds are allocated to low income countries.

ACTIONS

In its first year of operation, through strategic alliances with partners, UNITAID has already demonstrated via the actions presented below how its added value can be effectively leveraged:

— *ARV against HIV/AIDS for children*

This Project was initiated in November 2006, in partnership with the Clinton HIV/AIDS Initiative, with a budget of US\$ 35.9 million to be executed until December 2007. Its main objectives included the expansion of HIV/AIDS treatment and care to 100,000 children, the stimulation of market competition and the development of paediatric formulations and fixed-dose combinations and the contribution to price reductions of antiretrovirals and monitoring and diagnostic tests. Up to present, the Project has reduced the price of ARVs on average by 40%, facilitated the introduction of triple paediatric FDCs and other paediatric formulations, and is funding the supply of diagnostics and treatment for more than 102,000 children, including more than 62,000 new treatments, in 38 developing countries. The UNITAID Board has approved a project extension for 2008, and gave a political “green light” for extending it until 2010. The extension for 2008 has a budget of US\$ 58.6 million.

— *Second line ARV against HIV/AIDS*

This Project commenced in May 2007, in partnership with the Clinton HIV/AIDS Initiative, with an approved budget of US\$ 45 million for that year, benefiting 26 countries. The Project’s ultimate objective is to influence the market to reduce the price of key second line drugs. Whilst promoting price reduction, the Project is stimulating market competition and incentivising new manufactures of antiretrovirals. UNITAID is currently supplying second line antiretrovirals for 56,000 patients in 20 countries. The UNITAID Board has approved a budget of US\$ 64 million for 2008 and the Project is expected to continue its price negotiation and supply activities until 2009.

— *Acceleration of Prevention of Mother-to-Child Transmission (PMTCT) and Scale-up of Paediatric HIV Care and treatment for 2007–08*

The overall objective of this Initiative undertaken by UNITAID together with UNICEF and WHO is to contribute to the acceleration of the global scale up of national PMTCT programmes with the explicit associated benefits of improved maternal and child health and survival in the context of universal access to HIV prevention, treatment, care and support services. With UNITAID funds of US\$ 20.8 million for the procurement and delivery of high quality HIV drugs, diagnostics and related PMTCT commodities, including more efficacious ARV combination regimens, for a period of 24 months to recipients in seven low-income countries (Burkina Faso, Cote d’Ivoire, India, Malawi, Rwanda, Tanzania and Zambia) and one low-middle-income country (Cameroon), the women and infants reached will be closely monitored against the specific targets set.

— *ACT scale up*

UNITAID, in partnership with UNICEF and WHO, delivered more than 1.4 million treatments in Burundi and Liberia, which faced risks of disruption in treatments in 2007. The close collaboration between UNITAID and its partners made it possible for the medicines to reach Liberia eight days before the expected delivery date. For Burundi, actual delivery date was within three days of expected delivery.

In late December 2007, UNITAID finalized a Memorandum of Understanding (MOU) with UNICEF and the Global Fund to scale up the delivery of ACTs in 8 countries through various grants under Rounds 1 to 5. This scale up Project amounts to US\$ 65.4 million and will support the identified grants for the remainder of the grants’ life. The beneficiary countries are: Ethiopia, Ghana, Madagascar, Mozambique, Sudan, Zambia, Cambodia and Indonesia. UNITAID has also committed to provide US\$ 21.5 million for 13 countries (Cote d’Ivoire, Djibouti, Eritrea, Gambia, Guinea, Guinea Bissau, Mali, Mauritania, Namibia, Somalia, Bangladesh, Cambodia and China) through the Global Fund Round 6 grants.

— *First-line treatments against tuberculosis—(1st Line TB—Transitional Grants & Strategic Rotating Stockpile)*

UNITAID, in collaboration with the Stop TB Partnership's Global Drug Facility (GDF), is supporting: through transitional grants, the minimization of the risk of stock-outs. Furthermore, through the establishment of Strategic rotating Stockpile(s), lead times and the overall treatment costs for drug deliveries have been reduced and cost containment of anti-TB drugs in the short-term (2007–08) has been achieved, with a view to securing price reduction in the medium-term (2009).

— *Paediatric formulations against tuberculosis—(Paediatric TB: Development of new child-friendly formulations for children under Age 4 & provision of appropriate strength paediatric drugs for children under Age 15)*

In January 2007, UNITAID provided financial support to the Global Drug Facility (GDF) of the Stop TB Partnership for the provision of appropriate-strength paediatric drugs for children less than 15 years of age and to ensure the development of new child-friendly formulations for infants under 5 years of age. A total supply of 150,000 paediatric anti-Tuberculosis treatments for children in 20 countries was provided.

With the financial support of UNITAID, GDF has been able, through pooled procurement, to generate significant price reductions for paediatric anti-TB drugs. UNITAID's funds have contributed to expand the supply of paediatric anti-TB drugs to approximately 600,000 children in an estimated 40 countries. This will be supplied over a 3-year period (2008–10).

— *Treatments against multidrug-resistant tuberculosis— (MDR-TB Scale-up Initiative)*

UNITAID, in collaboration with the Stop TB Partnership and the Global Fund to Fight AIDS, TB and Malaria, is helping to increase access to, and affordability of, quality-assured 2nd Line anti-TB drugs for use in MDR-TB control. UNITAID's funding would make it possible (through GDF) to procure and supply an estimated 4,716 patient treatments to MDR programmes in 17 countries by the end of 2011.

To date, this partnership has achieved: the establishment of a Rotating stockpile production initiated by procurement agent; a continuation of joint activities with WHO prequalification programme; and the securing of competitive prices via direct negotiation.

— *Support for the prequalification of drugs*

UNITAID is a major funder of the WHO Prequalification Programme with US\$ 1 million in 2006 and US\$ 6 million in 2007 to support its mission in influencing the market by facilitating and speeding up the pace at which prequalified key HIV/AIDS-, tuberculosis- and malaria- medicines are made available. The Project also carries out testing and sampling of medicines funded by UNITAID projects, an activity which is being developed with national regulatory agencies, with the objective not only of certifying the quality of drugs, but also of strengthening national capacities.

UNITAID and the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria

UNITAID responded to a request from the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria (GF) for the purchase of drugs under Round 6, Phase 1, to an amount of US\$ 52.5 million. It has been agreed that UNITAID funds will be used exclusively to finance 2nd line ARVs to an amount of US\$ 8.7 million, ACTs to an amount of US\$ 21.5million, MDR TB drugs to an amount of US\$ 10.3million, Paediatric ARV to an amount of US\$ 12.0 million. The Global Fund allocations to beneficiary countries will be consistent with UNITAID eligibility criteria (at least 85% to low income countries).

Last update: 30 January 2008

Examination of Witnesses

Witnesses: DR JORGE BERMUDEZ, Executive Secretary, and DR PHILIPPE DUNETON, Adviser to Executive Secretary, UNITAID, examined.

Q662 Chairman: Thank you very much for coming and for the evidence you have already given. We have about one hour. You will have an opportunity to see the transcript, because the events of today are being recorded, and you will have the chance to correct any

factual inaccuracies or anything you would like to clarify. If you feel you would like to send us any further information, if at the end you feel you have not dealt with everything, please do. Perhaps I could start by asking you to introduce yourself. I

21 April 2008

Dr Jorge Bermudez and Dr Philippe Duneton

understand you are the Executive Secretary of UNITAID, but perhaps you would give us a little introduction as to what your job is and then we will go into questions.

Dr Bermudez: Thank you, my Lord Chairman. About myself or UNITAID?

Q663 Chairman: About yourself in relation to UNITAID.

Dr Bermudez: I think you have all the information we have given you on UNITAID.

Q664 Chairman: Your role in UNITAID.

Dr Bermudez: I will leave you two advance copies of the report of 2007. That is our first report. We just finished it for our Board two weeks ago in Brazil. These are advance copies, it is being printed. It is a very good overview of what we have done during the last year.

Q665 Chairman: Thank you.

Dr Bermudez: My name is Jorge Bermudez. Originally I was a medical doctor with a Masters in Science in tropical diseases and a PhD in public health. I come from Brazil. I have worked almost all my life in the national health system of Brazil, the Ministry of Health, at the province and state levels. I directed the National School of Public Health in Brazil. In 2004 I moved to Washington as a Unit Chief for essential medicines, vaccines and health technologies for the regions of the Americas. I worked for almost three years in Washington, responsible for Latin America and the Caribbean regarding medicines, vaccines and technologies. As you are aware, UNITAID was launched in September 2006, initially by five founding countries—Brazil, Chile, France, Norway and the UK. After UNITAID was launched, a hosting agreement was decided with the World Health Organisation and all posts have been filled by the World Health Organisation criteria. I applied for the post of Executive Secretary to UNITAID and was selected and came to office in July 2007, almost one year after it was created. From July 2007 I have been responsible for the day-to-day activities. I lead a team of 16 professionals from 11 or 12 nationalities. We are committed to all the bye-laws and principles that were founded with UNITAID and have been developed and approved during all the Board meetings. As to our governance structure, we have an Executive Board composed of 11 members. Those are; the five founding countries, a representative from the African Union and a representative of the Asiatic countries, (currently from Korea), a representative from NGOs, communities living with the diseases, the private foundations (currently the Gates Foundation) and the World Health Organisation. That has met seven times up until now and our last

meeting was two weeks ago in Brazil, for the first time outside Geneva. All of the decisions of UNITAID are taken by that Board, by all its members, of course instructed and prepared by the Secretariat, and then it is up to us to implement all the actions that UNITAID has developed during the last year and a half.

Q666 Chairman: Thank you very much, that is a very comprehensive summary. One of the things that struck me about UNITAID was that it is quite an unusual organisation in the way that it was born, if I can say that, and it is also a “coalition of the willing”. I understand you have a few more country members now. How does that affect the way you work? Is it actually an advantage to have a coalition of the willing? Or do you feel it would be better if many more countries of the world were represented on it and there may be limitations to that structure? Is that right or not?

Dr Bermudez: I do not think there are limitations, because one of the initial ideas of UNITAID was not to overlap with what is ongoing, to have an additional value and select specific niches that were not being addressed to really make a difference. On the other hand, it is very important for us to have predictable, long-term --- *Dr Duneton .arrives at this point.*

Q667 Chairman: Welcome! We have done the introduction, Dr Duneton. Please complete your answer, Dr Bermudez.

Dr Bermudez: The basic ideas were additionality, not overlapping, specific niches to be addressed—and, of course, having predictable, long-term sustainable funds in order to comply with our main objectives, namely, to impact market dynamics, to extend the availability of products (because we only work with products), lower prices in markets, therefore stabilising the markets, and adding quality to the products they were using. In that sense, with eight countries up to this date, we have developed a model similar to what was proposed by UNITAID as a tax on airline tickets, so that will be a permanent tax that is predictable, or a multi-year commitment, as some countries (the UK and Spain) have already placed for several years. That brings us stable financing that does not depend on the willingness of the governments to address other organisations as they have to negotiate every year. As this is predictable, we can negotiate long-term agreements with manufacturers, we can stabilise the market as we have forecasts for several years and, therefore, it is attractive for manufacturers. I do not think we are a coalition of the willing as you say but, let us say, committed countries with stable mechanisms that will ensure predictability. We do not work in the areas that others are working in, we work in

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complementarity with them—the Global Fund, WHO, UNICEF or any other organisations. Let me just introduce Philippe Duneton, our Deputy Executive Secretary. He comes from France and he may be the only one who has been there since the beginning of the creation of UNITAID working on the proposals and is now the Deputy Executive Secretary.

Q668 Chairman: You are very welcome. I understand you had a tiny problem getting here. Just to say to you that these events are recorded and you will have an opportunity to look at the transcript before it is made public. Just to finish off that question, in a sense you have a sort of programming function and a financing function. But how do you exercise oversight into how that is done to make sure that what happens on the ground is what you want to happen, if you like, making sure that your delivery is what you believe it ought to be?

Dr Bermudez: To continue with my comments on the last question, as we work in specific niches and only with products, all of our activities are dedicated to ensure products. We do not work in other areas, we let our partners work there. We do not work alone, we work with well-recognised partners that have field offices, country offices, implementing agencies or even procurement agencies, or other types of actors that will ensure within the country that the products that are funded by us—the products are funded by us, not the strengthening of the health system or the procurement and supply management system in the countries—arrive, and that is conducted by our partners. We work in other key performance indicators. We have four main objectives: to ensure the availability of products; to ensure an adequate price of products; quality of products; and delivery of products. For each one of those objectives we have developed indicators, and in each one of our programmes we have analysed all the four indicators to see if we are impacting on price, quality, availability and lead time. Last year we presented to our Board in December an analysis of HIV/AIDS—related programmes and now we are doing that with TB and Malaria. In all of our programmes we have reached adequate results based on the indicators that we have developed. Another issue I mentioned previously was that we only work in specific niches that are not addressed. For example, in HIV/AIDS everybody knows that the Global Fund has a very big programme on first-line antiretrovirals, so we do not know work with first-line antiretrovirals. We discussed that with the Global Fund and are funding second-line antiretrovirals for resistance to first-line and paediatric antiretrovirals. There was a gap in paediatric antiretrovirals because nobody was addressing that. In TB we are working with multi-drug resistant TB and the Global Fund says

UNITAID is responsible for that, and we work with them and other organisations addressing multi-drug resistance. In Malaria we are working with the Artemisium compound, ACTs, that is the future for Malaria, and we are also engaged in a multi-taskforce that is dealing with the so-called Affordable Medicines Facility for Malaria. That puts together WHO, UNICEF, UNAIDS, UNITAID, the Global Fund and the World Bank, working to make sure that we will have products available worldwide for Malaria. We will address quality, the pricing of these medicines, children's medicines. Thanks to our long-term financing, we have introduced new products in the market because it is attractive to manufacturers. In TB and paediatric antiretrovirals we have new fixed-dose combinations that are much more pleasant for the child to take and much more quality-assured because they have been pre-qualified by the World Health Organisation scheme.

Q669 Chairman: The production of a good quality drug is one thing, the delivery of that drug to the individual who needs it, given the problems in some developing nations, is another. How would you have confidence that you are delivering that sort of quality to the individual who needs the drug?

Dr Bermudez: Quality for the manufacturer and the WHO is clear, because we are addressing that and our new product will be delivered to the market. How you make sure those products will be delivered to the people who need those products and that they are of quality, that is why we work in partnership with other organisations that work in that field, and we ensure that by means of agreements with the Ministries of Health of other countries. We do not work out of the health system. All of our programmes have agreements with the Ministries of Health in the countries that are receiving the products to make sure those medicines will flow through the health system and be adequately received, stored and distributed through the supply system. We have Partners who have field officers who will monitor that for us as well.

Chairman: Thank you. I think Lord Avebury would like to ask about your relationship with the World Health Organisation.

Q670 Lord Avebury: Just before I come on to that, could I ask whether you are planning to expand the number of contributors. I think it went up from an initial five to 27. Are other States coming on board? Is the airline tax being extended to further carriers beyond those who signed up originally?

Dr Bermudez: I will answer that in two stages. We began with five countries supporting that, and now some African and other countries have said that they want to support that and have come on board, either by the air tax or by implementing in other ways or by multi-year stable financing. We have been discussing

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this, and other countries have said they want to, but they want to have more details about how they can implement that. Some countries are working on that. A new idea that we have had approved by our Board and in a conference call last week is a proposal—and you have probably heard that our chair is a former Minister of Foreign Affairs of France, the Under-Secretary of Ban Ki-Moon, the United Nations' General Secretary—for innovative mechanisms for financing development. He has been committed and talking about the possibility of a voluntary solidarity contribution that would be managed throughout the global data systems in the world. We are aware that 65 per cent of air tickets that are issued worldwide are issued through three main global data systems—Galileo, Amadeus and Sabre—that generate internet-based transactions. The three CEOs of those agencies have agreed to work closely with UNITAID to see the possibility of implementing a voluntary solidarity contribution, as some other actors have done in hotel bookings. If correctly addressed, in the most pessimistic situation that would add about \$300 million per year up to \$1.8 billion that could be reached if we implement a voluntary solidarity contribution. That is an idea that is being rapidly developed and it has been announced since our chair, Philippe Douste-Blazy, was named Under-Secretary of the UN.

Q671 Lord Avebury: It sounds like a terrific idea, except that it conflicts a little bit with what UNICEF are already doing on airline tickets, does it not? They have a voluntary contribution that people are asked to pay when they get on board the aircraft and there is a leaflet on the seat which invites the passenger to pay something towards UNICEF. If you are going to require this voluntary contribution to be made at the time of booking, then a lot of people are going to say, "Why should I pay twice?"

Dr Bermudez: Then they do not pay twice.

Q672 Lord Avebury: Otherwise it is a tremendous idea. Could I then come on to your relationship with WHO and ask why it is that WHO could not have undertaken the functions that you have described? Was it simply because there was a limitation in their constitution? If that was the case, why would it not have been better to alter their constitution so that they could have done the work that you are now doing?

Dr Bermudez: First of all, WHO is a UN technical unit and we do not consider ourselves a technical unit. We rely on WHO technical expertise. We are an operational unit. WHO has offices in other countries and other regions, it works mostly with capacity building, strengthening health systems, and with guidelines and documents, workshops, seminars, Standard Treatment Guidelines, and we adopt those

for our work. WHO is not a procurement agency or a funder of products. They have a model list of potential medicines, they have a pre-qualification scheme that works within the UN system, but they do not work with procurement and do not have the lead time that is needed to rapidly disburse and attend to the country's needs. We think that WHO have their rule and we respect their rule, we do not do technical activities but we rely on WHO's technical actions and their solid background. They do not do procurement unless it is necessary for small issues. They do not act in the areas that we are acting in.

Q673 Baroness Whitaker: Could I just ask, is it that WHO would advise you on which drugs you ought to go for? Is that how they would come in? Or are there other ways?

Dr Bermudez: WHO has Standard Treatment Guidelines for paediatric treatment for HIV/AIDS, for TB, for Malaria, and we use those as guidelines. We see what is addressed by other Partners and what would be the need for second-line antiretrovirals, for paediatric antiretrovirals, according to WHO guidelines, because they have standard guidelines for pregnant women, for adults, for children, and we make sure we do not overlap with that. For procurement and delivery we use other Partners and we go to the countries and the countries' Ministers of Health, sign agreements to incorporate that into their health systems and we fund it.

Q674 Baroness Whitaker: Does it suit you how you are lodged within the intergovernmental machinery? Are there different roles or different powers that you would like to have? Or, if WHO were differently constituted, would that help you at all?

Dr Bermudez: It is very clear to us what are the different roles of the different organisations and it makes it easy for us to work with WHO, UNAIDS, UNICEF, the Global Fund, because we have different architectures, different business models, different financial activities and complement each other. We are very much aware and have discussions with them. One of our major partners is the Global Fund. More than a year ago the Global Fund's Board and UNITAID's Board requested that we work together to see what roadmap we could develop jointly so that we do not overlap and what would be the added value that we could have in the strengthening and scaling up of access to products for the three diseases, because the Global Fund also works with the three diseases. We have found our role, their role, the complementarity and we work together with them.

Q675 Baroness Whitaker: So structurally you are where you want to be?

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Dr Bermudez: Yes, structurally we are a lean secretariat hosted by the WHO, so we are on the health side and that is important for us because we work with a health perspective in delivering products. We are gaining experience with their expertise in the three diseases. We interact very strongly, almost every day, with the Department for HIV/AIDS, the Department for TB, Department for Malaria, the Partnerships they have, as Roll Back Malaria and Stop TB, and the Medicines Department and the health system. They do their work and we are an added-value to their work.

Q676 Baroness Whitaker: Thank you. Could I finally ask, do you give any priority to local manufacture and accreditation, because that would have eventual health benefits in that it would increase growth, it would increase capacity? For instance, I think Artemisium grows in Tanzania; I do not know whether Novartis cultivates it there.

Dr Bermudez: We are supportive of that, but we do not work alone on that because other organisations have very specific roles, for example UNIDP, the United Nations Industrial Development Organisation. We have worked with them to see how they can strengthen local manufacture in areas that we will have a forecast of and that will justify having local manufacturing. Your example is very clear where you talk of Artemisium in Africa in Malaria, where we are working on that. Also, pre-qualification is not for us, the World Health Organisation will pre-qualify manufacturers, examine their dosage, make sure that they comply with good manufacturing procedures, and we can fund the products. But we will only fund pre-qualified products to make sure that we have quality. In that sense, WHO is supporting manufacturers for them to reach this status of pre-qualified drugs and manufacturing.

Q677 Lord Desai: There are a lot of overlapping agencies around, and one of the questions is; can you simplify. In your case there is the Global Drug Facility, and I wonder; is there a rationale for you guys getting together and going into the Global Fund? Or is there no advantage to that sort of streamlining?

Dr Bermudez: Initially, the Global Drug Facility only works with TB. In TB we are Partners with the Global Drug Facility because in some countries they have Regional Offices. We established a partnership with them, and for first-line TB, for multi-drug resistant TB, we work with the Global Drug Facility. The Global Fund has a completely different architecture. When we worked with antiretrovirals, when we were assessing the products that we deliver, one of the issues we compared was the lead time that we had to deliver products. Let us say we sign an agreement. How much time does it take between the

signing of the agreement and for the product to be delivered in the country? We compared that with PEPFAR, the USA programme for AIDS relief and the Global Fund, and our lead time takes weeks: PEPFAR takes months, sometimes a year; and the Global Fund takes years. They are not intended to be a procurement agency. Their strategies are based on rounds that they discuss with the country and in that sense the country applies for grants from the Global Fund, and in those grants they have the strengthening of the health system, human resources, products and diagnostics. From the signing of that to the end takes one, two, sometimes three years. They are completely different architectures. We consider that we have a specific role in funding products, shortening lead times, supporting WHO pre-qualification and ensuring the scaling-up and a rapid response. We had two emergencies last year because of a stock-out of malarial medicines in Liberia and Burundi in Africa. We discussed this with UNICEF and WHO, and in four weeks the medicines were arriving in the country, so we prevented stock-outs of medicines. I can assure you that the Global Fund does not work with emergencies because they have long-term financing for the countries.

Q678 Chairman: You do not see yourself as an organisation that mainly focuses on an emergency, you see it as more general than that?

Dr Bermudez: Yes.

Q679 Chairman: I suppose this is what we are struggling with a bit. We have had people say to us that there are so many actors in this whole international field that it is difficult to get coordination without overlapping and, therefore, wasting resources. There is another argument that says that all of these organisations are doing a good job and all we have got to do is get the coordination right. Those are the two arguments. How would you evaluate those arguments, if you like? Do you think you are quite relaxed about the number of organisations? Is the coordination good or bad? Or is there room for rationalisation of the number of organisations?

Dr Bermudez: First of all, the other organisations are there and we will not discuss whether they should be there or not. We have a very specific additional role. One of the issues that needs to be addressed, and we have discussed this with all the other organisations, is how to coordinate the in-country actions, because in-country there are several organisations acting with different Partners, different delivery mechanisms, different quality standards, so it is very difficult for countries to receive sometimes. We have discussed the supply systems in several African countries and are amazed when we see the numbers of organisations that fund, that deliver, that work with

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human resource building in the countries, and sometimes they do not speak to each another, there are four, five, six or ten organisations working in a country. When we see countries in crisis, that is worse because we have international aid flowing and everybody is eager to help and in an emergency that is very clear. We are very specific in that we only fund products that others are not funding. We do not work with emergencies, but we have because, when we realise the only way to avoid new cases of resistance is to avoid stock-outs, we work with those emergencies just to cover certain gaps in partnership with other organisations when we realise that nobody is funding that. Our main mission is to fund products, let us say commodities, for diagnostics, for treatment, where they are not currently funded by other organisations. We always work with the idea of additionality and not overlapping.

Q680 Lord Desai: My next question is related. You mentioned running out of drugs in one or two situations and also the strategic rotating stockpiles. Can you say a little bit more about that so we understand.

Dr Bermudez: When we were discussing with Stop TB and the Global Drug Facility, there was a problem last year that 18 countries in Africa had been granted Global Fund grants but they would be receiving funds for those grants in two or three years. Most of them were being covered by the Global Drug Facility and Stop TB but were running the risk of stock-out because of the gap between the end of the financing they had for those medicines and the time they needed to receive the Global Fund funds to be able to continue. We took to our Board a strategic decision: “This is an emergency, it is not our current business but we have been requested by WHO, UNICEF, the Global Drug Facility and the Global Fund to see if we can work together on a rotating stockpile of medicines—a transitional programme, because we will not maintain that for the rest of the years—to avoid stock-outs and the emergence of resistance and people who will not receive their medicines”. The Board understood that it was an exceptional measure that should be approved and supported, but not a normal activity that we would undertake. That was helped by creating a stockpile that was managed between the countries as necessary and was administered by the Global Drug Facility.

Q681 Lord Jay of Ewelme: I would just like to go back one stage, because I want to be quite certain I understand what you do. I understand that, if there is a drug which exists and has received pre-qualification and is acceptable, then it is comparatively straightforward; you would identify a need, you would talk to UNICEF or whoever, you would order it and deliver it as soon as you could to the deliverer,

as it were. That seems clear. Where I am slightly less clear is that you said earlier on you only purchase drugs for which there is WHO pre-qualification. But do you act rather like advance market commitments in the sense that, because people know you are there and you may put in a big order for something, that encourages research, encourages development, encourages companies to go for pre-qualification, so you are acting as a spur to the research and development of drugs as well as purchasing them?

Dr Bermudez: Yes.

Q682 Lord Jay of Ewelme: Could you just give an example of a drug that was not quite there yet until you came along, if you see what I mean?

Dr Bermudez: I will mention two points. First of all, when we began to discuss the paediatric ARV programme, there were 40,000 children on treatment in the world. We discussed this with the Clinton Foundation and decided to introduce 100,000 new treatments per year during three years, so in 2007 we introduced 100,000 and then we had 140,000; in 2008 we will have another 100,000, so 240,000; and in 2009 it will be 340,000. The needs that are estimated in the world are around 500,000 to 600,000, so we will be responsible for most of the paediatric treatments in the world. That led an Indian manufacturer, Cipla—

Q683 Lord Jay of Ewelme: At that stage there was no drug?

Dr Bermudez: There were adult drugs that were used by children.

Q684 Lord Jay of Ewelme: There were no drugs specifically designed for children?

Dr Bermudez: No. There was no fixed-dose combination, three drugs in one pill for the children.

Q685 Lord Jay of Ewelme: So you were identifying the need with the Clinton Foundation for a product that did not exist?

Dr Bermudez: Yes. The three products existed individually but nobody had put them together. Cipla did that for the first time. That was pre-approved by the US Food and Drug Administration and the WHO recognised it, so now the product is being used not only by us and the Clinton Foundation but by other organisations in other African countries. When we support the WHO pre-qualification scheme, WHO in its report of 2007 on pre-qualification stated, “Thanks to UNITAID funding, 31 new products were pre-qualified in 2007”. We have 31 new products that would not have existed pre-qualified for the three diseases. Most of them are for HIV/AIDS because the market for HIV/AIDS is larger. We are trying to move faster to Malaria and TB as well. Last year we had 31 new

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products pre-qualified by WHO related to UNITAID funding.

Q686 Lord Jay of Ewelme: You are value-added, therefore? First of all, you have got the money because the money is coming from the 27 countries?

Dr Bermudez: Yes.

Q687 Lord Jay of Ewelme: Secondly, you are developing relationships with a whole series of manufacturers, is that right? What you bring to the Clinton Foundation or UNICEF or some other donor is the ability to go and talk straight away to the manufacturer and say, “This is what we want and what we would like you to develop”.

Dr Bermudez: This is what will happen in the next two or three years.

Q688 Chairman: If you would like to come in on this—I see you nodding, Dr Duneton—please do.

Dr Duneton: No, thank you, I do not have much to say on that. We had the chance and the opportunity to demonstrate what was initially in our constitution. The example chosen by Jorge about the FDC/ARV paediatrics is also the same in TB because it was a question put by GDF. When we started discussions with GDF, they had a project they had had for three years to have a specific combination for paediatrics, but they did not have any money to do that. In one year we provided the first combination for TB in partnership with GDF. By the way, it was a surprise that we had a good quality product and with the same money we could treat four times more children than we expected. It has a market dynamic impact. The important word is “dynamic,” because when you change to move something it has some positive consequences.

Lord Jay of Ewelme: If I could just make a comment. It seems to me that the speed with which this has got off the ground and is operating, given the speed at which UN organisations normally operate, is actually pretty remarkable. It was only three years ago that this was thought up and you are now sitting here saying to us, “We have already had these discussions, we have ordered the drugs and they have been used”. It is quite remarkable.

Q689 Lord Howarth of Newport: You mentioned that among your ambitions is to focus on the procurement of second-line drugs. These are fantastically expensive—\$4,500 per TB treatment, and in the case of ARVs something like ten to 20 times the cost of first-line treatments. While I am extremely pleased that the UK has made a commitment to support you for 20 years, you also talk in your evidence of a “dearth of predictable long-term funding”. More and more patients are going to need these second-line drugs and that may bring the

unit cost down, but how confident are you that you are going to be able to see this through and afford the cost of this programme?

Dr Bermudez: Your issue is relevant because it really is very expensive as we increase. When we look back to the past and see where HIV/AIDS was 20 years ago, nobody expected us to be able to fund HIV/AIDS. Everybody said it would be unfundable because of the cost, but the cost has been brought down for first-line medicines and they cannot go lower, because they are at the lowest price and we have more than one million people in treatment with first-line. On second-line drugs, as Philippe said, we treat three children now where before we treated one. It is not so easy in TB, because the market is more difficult and active principle manufacturers are not so well-known. We know less of the market on the TB drugs than we know of the ARV or HIV/AIDS products. We are analysing all the global market manufacturers on active principles of the final products to see how we can link one with the other to make sure that we will have stable manufacturing throughout the years. If prices are not brought down, we will reach a point where we will not be able to fund more. In TB we also have an additional problem in that for second-line TB we have to invest in diagnostics, because in many cases we do not know where they are and the countries do not know. If we want to advance, one of the things we have discovered is we need to invest in diagnosis. We will not be able to fund MDR-TB alone but we are one of the major funders. We are treating 5,000 MDR-TB patients and have committed to a project with a global representative of the Green Light Committee to expand as much as we can. I agree with you that it is a very difficult problem, and it is unpredictable as to whether we can fund in the long-term, but we will do our best to continue and lower prices now.

Q690 Lord Howarth of Newport: Your business model has already, through the use of your purchasing power, demonstrably been able to bring down the costs of certain drugs, but where the drugs do not exist there is another set of problems, is there not? You were speaking of TB, and I think you mentioned in your written evidence that paediatric TB is a neglected field. Presumably, that is a consequence of market failure, whereby the drug companies are interested in producing new products to meet the needs of the affluent West but not of the developing world—you cite appalling statistics: less developed countries 84 per cent of the world’s population, 93 per cent of disease, 11 per cent of global health expenditure. This is market failure on a colossal scale. Do you see your organisation having the purchasing power and the firepower in the marketplace to be able to commission new research so that new products are produced to meet the needs

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of the developing world that are not being financed on the present market model?

Dr Bermudez: Yes. In partnership, of course. As we have mentioned, we do not work alone and we will not be able to fund research.

Q691 Lord Howarth of Newport: No, it is very expensive.

Dr Bermudez: But we have other Partners we are working with. For example, I can mention TDR, Tropical Diseases Research, in WHO and the Drugs for Neglected Diseases Initiative and various trans-national companies and foundations that are dealing with research and working with, let us say, DNDI, (the Drugs for Neglected Diseases Initiative) in developing new products for neglected diseases, and I think TB would be considered in that. At this moment we are not committed to fund research because others are doing that.

Q692 Lord Howarth of Newport: Is that because the costs of it are simply too great for you to contemplate? Or because it is a task that others will perform?

Dr Bermudez: It is both. It would need too much funding and others are dealing with it. What we can do in partnership with those is to try to forecast what the future market will be. We had the introduction of paediatric TB drugs after we began to work with Stop TB. That will be a predictable market if we foresee that in the years to come we will have an increasing demand and it may be attractive for industry. We may have the support of industry from other organisations, such as those I mentioned a few moments ago, and you need to work with other organisations that may support manufacturing.

Q693 Lord Howarth of Newport: Meanwhile, to overcome the problems that there are with intellectual property rights you are focusing on your scheme for patent pools. Will you tell us more about that and expand on that proposal—how you see that working and who would be your Partners in terms of getting things to happen?

Dr Bermudez: It is a very incipient activity, or non-activity, but it is a discussion within UNITAID. We and the French Government received a request from NGOs, especially *Médecins Sans Frontières*, to try to work on the concept of patent pools and how that exists in other areas—in aviation, music—but has never been applied to medicines in the pharmaceutical setting. We were asked if UNITAID would be able to move ahead on establishing potential patent pools that would enhance success for medicines, especially fixed-dose combinations. We opened a tender, commissioned a report with IPDS from McGill University in Canada and that delivered a first report. I just want to go back some years and

say we strongly think this is a continuation, initially of the UK CIPR (Commission on Intellectual Property Rights) that delivered a report four or five years ago. Then the Commission on Intellectual Property Rights, Innovation and Public Health in WHO delivered a second report, the CIPIH, and now the Intergovernmental Working Group continues to discuss how to move. These are three sequential movements in three products that have been brought forward and we are following very closely. Based on McGill University's report that says that patent pools are feasible, legally and administratively—of course, it is a sensitive area because it deals with intellectual property and the right to health—it would be feasible and we need to move to see what would be geographic coverage, coverage of medicines, which products, how to deal with voluntary licensing in a patent pool and, if it is an issue, to deal with compulsory licensing in a patent pool, how would that deal with other stakeholders. Based on that report we had an initial meeting of a small group of people, which included people from academia, NGOs—not from governments, because we did not put the countries in because the countries have to approve or not of what we are doing. We moved to try to figure out what are the steps that would be necessary and submitted that to our Board two weeks ago. Our Board said they see a great advantage and they asked us to continue. We will still be working on what will be the potential of a patent pool, starting on the principle that initially it will be a voluntary licensing patent pool. It is for countries to apply compulsory licence requests from a patent pool, but it is not an idea that will begin as a compulsory licensing patent pool, because we need to bring the pharmaceutical industry and innovative engineers in to discuss that with us and we will address it then—what will be the governance structure for that, the constituency for that and the initial needs and steps to be taken. That will remain as an issue to be discussed with our Board, and our Board will take the final decision, not at the next Board meeting but in two or three Board meetings' time. We understand that is an issue that will continue with some months of discussions because it is not an easy discussion. On the other hand, UNITAID has been called as a concerned entity in the Intergovernmental Working Group, so we are following that closely.

Q694 Lord Howarth of Newport: Do you anticipate that you will have the endorsement and practical collaboration that you will need from some of the other organisations that obviously have an interest—the World Trade Organisation, WIPO and also the World Health Organisation? Are they likely to be on board?

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Dr Bermudez: Yes. We invited all of them to the discussion and it included the World Health Organisation and WIPO. The WTO was not able to come, but they will be on board and we will continue to discuss this with them, of course.

Q695 Chairman: Why was it not possible for the World Trade Organisation to come?

Dr Bermudez: It was just one meeting.

Q696 Chairman: You have no problems in discussions with the WTO?

Dr Bermudez: No.

Q697 Chairman: You would not do that through government, you would do it directly as UNITAID?

Dr Bermudez: As UNITAID, we want to have an independent group that will have a proposal that can be taken to our Board. We have followed very closely the IGWG discussions and sometimes there are some impasses and tense situations. We do not want that to be brought to a group that is discussing how to move. Of course, when we sit with the governments, they have their points of view, and we understand that clearly, but we do not want that to be an intergovernmental discussion between two governments, we want to have impartial information to take to our Board, and then our Board will discuss that. Our Board has the UK, Norway, Brazil, Chile, France, the Asian countries, African Union, NGOs and WHO to discuss that.

Q698 Chairman: You obviously have discussions with the pharmaceutical companies about pricing directly and so on for things you might buy, but what about their overall policy. Would you discuss that with them or not?

Dr Bermudez: For a patent pool?

Q699 Chairman: Yes.

Dr Bermudez: We will discuss with them but we want to have a clearer idea of what are the different options before having that discussion with the pharmaceutical industry.

Q700 Chairman: Their argument would be that they have got to have sufficient money to do the research, and the other side of the argument is that it is too expensive to deliver the drugs even though you have brought new money to it, if you like?

Dr Bermudez: We will have that discussion with them at any stage that we are able to move.

Q701 Lord Avebury: When we were talking a few minutes ago about the very high cost of second-line drugs, I was looking at your written evidence where you said that the cost of the second-line MDR-TB treatments could be brought down by 20 per cent

during the currency of the commitment of the \$20.8 million from 2007-11. Is that based on contractual discussions with the manufacturers? Is there an advance market commitment which you are discussing with them? Or would that be a useful tool to help bring the price down?

Dr Bermudez: Those are initial discussions based on the current manufacturers' price of the active principle ingredients and the possibilities of working like we have done with ARVs, for example, with the cost-plus methodology. All the costs need to be known and some companies are open to that, but others are not. Based on that assumption, we would have an estimate of what the impact would be, but we have not discussed that thoroughly with the manufacturers.

Q702 Lord Avebury: Are you thinking about an advance market commitment?

Dr Bermudez: Not in the sense that it is being used with vaccines currently. That is an open idea that we need to follow very closely. It has been used in vaccines, but vaccines and medicines are completely different models because of the time of development of vaccines, the strains that are necessary, the specificity of manufacturing. In pharmaceuticals you have a much shorter cycle, a faster return to manufacturers and it is a completely different approach. We understand an advance market commitment as is being done for vaccines will not be discussed relating to medicines now. It may be a possibility, but we will not say at this stage we will do something like that.

Q703 Chairman: You have enormous experience and it is clearly very focused on what you are doing, but it must have given you a very good picture of what is happening in the world of disease and treatment and the international organisations. If you step back from your own organisation, put that to one side for a moment, and if you were looking at this whole area, WHO and all the many organisations, and I asked you what are the problem areas that are not being covered and what are the real pluses of it, what would your answer be?

Dr Bermudez: One issue is that phrase that has been raised several times here—medicines are in the north and patients are in the south, the imbalance between what has been manufactured between offer and demand, what has been manufactured, delivered and what is the potential in years to come. We have introduced a different view in some of the areas where we have worked. We have seen the price of second-line ARVs being brought down, so they are three times less than was initially thought. We need to have an overall multi-stakeholder initiative that understands that access to medicines are a part of health and have to be delivered. Some countries are

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able to pay and some countries are not able to pay. We are funding and our constitution is very clear, that 85 per cent of our resources has to go to low income countries (and we think that is correct) and only 15 per cent to lower-middle income countries or medium-middle income countries. Many of the low income countries are not able to pay, so we need to know how to expand the availability of resources to treat those diseases as the global emergencies that they are.

Dr Duneton: I think it is obvious, and all the organisations recognise the need to find a better way to strengthen the capacity at country level. I will give an example. Of course we want to be focused on the product; but, having said that, we need to think what the product will be used for. We have certain limitations because we do not want any overlap. In the case of diagnostics, it is not only a question of devices and commodities, it is a question that is more about the service. It is just an idea for now, but we have discussed that with Partners and industry and they have shown some interest, saying we could organise the support. By the way, we are already doing that through the Clinton Foundation for diagnostics for paediatrics, not only paying for products but for the results. That is exactly the same way that we consider this in the northern countries. We are not paying for a PCR device or a part of this, because that does not work. In fact, in a lot of countries in the south it does not work because you can have the device but, if you do not have the human resource to use that kind of device properly, you have nothing and you have paid for nothing. I have tried to look from outside the organisation but, in a way, it is a question not only for us but also for our Partners. It is useful to think in that way of something

a little bit different and saying we have that impact on the product. But, if we are paying for a service, it could be something for us to think about again, not only us but with Partners and industry.

Q704 Chairman: What sort of organisation would that be that would do that?

Dr Duneton: Just as an example, the Clinton Foundation. With the experience of others we have started to think about that, and that is the way it works now. We have had initial discussions with UNICEF on that, with major industries like Roche or Abbott, not trying to set something but to see the idea.

Q705 Chairman: The shape in a way?

Dr Duneton: Exactly. It was a recommendation issued by the assessment that we have paid for that, when we assess the diagnostic part of TB, maybe there is a need to think in that direction. It is something on how to move in the next three years maybe.

Q706 Chairman: If you get any more thoughts on that in the reasonably near future—we have to report in July—please let us know, because it sounds quite interesting. Any further questions? Is there anything you have left out at all that you want to raise or you feel we have missed? Is there anything at all you would like to say?

Dr Bermudez: No, thank you very much.

Q707 Chairman: Thank you very much.

Dr Bermudez: We have to support more than 80 countries and I think we are moving forward in the right direction.

Chairman: That sounds very good. Thank you.

TUESDAY 22 APRIL 2008

Present:	Avebury, L. Desai, L. Jay of Ewelme, L.	Soley, L. (Chairman) Whitaker, B.
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Examination of Witnesses

Witnesses: DR HAILEYESUS GETAHUN, Medical Officer, Team Leader, Ms DIANA WEIL, Senior Policy Adviser Stop TB Department and Ms LOUISE BAKER, Senior Strategist, Stop TB Partnership Secretariat, examined.

Q708 Chairman: Good morning. We have an hour, we have to finish by ten sharp, when we have to be out of this room. The events today are being transcribed and you will see the transcript before it is published, so you can correct any factual matters. If there are any issues that we do not cover or anything you would like to add, please contact the Clerk. Can I ask you to introduce yourselves because we were not quite sure who was coming.

Ms Weil: We had a change of dates.

Dr Getahun: My name is Haileyesus Getahun. I am a medical doctor by background and work as a Medical Officer and Team Leader for TB/HIV issues in the Stop TB Department.

Ms Weil: I am Diana Weil. I am a policy analyst of the local economy by training but am a WHO Senior Policy Adviser for the Stop TB Department, so I work with the Director of the Stop TB Department at WHO, which houses the Stop TB Partnership, so we work in collaboration, which is why we are here together.

Ms Baker: I am Louise Baker. I am the Senior Strategist for the Stop TB Partnership, which is an international partnership housed at WHO.

Q709 Chairman: Thank you very much. Thank you for the information you have already given us and for coming along and giving your time today. Clearly you are a one-disease organisation, and I would like you to start by giving us a little summary of what you think your main purpose and aim is other than stopping TB, which is self-evident. If you could tell us something about the major sources of funding and how you seek to prioritise your spending, that would be useful to us as well, and how you work with the health systems of countries. Who would like to start on that?

Ms Baker: I think it is probably me to start on that.

Ms Weil: If it is a question as to the Partnership, we will talk about the Partnership, and then we can talk about the relationship with WHO.

Ms Baker: The Partnership is now a grouping of more than 700 agencies from around the world, and they range from major international organisations, so some of our major Partners—WHO is our housing partner but there are other international agencies

that form part of the Partnership—are the World Bank, DFID, USAID, the European Commission, et cetera. We are a large partnership. The function of the Partnership Secretariat is to coordinate the actions of the various partners who have made a commitment to fighting TB. Our work is based very much on the WHO Stop TB Strategy, but on the basis of that strategy we have a global plan to stop TB which tries to look at TB in a fairly holistic way. So it is looking at all aspects of countering the disease from implementation on the ground through research, advocacy and communications. We work on the basis of seven working groups, so our Partners are arranged around their areas of interest. We are focused on a single disease, absolutely, but I think we are focused on it being very much aware that tuberculosis is a disease of poverty. So, for example, in our working group on implementation, called DOTS expansion, we have a subgroup on TB and poverty which is looking at social determinant issues and poverty-related issues, so it is not looking at it purely from a medical perspective. When you say the major forms of funding, it is quite a complicated explanation.

Q710 Chairman: I have worked that out!

Ms Baker: There are 700 Partners, but we are not a funding agency. We do not channel funding particularly. If funding comes in, we try to distribute it fairly but we do not channel funding to our Partners. We are a loose affiliation, a loose Partnership, with common aims and goals, but we do not fund their major work plans.

Q711 Chairman: That comes from where?

Ms Baker: Their own funding streams. For technical assistance matters WHO would go out and raise its own funding to do technical assistance for tuberculosis. Other Partners would do the same thing. If you were a TB researcher, even though we are all working for the same global plan, you would go out and find your own funding for tuberculosis research. What we try to do is make sure all the Partners speak coherently around the plan and are aiming in the same direction. It is about coordination and facility of a positive move rather than control.

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When we talk about our sources of funding, we talk about the funding for the Secretariat, which is housed at WHO.

Q712 *Chairman:* And who funds that?

Ms Baker: Mostly bilateral donors. We get very generous funding from the UK, we get funding from the Netherlands, Canada, USAID, both through USAID and PEPFAR, from the Bill & Melinda Gates Foundation. A broad range of Partners fund the work of the Secretariat, both the work around advocacy and communications and also the work around the Global Drug Facility and the provision of drugs.

Q713 *Lord Desai:* What is your value-added? If everybody is doing their own work, what are you doing?

Ms Baker: OK. We are in the process of going through an external evaluation looking at exactly that. The McKinsey Company has come in and done an evaluation. It is avoiding duplication, so we make sure our Partners are not doing the same thing, that we complement each other rather than do the same thing and compete. Certainly in the evaluation it appears that the added value of the partnership has been about developing a common strategy so that there is no counter-messaging. We are all very much in line with each other and driving in the same direction, and there is none of the squabbling that you might get if there was not a common plan.

Q714 *Baroness Whitaker:* I appreciate that your job is to make the single parts of the engine all move in the same direction, but what happens if there is a big organisation of any kind which is not in your 700 and is going in a slightly different direction, which is a perfectly reasonable thing but not helpful for some reason or another. Do you try to draw them in? What do you do about other engines which are going across your path?

Ms Baker: I hope we have tried reasonably successfully to convince everybody. The process of writing the plan is almost more important than the plan itself.

Q715 *Baroness Whitaker:* Of course, I understand that. Do you have a problem with donor preference? For instance, say a big private donor, Mr Warren Buffet, decides he wants to do his own thing and have a really nice product and it is not what you think ought to be done. What do you do about that?

Ms Weil: We have a Coordinating Board. The Coordinating Board involves members of DFID and others who collectively can send messages. For example, they have written a letter to the Global Fund suggesting that the Global Fund creates a seat for the Stop TB Partnership, and there are similar

discussions around the Roll Back Malaria Partnership to represent the whole community, so that as a Board they can collectively react to outside forces.

Q716 *Baroness Whitaker:* Bring influence to bear?

Ms Weil: That is right. The other thing Louise is bringing out is that, because we provide a coalescing of the evidence around why we should be doing research and implementation at the same time, we hope that is pretty convincing evidence that we should be going on the course we are and, if not, one of the one great elements of the partnership is that it is a place for debate. We have had some pretty hefty debates over the years about how to respond to certain controversial issues. How we relate with the HIV community, which Haileyesus can discuss later, is an important element where there has been a lot of debate, but we are coming around to a consensus now.

Q717 *Baroness Whitaker:* Broadly it works, you do get other bits not in the engine at least going in the same direction as the engine?

Ms Baker: I think so, yes. Obviously we have moments, there are points of conflict and debate and discussion, but in general we all seem to agree that it is a common plan and a common strategy. It is very strongly based on WHO's technical strategy, so that has been a first step, and then the way of getting there has been a process of discussion and debate.

Q718 *Lord Jay of Ewelme:* Is it not a two-way street? You produce your plan and you will communicate with some of the 700 members. But, if you are one of the 700 members, say a small member operating somewhere in Africa or Asia, would they be fairly regularly in touch with you? Or would they be taking the initiative? How active would they be?

Ms Weil: Obviously today it is a totally different ballgame in the way that people engage, so they can become very vocal very quickly through that means, for example civil society.

Ms Baker: What we try to do is break them down according to working group, so there are working groups of people working on implementing TB control in the countries and working groups on advocacy and communications. The one I am most closely involved with is advocacy and communications. We have a calendar of activities that we want to get people involved in and enthusiastic about, the key one being World TB Day which is at the end of March—24 March. Then we produce common branding, common messaging and we communicate with our Partners and try to get them doing activities in their countries so that they are raising awareness around a common message.

Dr Getahun: The added value of the partnership is particularly as Louise mentioned, the fact that it is structured into seven working groups that have their own objectives and their own mechanisms working in countries and at global level. The main advantage is that the working groups bring different stakeholders and players to a common goal, and they debate and share experiences, and this has been very useful for the TB/HIV cause because both communities are not homogenous, and it has helped bring them together to discuss their issues, to debate and exchange best practices and experience. That has been crucial to accelerating the implementation and saving lives.

Ms Weil: In this packet you have a sheet that is called TBTEAM, it is near the back of the materials in the white packet. TBTEAM is a mechanism of the partnership that WHO provides a secretariat for. What that does in this period of the Paris Principles and development harmonisation is to try to get all the technical partners that are helping at country level to be sure they are not stepping on each other's toes and becoming onerous for the government in burdening them with different policies and different missions. If a request comes in from a country, for example, to work on a TB/HIV proposal that is going to go to PEPFAR or the Global Fund, to find the most experienced technical assistance provider that is already in that country or has experience with that country or the region to assist them, and there is general knowledge that is who is going to assist them and it meets the needs of the country. It is driven by the country's demand for assistance. We know in the development field, particularly in some fields like AIDS where you have this proliferation of people trying to assist countries, that that is a way in which you can get into quite a mess of overlapping missions. This is moving into quite an evolving and solid instrument for keeping people in touch with each other about what is happening.

Q719 Lord Avebury: I just wanted to ask why it is not necessary to have the equivalent mechanism for other diseases. If you say that in Stop TB the advocacy and communications is focused through your working group, why is there not a similar working group for, let us say, malaria?

Ms Baker: There is a similar partnership. There is the Roll Back Malaria Partnership. They would say they attempt to do the same thing.

Ms Weil: You could say that TB, in a way, is a simpler field than AIDS, for example, because of the history of how people got involved. It was a long-standing disease, there were very deep partners who have been involved for a long time, a lot of communication over the years, more consensus around technical strategy and easier strategy probably. People have been reflecting and we have all been sharing information between the AIDS, TB and Malaria communities

about how we work, and the Malaria community has started organising working groups and now has a special envoy from the UN similar to what we have. There is this learning from each other across the trends. Historically, TB has had an even history on development and that may have had to do with this technical strategy, and clear operational technical partners that have been in the field for a long time.

Q720 Lord Desai: From what I gather, you are only a coordinating body and do not do any investment. We have been told that there is a lot of vertical investment in specific diseases to the neglect of the horizontal investment required for local healthcare systems. What is your view on that balance?

Ms Weil: There are a couple of major things that we have been doing. Many members in the Stop TB community since the 1990s, when there was quite a lot of investment in structural adjustment and efficient health systems and there was not much investment in disease control, (there was a disinvestment in disease control) started documenting what was happening with disease control programmes at that time. As you know, there was a great increase in attention to disease programmes because of HIV, Malaria and TB and the effects of those diseases, so we saw the creation of the Global Fund and we have seen this great infusion of new funds for diseases. We are now seeing the reverse, very heavy funding of some disease programmes and, as you said, not sufficient funding on health systems. Our community has got involved in a couple of ways. One is that we have been very deeply involved with our Partners and bilateral agencies in developing guidance on how we contribute to health system strengthening through what we do, through the disease angle, through advising the Global Fund. Many of us were involved in a consultation with the Global Fund on how they should invest partially in health systems in addition to the ways that they invest today. We have been involved in documenting how health systems power investments. Disease control can also contribute to health systems through logistic systems, innovations, basic capacity building and providing resources for general staff. In TB at the service level many people work on multiple diseases, so if you can invest in building that capacity or expanding the number of community health workers, then that will have a follow-on effect for other diseases. We work with Global Workforce Alliance, the Health Metrics Network, the International Health Partnership on health system strengthening that your Government has put the lead on. We are all engaging in trying to define best how we strengthen systems and learn lessons from individuals' fields. One more example is that in TB control we have been one of the fields that has done the most with drawing in non-public

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providers. So how we do the best with private providers in the developing world where in the past many were doing very poor practices, and many are still doing that, but how to bring them in, engage them and ensure they are part of the overall system for fighting diseases. We are just coming out with a policy document on how national TB programmes contribute to health systems. Overall, I think in the community we share the view that there has to be a growing pot, we need to invest more in disease control because we know that we are getting results through disease control, and we also need to develop much more financing and much more efficient financing on funding health systems, particularly primary care.

Q721 Lord Desai: Do you have a view on prevention versus treatment? What is the balance of investment between prevention and treatment?

Ms Weil: TB is both prevention and treatment at the same time because, if you treat infectious cases, you are also preventing transmission, if you are finding them and treating them fast enough. TB is not exclusively a treatment programme, it is also prevention.

Q722 Lord Desai: There are no pre-diagnostic things you can do to prevent the onset of TB?

Ms Weil: There are. In the developed world we have preventive therapy for those who are found to be infected with TB but not having the disease, and we are trying to extend that to those with HIV infection who are at high risk. If we catch people early enough with their infectious disease, which is the first step—because there are so many people with active disease in the developing world who have not been detected, so through new laboratory methods, getting existing lab methods out there, we hope to find people earlier and prevent that transmission. In terms of the research front, we believe that, if we can develop new vaccines against TB, that would be the best scenario possible. We are not there yet but we have many in development. At the bottom line, the key is to be communicating across these terrains, especially in-country, to be sure that disease programmes are communicating with the health planners and there is a common national health plan that incorporates interest in prevention treatment and other infrastructure issues for health systems. But we are not there yet in many countries. Haileyesus knows the situation in Ethiopia.

Dr Getahun: This leads to the question of the neglect of TB research in general. We do not have any good and best diagnostic tools to confidently diagnose TB either in an HIV-infected or non-infected patient. We still rely on microscopy, which is 100 years old. It is very difficult without having that robust tool to focus on preventing TB. That is why our programme is

more a treatment programme. That is another area that really needs critical focus.

Q723 Lord Jay of Ewelme: We have had lots of evidence about the extent to which TB and HIV are interlinked, but we have also had a certain amount of evidence that sometimes at national level, sometimes at local level on the ground, they are treated in rather separate ways and that somebody who comes to a clinic with TB will not get tested for HIV and vice versa. Dr Getahun, you said earlier on that you were involved in a WHO TB/HIV programme and I just wondered what you were doing, or what the TB Partnership were doing, to try to ensure that on the ground the links between the two are properly recognised.

Dr Getahun: This is an interesting question. We are much more optimistic at the moment. Had it been three or four years ago that statement would have been absolutely true. I am not saying that patients are still not seen separately and not tested for HIV when they have to be tested, but the point in general is that changes are coming from where we stand now. This is because WHO took the leadership in 2004 to provide countries with clear policy and strategy clarifying what needs to be done. We have a 12-point policy which is simple and clear and we have promoted that policy with advocacy. Our slogan during that time was, “Two diseases in one patient”. An HIV-infected patient should not come on Mondays for TB and on Thursdays for HIV. This message has got into the countries and we are seeing encouraging things.

Q724 Lord Jay of Ewelme: I can see it could be comparatively straightforward to produce the plan for that. But how far is it really getting through on the ground at national level and also at local level? Let us take Ethiopia, as that is a country you know well.

Dr Getahun: In your folder on the second page there are the latest figures, which have shown a significant multi-fold increase in the last couple of years. For example, those TB patients tested for HIV were around 20,000 in 2002, but in 2006 we were able to test 700,000 TB patients. It is not enough, it is only covering 12 per cent of all TB patients and still not up to the level that it should be. The rate of increase is encouraging and we want to keep that momentum. We are in a different phase now to bring the HIV community particularly in to TB, and that is where our programme really lies, especially those interventions that are intended to save the lives of HIV-infected patients by screening them for TB, because most of them have a higher risk of TB even if they are taking antiretroviral drugs, and providing them with preventive therapy to prevent TB infection when they come for HIV care. These interventions are far below where one would assume and our focus is to push for the HIV side to take up these

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interventions. It is encouraging but we are far, far below the targets and we need to push.

Ms Baker: I might just add something on that. It is still the case that every three minutes somebody living with HIV dies of TB, which is ridiculous. We have a special envoy to Stop TB appointed by the Secretary-General of the UN, who is the former President of Portugal, Jorge Sampaio, and, very much in line with what Haileyesus was saying, the political push to try and make looking at the two diseases a more integrated, more holistic approach is coming from the Secretary-General and the special envoy. On 9 June this year at the UN, prior to the High Level meeting on HIV/AIDS, there will be a half-day session on TB-HIV that the special envoy is calling that will be addressed by the President of the General Assembly, the Secretary-General and the leaders of the H8 agencies, so Dr Chan from WHO, Michel Kazatchkine from the Global Fund, and Peter Piot from UNAIDS. It is a culmination of our work on trying to attract the HIV community.

Q725 Lord Jay of Ewelme: That all sounds great, but that does not in itself mean that on the ground things will change, does it? Do you have a Focal Point on the ground country-by-country trying to push this message through? Would that be your people or the Global Fund?

Ms Weil: Part of the issue for this meeting is the fact that in many countries you have HIV/AIDS Commissions, which operate at a political level which is far higher than any TB programme, which is basically in communicable diseases in the public health authority, so they are operating at indirect levels. For AIDS authorities, TB is one of the many issues they are concerned about but it often gets lost in the mix. This agenda is to raise it on the radar that you can achieve huge achievements with HIV-TB action now.

Ms Baker: Most of the people participating in the meeting will be at very high political level, hopefully more than Ministers of Health, and certainly the AIDS Commissions are responding mostly to Prime Ministers and Presidents, so it is to try and raise the political agenda around that.

Ms Weil: For example, institutions like in the UK and many others have produced AIDS strategies but, unfortunately, for example, the UK strategy has very little coverage on the TB-HIV co-infection issue.

Q726 Lord Jay of Ewelme: That is an interesting point.

Ms Weil: That has been technically there forever, but politically as part of the work plan it is putting it on the agenda as being one of the key elements. That is why today our colleagues, Mario Raviglione and Dr Paul Nunn are not here with us because they have just travelled to Chiang Mai, Thailand, to participate in

the first ever technical day of the Programme Coordinating Board of UNAIDS that is going to address TB-HIV for the first time. That is a step in the right direction thanks to Peter Piot and many other advocates in civil society who pushed for this.

Dr Getahun: What we need is political leadership on the HIV side at country level. We believe that all of these global efforts will really help to realise that at country level.

Q727 Lord Jay of Ewelme: It is the HIV side, as it were, that needs to recognise the importance of TB?

Dr Getahun: Yes, we would say that, but not always. The TB side, particularly in Asia, should also take this up.

Ms Baker: Failing to address TB undermines the investment in HIV and undermines the work of the HIV community.

Q728 Chairman: Does linking TB with HIV when you are talking to the political leaders make it easier for the political leaders to address the HIV issue which otherwise is a difficult one to address at times?

Ms Weil: For example, in South Africa the issues around XDR-TB, this extensively drug resistant form of TB, probably did wake up some of the political leaders on the issues of concern around responding to the risks for HIV-infected people who are seeking care and finally receiving care. I think it became a public issue, not just for the HIV community but for the community as a whole, because everyone was so worried about the risk of a very lethal form of disease and the effects that had been shown and documented in South Africa. In a way, I think it opened up the terrain that this is not just an HIV community issue but a public issue. Whether it helps the HIV community overall to address TB, I am not sure.

Q729 Chairman: Help recognition. South Africa is a good example that is in denial on the problem of HIV in a sense, so it seems to me it is easier to talk about TB-HIV than just HIV, is that right?

Dr Getahun: Particularly in sub-Saharan Africa, where up to 50 per cent of HIV positives die of TB, that needs to be considered. There is not much leadership in HIV. With the expansion and the scale-up of antiretroviral treatment, which gives protection from developing TB disease, that was their intention, "If we scale-up antiretrovirals, we should not have to worry about TB treatment". The fact is that, despite patients taking antiretrovirals, the risk of TB is increasing, it is not going down. In a way, that sends a message to the HIV community that on top of the XDR issues they have to consider TB. We are not there yet.

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Q730 Lord Jay of Ewelme: Could I ask one completely different question. These are fascinating documents, which I look forward to reading, but there is one which one says: “The TB target for 2015 UN Millennium Development Goal is to have halted and begun to reverse incidence. Current assessment on target in all regions except Europe”, which is quite surprising.

Ms Weil: As a region as a whole we have to say in Europe, but in reality it is Eastern Europe which is behind. In Western Europe you are right on course and well beyond, moving rapidly.

Q731 Chairman: That is a relief, I can tell you!

Ms Weil: In Eastern Europe the biggest challenge has been that there has been a dramatic increase in TB since the fall of the Soviet Union, so to reverse incidence again we have now stabilised, but in terms of decline we are not documenting that decline yet. There is a very severe problem in Eastern Europe because it is not something that you can turn around quickly, particularly when it has penetrated some of the most difficult parts of the population—the prison population, the poor, alcoholics, drug abusers—and where you have seen this very rapid emergence of drug-resistant disease. It is not an easy turnaround. We had this Berlin Declaration that the UK Government was involved in and we had a meeting of 46 governments with high-level delegations, and they produced a very strong Declaration. I cannot say necessarily that we are totally convinced that the response since that Declaration has been up to that enthusiasm, but there was a strong recognition that something needed to be done, particularly with domestic financing, as many of the Eastern European governments have more of their own financing available as well as ongoing concern from the development community for the poorer countries.

Ms Baker: One of the things we have been doing is working with the European institutions on developing a plan and in the 27 Member States of the European Union region there are five Member States of the EU which are classified in the WHO list for the whole of the European region as being high priority countries. The countries of the Baltics, Romania and Bulgaria continue to have a major problem with multi-drug resistant TB. There is an action plan at EU level, but TB does not respect those borders and those borders are not that tight.

Lord Jay of Ewelme: There is free movement, of course, which has implications for the rest of us. Thank you very much. I am sorry to have interjected.

Chairman: No, that was useful.

Q732 Baroness Whitaker: I would like to explore the relationship with WHO, which I think you call your host?

Ms Baker: Yes.

Q733 Baroness Whitaker: It is really a question of what influence or control they might have and how it works.

Ms Weil: She has to speak honestly in front of us because we are WHO!

Q734 Baroness Whitaker: In so doing, could you explain why you are not, in fact, a straightforward bit of WHO, an agency, a grouping?

Ms Baker: It actually works remarkably well in TB. I know that is not necessarily the case for all of the partnerships, but in TB it works reasonably well. Administratively, we are housed by WHO, so that is the technical way of describing it. We follow all of WHO’s rules on HR recruitment, procurement.

Q735 Baroness Whitaker: Do they do your accountancy and legal advice, personnel and all that?

Ms Baker: Yes.

Q736 Baroness Whitaker: So it is common services, as it were?

Ms Baker: Yes. We follow those rules and are very much in line with all of those.

Q737 Baroness Whitaker: That is for the “housekeeping”.

Ms Baker: Yes. I am WHO staff, so my loyalty is to the organisation, but I have a political loyalty as well and that is to the Coordinating Board. There is administrative responsibility, loyalty and efficiency to WHO and political instruction, if you like, comes from the Coordinating Board of the Partnership.

Q738 Baroness Whitaker: If the WHO Board thinks you should be emphasising something slightly different, what do they do with their opinion?

Ms Baker: WHO is a permanent member of the Coordinating Board.

Q739 Baroness Whitaker: So they are one among several?

Ms Baker: One amongst 34, but they are very clearly recognised as an important Partner, certainly more than one among equals, let me put it like that. They are an important player on the Board. It has not ever actually happened that WHO has vetoed anything on the Coordinating Board, but WHO voices its opinion very strongly and Partners take that seriously. Again, coming back to the plan—I sound repetitive—we went through a long process of agreeing the direction that we would all go in and that has certainly helped. In terms of the housing arrangements it works relatively well. WHO is very much part of the political decision-making as well.

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Q740 Baroness Whitaker: Are you and all of your staff employees? Will you return to some other job in WHO eventually?

Ms Baker: I hope so.

Q741 Baroness Whitaker: Could you?

Ms Baker: Yes, absolutely.

Q742 Baroness Whitaker: What about the International Health Partnerships, how do you fit in with all of that?

Ms Baker: International Health Partnerships, the other partnerships?

Q743 Baroness Whitaker: Yes. You call yourselves one of them?

Ms Baker: Yes, we consider ourselves to be an International Health Partnership.

Q744 Baroness Whitaker: How do you liaise with the others, because there are things which affect TB like migration, transport?

Ms Baker: Absolutely. We have a Partnerships Officer who is responsible for outreach to those kinds of International Health Partnerships and developing those relationships.

Q745 Baroness Whitaker: Sit on their committees?

Ms Baker: Yes. In fact, we are developing a Memorandum of Understanding with the Global Health Workforce Alliance and with the Health Metrics Network as two other International Health Partnerships. We have a Memorandum of Understanding with the Global Fund. We work very closely with the Roll-Back Malaria Partnership and would represent each other even, if required, on various boards. If one partnership was not able to be there, then we would speak for each other, for example at the Global Fund.

Q746 Baroness Whitaker: For instance, might it be that a programme that you are anxious to have promulgated would set up an infrastructure which would also deal with Malaria, I do not know, training local workers? Does that happen?

Ms Weil: For example, all the discussion around Malaria right now, the provision of Artemisinin-based therapy, is a big challenge because it needs to be much more widespread delivery through public and private channels than TB drugs. The TB Global Drug Facility was established back in 2001, and a lot of similar questions arose with the development of that Drug Facility. So there is a lot of learning from that experience, not that they are going to adapt it completely but using that. For example, UNITAID, the mechanism for providing financing for supplies, is supporting various of these partnerships working with the Global Fund, working with the Global Drug

Facility, working with the Malaria community and AIDS community. There is a lot of cross-referencing. Many of us are housed in the same offices, so we see each other. Bilateral initiatives, like the US PEPFAR initiative, initially started in a very unilateral separate way, but Dr Getahun and colleagues have worked extensively, even though that is far from partnership, and it is beginning to broaden out in terms of its interactions and working very much on national plans with the working group on TB-HIV in the partnership which Dr Getahun coordinates.

Q747 Baroness Whitaker: Would you say that this very developed networking actually contributes to infrastructure development at quite low levels in countries? Can you see what we would call a sort of audit trail?

Ms Baker: The one I would highlight at some point going forward is the Global Drug Facility is one aspect of suppliers to countries and the development of drug management capacity in countries, but our technical assistance is provided by technical partners, WHO being the lead but then other technical partners coordinated, which obviously helps as well. The new initiative that is being developed at the moment by the Partnership is the Global Laboratory Initiative, which may be coming back to the idea of health system strengthening. In TB we certainly recognise that we deliver TB programmes better when there is a good health system, when you can diagnose people properly and treat them at the most basic local level working so we are now collaborating on developing a good network of laboratories and basic laboratory kits so that people can do diagnosis at the lowest possible level.

Chairman: There is a wider issue of health architecture here on which I would like to bring Lord Desai in.

Q748 Lord Desai: One of the things we have been told in our evidence by the British Government is that the architecture of international health intervention is “crowded and poorly coordinated”. We have been exploring this. We would like to have your views on this. Do you think there is scope for rationalisation, for a merging of people?

Ms Weil: Compared to maybe three years ago there has been a lot more coalescing around this quandary of how we deal with this proliferation of partnerships and the issues around harmonisation, the concerns of governments and dealing with this flood of new money but also the imbalances in their use. I attended a meeting that the GAVI Alliance organised on their health system strengthening investments, and they invited all the major donors, all the major partnerships, those of us from WHO involved in health system strengthening issues and disease control. One of the things that came out of the

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meeting was that somebody said that the international health architecture, they meant to say is changing every year but they said every day—and, in fact, everybody laughed because it *is* changing every day. How do you deal with that? The question is that there are more networks now of people communicating at the global and regional levels than there were before across diseases which is relevant. At the national level there is much more focus on common responses, like on the human resources front—we have not solved civil service reform but at least people are investing again in community health workers, so if they are going to invest in community health workers they are certainly not going to be TB-specific. Some of them may be HIV-specific right now, but that is not the ultimate aim. How do you ensure that you can give the capacity to a community health worker that is not going to overwhelm them but they could actually do work on Malaria, TB and HIV, immunisations and maternal health all at once. That is a tall order. We have a long way to go because, while people say they want to combine efforts, some independent donors and governments still are funding in a very directed route because of their rules and regulations, and that is necessary to feed the results back to their governments and parliaments. We want to produce consolidated reports, only one report per disease, but in fact we have multiple responsibilities to multiple donors. So how do we ensure, for example, that reporting requirements and financial requirements might be streamlined a bit more because that is really what takes up a lot of people's time.

Dr Getahun: Having many stakeholders is good for resource mobilisation and giving attention to those diseases, but an important line should be to work under the national government, under the national plan. For example, UNAIDS for HIV is promoting this Three Ones policy: one monitoring and evaluation system, one coordinating body and one national plan. The comparative advantage of WHO to make sure all the stakeholders and partners are coordinated is really high, because our comparative advantage is to work with ministries of health and governments to make sure that their plans are coordinated and responsive to their needs. Our comparative advantage is also high from that aspect.

Ms Weil: One more technical point to raise is that, as Dr Getahun says, in the global plan, for example, we did costings on what we believe it is going to cost to reach the MDGs, and WHO monitors through data received from national governments every year how much they are receiving. The next step is to say the Global Fund has relied on project proposals over the last few years and now they are moving to the notion—they are having their Board meeting in a couple of weeks, they are still discussing this—to fund disease control strategies and national health

plans. So you do not have to do a project every time, but you give your partial support to a national plan. The Partnership's help is to ensure that we can come up with costed medium-term plans for TB that can get slotted into a national health plan following the same criteria that other people are using for costing. We are doing that right now with about 35 African countries to help them be sure we have fully-costed five to eight year plans that can go into a national health plan along with immunisation and child health, et cetera.

Q749 Lord Desai: Is the problem that the way governments give money makes things complicated because the donor governments themselves have confused architecture, ie they give money separately for separate diseases, they want separate accounting, they do not believe in pulling everything together? If the governments were more sensible and just gave a large dollop of money, would that make life easier?

Ms Baker: It comes back to your health system strengthening. I may be being politically incorrect here but, if I make a parallel to a country I know best, we would look at a national health service and say absolutely we want a functioning national health service, but there are political pressures on governments of whatever shade in any country to provide specialist cancer treatment that is perhaps above and beyond what the basic national health service provision is. Yes, there is a crowded and uncoordinated even, perhaps, global health architecture but that is about saying the national health service, the basic health services in countries, need funding. So they do need that pool of funding into a national health service but, in order to deliver the results that donor governments and national governments—whether they are in endemic countries or in donor-rich countries—want to see, you also need a coordinated effort and attack on the real health issues in the country, the real killer diseases in the country.

Ms Weil: Our biggest concern right now is that the other extreme would be to fund just a national health plan, but most governments do not have very specific national health plans. If you funded in many countries now a basic four-page or 30-page national health plan, what you could be funding is just the old practice of over-funding of hospitals, not enough financing of primary care, not clear deliverables. So it is somewhere in-between producing results and also helping strengthening national health plans, so that they get more specific and it is clear what their strategy is for creating a better health service as opposed to just funding the status quo.

Ms Baker: I think the Partnership contributes to that. The idea, and I think we are succeeding relatively well, is that in each country we are able to speak with

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a common voice and contribute to that discussion and debate.

Dr Getahun: In my personal view I do not think there will be a one-size-fits-all approach, especially for the donor governments, because it depends on the local context and the local governments. One thing that has to be emphasised is that these are specific programmes that are important for those underprivileged communities, particularly in Africa if you take HIV, TB and Malaria. Caution has to be exercised to make sure that things are not dismantled or whatever. That is why I say there is no one-size-fits-all answer.

Q750 Lord Avebury: We have talked a little bit already about MDR and XDR drug resistance. I must say the figures you give in your pack are pretty alarming—for example, that there is half a billion shortage of funding and only six countries in Africa have got any ability to provide data on MDR-TB. That is one of the reasons why the map which indicates where XDR-TB has been confirmed concentrates heavily on the developed countries. It is not because that is where XDR-TB is occurring, it is simply because it is detected there. I wonder if you can tell us what your Partnership is doing to address these enormous gaps between the actuality of MDR and XDR-TB on the ground and what the donor governments and funding agencies are doing about it.

Ms Baker: There is a working group on drug resistance that brings together all of the Partners who are working in the field of fighting drug resistance. There is a plan in the Global Plan to scale up from treating a relatively small number of patients with drug-resistant TB to a much larger number to hopefully try and control the growth in the epidemic. The emergence of XDR-TB at the end of 2006 has reshaped the way that we are looking at drug-resistance, in that multi-drug resistant TB is horrible, it is nasty, you are using the drugs we do not use in the first-line fight against TB because they have horrible side-effects, they are very old, and they take at least two years of not very pleasant treatment to cure a multi-drug resistant TB patient. XDR-TB is even more resistant to those second-line drugs and for very many patients, particularly if they are HIV-infected, there are few very places you can go, so the mortality rates are incredibly high and the experience in South Africa was quite terrifying in a clustering of cases. We are very much pushing the Three Is, particularly in terms of dealing with people who are also co-infected with HIV, so infection control. We are very much encouraging a scale-up of dealing with drug resistance, the capacity to do diagnostics, particularly in Africa. We are looking at trying to do more research to find the tools that enable us to do

the diagnosis better and to be able to treat people better.

Ms Weil: In follow-up to that there are two things to note. One is that, while we do not have enough laboratory capacity in Africa—and that is what this Global Laboratory Initiative is meant to address—we do have quite rapid response from some sources. It is insufficient but it is a beginning. At its last Board meeting UNITAID awarded a joint approved proposal between the Stop TB Partnership's Global Drug Facility, the Global Laboratory Initiative, whose secretariat is based in WHO, and FIND, which is an innovative not-for-profit public-private partnership just across the street largely funded by Gates which is opening up access to new diagnostics and working on market mechanisms to reduce the price of those new diagnostics. They have just awarded \$26 million to begin to try to expand laboratory capacity in some countries. We did receive financing through discussions with Gareth Thomas when we first learned of the XDR documentation in southern Africa and how to quickly respond, which did make possible some of our initial surveillance work and some of the technical assistance to do assessments in some of those countries. We have had some response, but certainly insufficient to create the capacity for an onslaught of the degree that we need. Investment in public goods, particularly from the UK Government and other bilaterals, in addition to the financing for the Global Fund, which is really country-specific, we have global needs around surveillance, innovation, piloting of new approaches and coordinated technical assistance that are under-financed. One further thing to say is we do not expect that the levels of MDR and XDR in most of Africa are going to be equal to those, for example, in Eastern Europe, so it is not just a matter of documentation. The rates are higher also where you have had more access longer to second-line drugs than first-line drugs. One of the good things—it is not a good thing from an access perspective—is that we have had less access to Rifampicin, which is one of our prime drugs, in Africa than we have in other parts of the world; there is a shorter history, so the drug resistance levels to begin with in most countries is lower. Our biggest worry is that, if we do not stop private sector supply of Rifampicin and many of these other second and third-line drugs that are uncontrolled and poor quality, and if we do not institute good normal practices for initial TB control, then we are going to be in deep trouble five or ten years down the road. Our biggest worries are countries like southern Africa, Cote d'Ivoire and Nigeria, where you have very vibrant private sectors, some disposable cash, more private access. We have seen this in Asia as well, like in China when there was not much control and everything was privatised. You can see where the emergence of drug resistance might

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be happening. Our best action is to prevent the misuse of these drugs to begin with.

Q751 Lord Avebury: This Global Response Plan which is in the pack is June 2007, so presumably it is well out of date?

Ms Weil: Yes.

Q752 Lord Avebury: And the developments that you have just been speaking of have occurred since this was published?

Ms Weil: As Louise said, that was an initial response for the first two years, and clearly we produced it part-way through 2007. In essence, we were just trying to show what it would take in the first couple of years. We have now done the calculations for how it revises the Global Plan we have sent around and we are looking to a medium-term strategy and how to address that. We are clearly behind, it is not a lost cause, and trying to figure out how we mainstream. One of the things Louise said was that we cannot have a parallel effort on MDR and XDR that is wholly out of whack with all the other things we are doing, so how do we mainstream this. We have just had a meeting of our XDR taskforce, and the biggest recommendation coming out of that is how do we mainstream into overall planning for national control efforts, finding centres of excellence so you

can train people and people recognise how they balance their investments in basic TB and TB-HIV and MDR, how they do all of that. It is not easy but we are trying to figure out a way so that it becomes a normalised approach.

Ms Baker: I think we also need to look particularly at the Eastern European region for this issue as well. For example, the UK development budget would deal with less developed countries, so there is not very much money in the UK's development budget for Eastern Europe and the former Soviet Union. That is not true from a European perspective, there is quite a lot of money for Eastern Europe and the former Soviet Union, but something like this, a health issue, struggles to get on the agenda. When you are talking about countries in Eastern Europe and the former Soviet Union, you are talking about trade, issues of markets talking to emerging markets and developing infrastructure, and there has to be a recognition that it is in the common interests of European Member States to try and tackle something like drug resistance in Eastern Europe and the former Soviet Union.

Chairman: I fear we are going to have to conclude it there, but that was very helpful. Thank you very much indeed, we are very grateful. If you do have any more thoughts or ideas, or there are things you want to elaborate on, then please write to the Clerk and send them through. Thank you very much for your comments—and good luck with your work!

TUESDAY 22 APRIL 2008

Present:	Avebury, L. Desai, L. Jay of Ewelme, L.	Soley, L. (Chairman) Whitaker, B.
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Examination of Witnesses

Witnesses: DR HARVEY BALE JR, Director General, MR GUY WILLIS, Director for Communications, DR STEFANIE MEREDITH, Director of Public Health Partnerships, DR RYOKO KRAUSE, Director of Biologicals and Vaccines, and DR ERIC NOEHRENBURG, Director of Public Health Advocacy, International Federation of Pharmaceutical Manufacturers & Associations, examined.

Q753 Chairman: First of all, thank you very much for your time. As you know, we are a Select Committee on Intergovernmental Organisations and our particular interest is the contagious disease question at the moment. Let me say, first of all, that the comments here will be noted by our shorthand writer. That will be produced in our report and sent to you in transcript form for you to correct any factual inaccuracies. I would also very much welcome it if, during the course of the questions, all or any of you feel you want to say something, please do so. If we do not cover some of the things that you think we ought to cover, then please say so and, indeed, when we finish this session feel free to write to the Clerk at the House of Lords and make any further points that you wish. Perhaps I could start by simply asking if you could introduce yourselves as to your jobs, so we know who does what. That would be helpful. Then I would like to ask a little about the organisation itself.

Dr Bale: Thank you. Perhaps I should start. I have been here for 11 years as Director General of the IFPMA. I will save the comments about what IFPMA is and more specificity until a little bit later. I am Harvey Bale. I am originally from Philadelphia but have lived in Switzerland for 15 years. I have done two stints in Switzerland. Eric, why do you not start at your end?

Dr Noehrenberg: I am Eric Noehrenberg. I am Director of Public Health Advocacy and Director of International Trade and Market Policy at IFPMA. I have been here almost nine years, very much involved in the whole question of patents and access to medicines. My primary responsibilities are discussions with the World Trade Organisation, World Intellectual Property Organisation and also the World Health Organisation in respect to patents and access to medicines primarily.

Dr Krause: My name is Ryoko Krause. I am Director of the Biologicals and Vaccines. I have been at IFPMA for eight years now and deal with all the technical, scientific and regulatory issues related to the biologicals and vaccines. Most of the work that I do is with WHO, and right now with all the vaccine initiatives with GAVI and UNICEF.

Dr Bale: I would emphasise her coordination of our Influenza Vaccine Supply Taskforce, given that you have avian influenza on your agenda.

Dr Meredith: I am Stefanie Meredith. I think I am the newest person at IFPMA, I have been here for a year and a half. I am the Director of Public Health Partnerships. I have come to IFPMA to work with the industry in developing partnerships, collaborative partnerships, with the aim of improving healthcare outcomes, access to healthcare. I came to this from a background working in major public-private partnerships, the Mectizan Donation Program, that you may know of, the Lymphatic Filariasis Donation Program, and a background in tropical medicine.

Mr Willis: Good morning. I am Guy Willis, Director for Communications at IFPMA. I have been with the organisation for nearly three years. One of my responsibilities is documenting the partnerships that the industry is involved in for the developing world.

Q754 Chairman: Thank you. My next question is just to get a clearer view of who the IFPMA represents. Is it all the companies? Can you just say a little bit about that, if you would not mind?

Dr Bale: In fact, up until 2005 we represented only associations. We had 55 member associations around the world from China, Russia, India to the US, Europe, Japan. We have membership now, which began in 2005, of 25 research-based pharmaceutical companies. Historically, this industry has been concentrated in Europe, North America and Japan. We also received our first Indian company, Nicholas Piramal, in 2007. It shows you that pharmaceutical industries are growing internationally with regard to the research capacity. We are a hybrid of company members and associations. From the UK we have both AstraZeneca and GSK. We have a number of the US companies, four Japanese, and we will add another Japanese company in the next few months, and we are hoping to get more companies in the future from developing countries.

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Q755 Chairman: Are there any of the large players, the large drug companies, outside your organisation?

Dr Bale: Only one or two. One for example, like Johnson & Johnson, which is a very diversified company into hospital products, diagnostics and a number of different areas, is a member through the (national) associations. In fact, more than one because they are in a large number of national associations. Nova Nordisk, a Danish company, is also not a (direct) member of IFPMA (but is indirectly, through a number of national associations). If you think of all the rest of them, Sanofi-Aventis, GSK, Pfizer, Merck, Lilly, etc, Takeda from Japan, the largest Japanese company, they are all members.

Q756 Chairman: Do you see the IFPMA as being the organisation that gives a voice to the whole industry and serves as the organisation that negotiates with the various health bodies around the world? Is that how you see yourself?

Dr Bale: Yes, although we will mainly negotiate, advise, inform or consult with or be asked by the international agencies. Our main interfaces are with the World Health Organisation, number one. We also interface a lot with the World Intellectual Property Organisation, the World Trade Organisation, UNAIDS and GAVI. We were very much at the founding of GAVI and Medicines for Malaria Venture. All of the international disease-related or health-related organisations, in some way or another, we have interaction with. At the national level, for the health agencies, for example the Department of Health in the UK, our member in the UK, the ABPI—the Association of British Pharmaceutical Industry—would be the interlocutor there. For example, we assist on global issues. I was in London last week talking to the DFID people about a project that they are launching next month called MeTA—Medicines Transparency Alliance—and Alexander will be there and his team and, together with a number of NGOs and governments, we will be launching the whole question of how do we bring greater transparency into the pharmaceutical supply chain. That is why we are here, in fact. When I first came 11 years ago I was advised by *Script* magazine that I should take IFPMA away from Geneva and put it somewhere else. But, when you ask the question where else would we be, the only other location would be, perhaps, Washington or New York, but that would still be far too parochial in the sense that most of the international agencies are based here. UNESCO is in Paris, the World Bank is in Washington, but the bulk of them are here.

Q757 Chairman: Thank you for that. Let us start with this general area, if we may, because obviously we are aware of the needs of drug companies to make profits and the need to invest in future research. We are also aware of the desperate need to deal with some very difficult diseases and the need for vaccines and drugs in that. We are aware of some of the things you are trying to do, but it would help us if you talked us through how you see it from your perspective. We have heard a lot from other organisations about the need for drugs dealing with these diseases around the world, the need for vaccines and so on, but we have not heard it from the industry point of view.

Dr Bale: Thank you for the opportunity to provide evidence to the Committee. Simplistically, we think of it in terms of three As. The first is availability, that is to say how do we get drugs in existence. One of the great failings in the last couple of years was a project to develop an HIV/AIDS vaccine. It will not be a complete failure at the end of the day, I hope, but how do we get products in existence. Availability is the first one. Secondly, it is accessibility. Once we have these drugs available, how do we get them from Point A to Point B. This is not a simple matter because of the problems of logistics and lack of infrastructure in many developing countries. The third issue is affordability. If they are available and accessible but not affordable, then, again, the system has failed. How we approach it is in all three areas. I will just make a few introductory comments and ask my colleagues to expand. The question of availability really means investment in R&D. Today the global pharmaceutical industry is investing nearly US\$60 billion worldwide in new medicines and vaccines. I would say 85-90 per cent of that R&D is carried out by companies in developed countries, the OECD, Switzerland, UK, France, the US and Canada, and the rest in developing countries. This means we have to have good regulatory systems, good intellectual property systems, good systems of communicating the innovations to doctors who prescribe the medicines, since we do not deal directly with patients, and a good economic financing system. In the UK you have the NHS and other countries have similar or different systems. The basic system is one of finance, intellectual property, regulation and communication. Again, the question then moves to accessibility, and here we are working with organisations. Stefanie has a project that we are beginning to work on in the Gambia about supply-chain security, how we build the supply chain and, on the other hand, how countries develop the necessary clinical facilities, the hospitals, keep nurses from moving away from developing countries and coming here to Europe or the USA. The brain drain from developing countries is an enormous and aggravating problem these days. That is the accessibility issue.

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Affordability: a large number of our companies, especially in the critical areas, such as Malaria, Tuberculosis and HIV/AIDS, have differential pricing programmes, which is to say that, depending on the company, they will take a no-profit approach or a below cost approach to pricing in the poorest countries. They will try to make up those losses in the developed countries, and in the middle-income countries they will have some differential pricing that varies according to the company. Tiered pricing, which is what we call it simplistically, is a very common practice, especially with the critical diseases, the ones that are global issues. This has been a traditional practice in the vaccine industry, even going back for a longer period of time than in the drugs field. Another way is through donations. Stefanie mentioned the Mectizan Donation Program for onchocerciasis and we have a donation programme underway for lymphatic filariasis. Companies are giving away medicines for leprosy, measles vaccines, et cetera. We have a company in Germany giving away mother-to-child transmission of HIV/AIDS drugs, a drug called nevirapine which is given away by Boehringer Ingelheim to some 45 developing countries. The way we try to facilitate this is first information. As Guy has indicated, we put together a volume, and I think there is a copy on the desk here, of the kind of partnerships that we try to foster. Then we are trying to communicate this as much as we can to the WHO, as Eric has mentioned before in his work with them, to make sure that people are aware of this. The kind of work that Ryoko does in vaccines is working with GAVI, because with differential pricing you still need funding, because generic products as well as brand-named products are simply not affordable to millions and millions of people around the world. It does not matter whether the product is an originated product or copied product; if you are going to spend \$200 to \$300 per year for AIDS treatment, very few people in Africa or India or the South Asian continent or many people in Latin America will be able to afford that level of expenditure on healthcare.

Q758 Chairman: Or second-line treatment for TB, which is presumably typical?

Dr Bale: Yes. Here is an area where the generic industry is not very present because many of the second-line drugs are very difficult to make. We have a partnership programme that is described in this booklet from Eli Lilly that is engaged in technology transfer to companies in South Africa, China, Russia, I think the other one is in Brazil, (in fact India, which has a much bigger TB problem than Brazil—364,000 TB deaths in 2002 compared to 13,000 in Brazil), around the world to try to build capacity to develop these very difficult-to-make

drugs. There are two tuberculosis drugs for the multi-drug resistance issue which, of course, is the reason we have to go to second-line TB. It is a combination. With that, maybe I could ask Eric, Ryoko, Stefanie and Guy if they want to expand on that, if that would be permitted.

Q759 Baroness Whitaker: Could I just ask for clarification on tier pricing. Is it possible to avoid somebody buying them in a country where they are cheap and smuggling them into a country where they cost a lot more? Do you take measures against that?

Dr Bale: This happened a few years ago with GSK. It happened because GSK was under a lot of pressure from countries to get the medicines into Africa. Medicines were shipped, but what was not done at the beginning, which has since been corrected, was there was no differentiation in the boxes and packaging and tablets. Today, what is done typically is that you send the medicines in—for example, Coartem, an anti-malarial drug, which is sold in developed countries and sold very cheaply, relatively cheaply although it is still an expensive product, is sold at cost in developing countries in a different tablet size, so you can tell the difference.

Q760 Baroness Whitaker: So the authorities can pick it up?

Dr Bale: Exactly, differentiation in boxing, packaging and in the tablet itself. It has to be approved by the regulatory authorities, of course, and it has to show the same efficacy, it is the same product, we are not selling a product to the Third World that we would not ourselves want to consume in the First World. You still have to try to differentiate that product along those lines, otherwise you get what we call parallel trade and re-exportation of the product and the product is lost to the supply chain.

Dr Meredith: I could, maybe, add something not on the tier pricing but on the donated products. As Harvey mentioned, there are four major drug donation programmes and all of these donation programmes are long-term, the companies have committed to donating the drugs for as long as needed, which is very different from the small-scale donations to clinics and emergency relief. When I worked in the Mectizan Donation Program, we did have problems because the drug is extremely effective, it is very safe, free, but it was not available on the market; and occasionally we had massive diversions which had to be managed and managed carefully. That is the same for our other drug donation programmes. What you have to put into place are very careful distribution channels. Once it has been nipped in the bud, there has to be good

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communication about the fact that drugs are free and how to get them.

Q761 Lord Jay of Ewelme: Could I ask a question about donations, to perhaps take one example. What proportion, as it were, of the total drugs needed are donated? In the overall treatment of the disease, how important is the donation programme?

Dr Meredith: Mectizan or ivermectin for onchocerciasis, right now more than 50 million receive treatment a year. When we started the programme we estimated that there were some 18 million people infected with the disease, but as techniques improved we discovered through better assessment methods and non-invasive assessment methods that, in fact, the number of people infected was far greater. The coverage is probably about 80 per cent of the total who need it and the remaining 20 per cent are not eligible—they are pregnant, under-age or ill. For Mectizan for onchocerciasis, the majority are actually covered now.

Q762 Lord Jay of Ewelme: By the donations?

Dr Meredith: By the donations. The drug is not available to be purchased. It is under another label, other packaging, as stromectol for other indications and for the First World market. With lymphatic filariasis, the problem here is having funds. When you have a free drug, it is not the drug that costs the money. Boehringer Ingelheim, which donates Viramune, estimated the drug was maybe about two per cent of the cost of people accessing healthcare. For lymphatic filariasis, which is global, it is bigger than onchocerciasis, only a few countries have really good programmes, because the funds that are needed to distribute the drug are not widely available, so it is not a lack of the drug, it is a lack of funding that impedes progress.

Q763 Lord Jay of Ewelme: It is the distribution network?

Dr Meredith: Distribution and healthcare infrastructure.

Q764 Chairman: That is really to ensure that the drug reaches the person in a state in which it can be used effectively, is that right?

Dr Meredith: Safe and effective, yes.

Mr Willis: As Stefanie has indicated, there are certain diseases for which donation programmes seem to be the most appropriate solution. The medicines that are available are cheap, they are effective, they are relatively easy to distribute. For those diseases that Stefanie has mentioned, you only need to give one or two tablets once a year, say, and then you have to go back and do it year after year. For the more complicated diseases, like HIV/AIDS and Malaria,

the pattern that we see is you have new generations of treatments, they are much more sophisticated, much more expensive, and in those cases the distribution model seems to be through the tiered pricing that Harvey was referring to. In the case of TB, the first-line treatments are old, well-established medicines, the problem is that you need to take them for a very long time and the problem is keeping patients on them. You go into treatment, you start treatment and within a month or two you start to feel much better and it is very difficult to keep people coming back to keep taking the treatment, having to do it every day in environments where it may be difficult for them to get to medical facilities. The WHO has recommended treatment which is Directly Observed Therapy, where you have to be in the presence of a health worker when you take the medicine, which is difficult to implement in countries where there is poor transport infrastructure and few health workers.

Q765 Chairman: The effects of the treatment are sometimes unpleasant, is that right or not? Somebody said to us they were unpleasant. That is the MDR one.

Dr Bale: With sleeping sickness, for example, the eflorithine and some of the other treatments are difficult to administer and some of the alternatives in the sleeping sickness regime are even worse. One of the issues we have is to try to find better formulations, easier to take, also fewer tablets. I am thinking of Coartem, where there is now a formulation where children will take a cherry-flavoured tablet which is a lot more palatable than the existing Coartem tablets, which are rather distasteful to children. That formulation is still in clinical development.

Dr Meredith: It will be out later this year.

Dr Bale: So it has just finished.

Q766 Lord Desai: As a professional economist, we always have a big debate about patents. All economists believe that they are a restrictive practice and, therefore, harmful. This is because all economists believe in a free market and, therefore, patents must be wrong. Clearly, that must be one of the big criticisms that you must be facing because they do hold up the dissemination of medicine.

Dr Bale: As a fellow economist let me answer that. Joseph Schumpeter was one who differed with that view. I know the view though, I am a student of the Austrian school and a number of the others. The question is the trade-off between long-term competition in the case of innovation versus the short-term grant of what was, I guess, 1625, the English Monopolies Act that reformed the old royal monopolies into the innovative model that was instituted for the so-called period of temporary monopoly or temporary exclusivity. It is not just

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restricted to medicines, it is also true in the case of biotechnology, environmental biotechnology, et cetera, that if you do not have an IP patent system with a so-called temporary period of exclusivity you will not deliver the new medicines, new antibiotics and new biologicals. This is why, during this period of time when the companies have the responsibility, they are more than willing, as our document states, to work with countries to make sure that the patent does not become a barrier to access to medicines. This is one of the big challenges that we have. We do think that over time the costs of clinical development will change as a result of the growing presence in developing countries of clinical trials, which are very expensive. If we look at the total cost of developing a drug, which can range from a couple of hundred million pounds to £500 or £600 million, the greatest part of that cost is the eight to ten years of clinical trial testing that the drug has to go through. It is a combination of the direct cost of having these trials in place, typically in developed countries, very expensive, and also the tied cost of the money that is invested, simply what you do not gain in interest or return on that investment that you put in as cash outlays on clinical trials. Many developing countries, China, India and others, are now working to improve their clinical trial structures, which would significantly reduce many of these costs. That is coupled with the growing competition globally in R&D. R&D itself is a competitive model. It is interesting and changing the way that the patent system affects the development of medicines. It used to be thought, and some still argue, that a patent guarantees you a profit. It is interesting that less than a third of the products that actually come out recoup their own R&D costs. The market is becoming extremely competitive, so that you have a large volume of relatively innovative medicines that have been developed over the last decade that will lose their patent status this coming decade. The estimate (the current annual sales of major, best-selling medicines who patents will run out in the next few years) is in the order of US\$70-80 billion (where the R&D companies that developed these medicines will be exposed to generic competition, which will significantly reduce prices and companies' ability to recoup their total R&D costs—for the medicines concerned and the lesser ones that struggle to make money) that companies doing R&D will have to compete with in the generic sector while at the same time trying to recover their costs. You are right on the patent model and I have watched both of these arguments. Personally, and philosophically, I tend to side with the Schumpeter argument, which is that the patent system helps set up the creative destruction of what has gone before through ideas and the genius of people that is applied to commercial enterprise. That

patent system has successfully done that, and I think we owe a lot to the UK historically for instituting those reforms over the years.

Q767 Lord Desai: You were saying in the introduction that only one Indian firm has joined.

Dr Bale: So far, because India—

Q768 Lord Desai: Why are they all out? What do they not think they are going to gain from joining you?

Dr Bale: If I could do a quick overview on the Indian pharmaceutical industry as we see it. There are three associations in India right now. One is the OPPI, which is our member, and it includes Indian and international companies doing R&D. By numbers of companies it is still a relatively small minority. The other two organisations are IPA, the Indian Pharmaceutical Alliance, which is an alliance of the more important Indian pharmaceutical companies, like Dr Reddy's laboratory, Ranbaxy, et cetera; and the IDMA, and there are some 7,000 Indian pharmaceutical companies roughly speaking. There used to be estimates of up to 20,000, but a good survey would indicate about 7,000. These are very small operations and have no capacity to do R&D. The emergence in 2005 of India adopting patent legislation—and, although many people criticised it, the fact of the matter is that India has embarked on a process of applying patents in the pharmaceutical sector—is now generating to varying degrees a large increase in the R&D of Indian companies. There is no doubt it is the right way to go because in the generic sector India faces enormous competition that is now emerging from China. If Indian companies do not move, as we would say, up the value chain of the R&D away from the purely generic commodity business, they will be in big trouble. The biggest leap was done by a relatively small company, but a very dynamic and growing company, Nicholas Piramal, that took the step of applying to IFPMA for membership. The others are not quite ready for that, but a number of them are members of our local organisations in a number of different countries, although they are not ready for it on a global scale.

Q769 Lord Desai: Because of some kind of entry barrier to joining you?

Dr Bale: No. A company that joins IFPMA has only two or three commitments. First of all, they should adhere to the IFPMA ethical marketing code on the advertisement or promotion of medicines. This carries with it some restrictions that do not apply to non-member countries. I was just reading a story that a major company in India, is promoting a drug for certain types of cancer which it has not been approved for. This type of activity in IFPMA would

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not be permitted, it would be a clear violation of the ethical marketing rules. The second commitment is to support IP protection. The third commitment is to establish and support good manufacturing practices. There are a lot of the companies in the world which do not produce products to standard and do not produce what we call safe and effective medicines. Those are really the three commitments and they are commitments that are political and moral quality commitments. Those are the only “barriers” to entry.

Dr Noehrenberg: I am also an economist. One often overlooked aspect on the question of patents and development and competition is the fact that patents create competition. Let us look at the AIDS field, for example. The first AIDS drug, AZT, was developed back in 1987 and it is a good drug and still used quite effectively. However, if that was the only drug on the market and you do not respond to it or you develop resistance to it, which unfortunately happens, you would be in very serious trouble. Thanks to the patent system, other competitors have had to find other ways of attacking the AIDS virus than by using AZT. If you look at India, for example, that has been copying and copying, they have a number of variations of AZT but none of them are innovative. Thanks to the patent system, thanks to forcing competitors to find different ways of tackling the HIV virus, we have about 26 different medicines on the market which are used in various combinations to effectively treat HIV in a variety of countries. I can see your argumentation, and we debate that quite often, but I think the creation of competition, the creation of public health benefits through the patent system is often overlooked but very important as well. The question of therapeutic competition on a variety of drugs also helps to keep prices down. If you look at the various sectors of the healthcare system treating AIDS, heart disease, cancer, et cetera, you will see that, although they are not exactly the same drug and the patent gives you a so-called monopoly over that particular drug and that particular indication, nevertheless, if someone else develops a different way of attacking the problem, the competition among those products helps to drive prices down. Indeed, when India passed the Act in 2005, Minister Nath, the Minister of Trade and Industry, said explicitly that he counted on such therapeutic competition to continue keeping prices down in India.

Mr Willis: A practical consequence of Indian patent legislation is that we are now seeing products in development for Tuberculosis and Malaria being done by Indian companies.

Q770 Chairman: I would like you tell us a bit more, if you could, about your relationship with some of the organisations, like GAVI on vaccines and

inoculation and WHO generally. You have talked about your three As—availability, accessibility and affordability—and my guess is that the affordability one is the one that there is quite a battle over. I wonder how you see the relationship between yourselves and those organisations out there saying, “Hey, we want to get drugs down to people who need them in an affordable way”.

Dr Bale: Can we start with the vaccines, because Ryoko has not said anything yet. You mentioned GAVI, and Ryoko is responsible for that area.

Dr Krause: As Harvey has mentioned, all of our vaccine members have committed to work with GAVI from the very beginning. They started their work in 1999 to prepare for the initiative of the GAVI Alliance to provide vaccines to children in the least developed countries. What they have been doing is supporting the infrastructure development of GAVI initially and then contributing to provide the vaccines through a UNICEF procurement system in large quantities of high quality vaccines for those GAVI recipient countries. I think there is a lot of confusion about what GAVI does. GAVI does not give vaccines, it focuses on two vaccines for the time being. One is basic vaccines which are used all around the world for measles, mumps and rubella. Those are not procured by GAVI. GAVI is focusing only on the Hib vaccines Hepatitis B vaccines and vaccines for Yellow Fever. They are trying to expand their remit to new world vaccines coming in, which are very high-tech innovative vaccines for Rotavirus diseases, Diarrhoea and Pneumococcal diseases. Those are the new-area that GAVI is starting to work on. Their success has been incredible, it brings all the funders together and uses the money and resources in a very effective way. The vaccine industries are at the table as a Partner. That is the difference between how the other organisations work with industry, because very often industry, although they come up with extremely good products, high quality and innovative products, is treated as somebody who is not contributing enough to the developing countries. The GAVI model is ideal that all industries can work together on an equal level as Alliance partners.

Q771 Chairman: On all the other drugs that these organisations want to get down to low cost, and an enormous amount of money is now going into it, is there real tension between you and these organisations about delivery of drugs at what they would regard as a price that will deliver the right outcome to people on the ground in sufficient numbers?

Dr Bale: I think overall that is a good perspective, a reasonably accurate perspective on the issue. I would underline the point that I would derive from Ryoko’s comment, which is to distinguish WHO, because

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when you ask who sits at the governing table, industry does not sit there, we are a non-governmental organisation. Who sits at the table are the Member States, the Health Ministers and their representatives. Who sits in an organisation like GAVI are the Global Fund and the Medicines for Malaria Venture. When you take something out of the official UN system and create a partnership, which is what these organisations are, you then find the industry typically at the table. It is a very interesting phenomenon which reflects the political structure and history of the UN as a Member State-driven organisation. We are going through debates right now with the WHO on who can sit in a room at a meeting. At the end of the day I think that debate will not matter too much, but it matters for the moment in the heat of battle. That tension is there and it is a tension between an industry that you started off by saying is in the private sector. There has been no other model that has been developed that consistently can deliver \$50-70 billion in R&D over a long period of time in a commitment like this, and companies that cannot go to the capital markets and borrow the money have to raise the money through venture capital and shareholders. They will not find a bank who will lend them \$100 million and say, "Here, go develop a new drug". At the same time, it is an industry that has a large foot in the public health sector, as you suggest, in which we have to be able to justify how we deliver these medicines at affordable prices, or in some cases when they are not affordable what can be used to get them to the people who are disadvantaged and without income. There is that tension, and it exists primarily at the World Health Organisation, I would say, where the industry is cooperating on a number of fronts. For example, Ryoko's group, the IVS, the vaccine supply taskforce, is very closely involved in preparations for avian flu. Here the problem is not the industry, the problem is one of the Member States, specifically Indonesia, which is threatening to upset the whole system of surveillance and sharing of the virus samples that threatens public health and is a violation of the International Health Regulations. We are not always the bad guy. In fact, if you ask the WHO, the more senior the person you talk to, the greater appreciation comes about as an understanding of what industry really does. At the same time there are a lot of people in the WHO who do not understand, do not want to understand, what the private sector does, it is not part of their world view. We deal with those people but sometimes we deal with them a little bit more contentiously than others. I am quite pleased. Over the years I think our relationship with the WHO has improved. There has been a better understanding, particularly under the last two Directors General, Dr Lee, who in an untimely way

died, and Dr Chan. I am hoping that will continue. We have added a specific partnership function with Stefanie in the last couple of years to try and reach out and work more with the WHO.

Q772 Chairman: Does UNITAID help you in the way that they work?

Dr Bale: That is an interesting case. We are not at the table with UNITAID.

Q773 Chairman: Why not?

Dr Bale: At the beginning we had a lot of dialogue with the French Government in particular, which was really the driver of their airline tax on funding, which I understand is yielding something in the order of €300 million a year.

Q774 Chairman: It is a lot of money.

Dr Bale: We have known Philippe Duneton for years, and Jorge Bermudez is the Executive Director. On a personal level we are on good terms, but officially we are not there with UNITAID.

Q775 Lord Avebury: Would it be helpful if you were?

Dr Bale: I think so, and we would be more than willing to on technical issues, on the issues where they are going to be running into difficulties. A few organisations came about rather quickly and UNITAID was a very quick development as a result of Foreign Minister Douste-Blazy's efforts to sell UNITAID and the tax. We went to meetings at the beginning with UNITAID and I remember sitting in two or three of them. But, when it comes to day-to-day interaction or participation, we are not anywhere in the governing organisations, nor is our French industry counterpart, who is very closely monitoring and following what is going on there. We wish them well and we would like to help, but theirs is kind of a smaller version of the Global Fund. In the case of the Global Fund, we are formally at the table through the private sector membership on the board, but the UNITAID organisation has not placed that structure into existence.

Q776 Chairman: You said they will run into difficulties. Why will they run into difficulties and of what type?

Dr Bale: For example, with regard to WHO and the vaccines field, there is very, very technical information that needs to be delivered and a lot of misapprehensions and misconceptions that we have been able to address by being in the room and discussing the issues at the so-called Intergovernmental Meetings that have taken place about what is the science of vaccines. In the case of HIV/AIDS, TB and Malaria, which is UNITAID's remit, there are going to be a lot of issues around the

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supply of the products, questions of whether and how fast you can develop fixed-dose combinations, which they would like to do, paediatric formulations, which is on their agenda, and fixed-dose combinations on their agenda. Industry can help with regard to the technical aspects of how to develop and deliver such medicines.

Q777 Chairman: Before I call my colleague in, is the implication that the sort of problems you think they might run into could be quite serious in terms of the failure of the drug regime or whatever?

Dr Bale: Probably even more so on the questions of delivery and quality assurance as well as the formulation of fixed-dose medicines.

Dr Meredith: I feel quite strongly about this. One of UNITAID's major foci is development of paediatric formulations where they do not exist already, and only the R&D, the research-based pharmaceutical industry, can actually do that. If you are not sitting at the table, there is not the dialogue. On the whole question around quality assurance, we know that, if you take the lowest price you are willing to offer, that does not give you the quality that is going to be needed in the long-term. Eventually UNITAID will need the private sector at the table. It is not just for drugs but also for diagnostics. They will need us. At the moment, to be honest, the reticence to having a dialogue with the private sector is coming from a few of the people on the Board; it is not the UNITAID people themselves, it is a few of the stronger voices, some of the Member States. I understand that recently they had an evaluation and assessment of a new partnership model they have developed, where there have been questions about why the private sector is not at the table, and perhaps this will lead to some changes.

Q778 Baroness Whitaker: Before I move on to generic drugs, returning to R&D I just wanted to ask you whether your members stimulate manufacture in countries where the need is greatest, bearing in mind that there is so much research in the West and so much disease in the South. If they do so, either through their own companies or other organisations, what do they do about accreditation standards?

Dr Bale: There is some of this in the material that will give you more detail than perhaps we have time to give you today. GSK, for example, right out there in West London, has been a good example of what we call technology transfer. They very, very carefully select their partners in the case of these medicines because their reputation is really on the line here. The types of technology transfer that occur, when they make sense, do make a lot of good sense. In the case of HIV/AIDS and GSK, they have done technology transfer with Aspen Pharmaceuticals, a generic

company in South Africa, to help with the distribution, because they feel that Aspen can better handle the distribution in the SADEC region, the southern African area, not in South Africa alone but in the regional context. Lilly, in selecting its partners, has spent over US\$70 million to develop these four partnerships with four generic manufacturers going to India, China, Russia, et cetera, to do that. Accreditation becomes a very important issue and it is done at a very micro level. You have to send manufacturing teams, and we have had some of this in the vaccine field. There is quite a bit of discussion going on right now about how we can build capacity in developing countries and in what way. Typically, the companies will start off with a very basic technology transfer agreement, which is called filling and finishing. Basically, you are taking an active ingredient that comes typically in very large drums, cartons, and sending these to the countries where they are put into the final tablet form. If you start to develop the skills with regard to that, then later on you can go to a more refined operation. Some companies, like Merck, have developed turnkey vaccine facilities.

Q779 Baroness Whitaker: Have they saved money on R&D by so doing? Not yet?

Dr Bale: No. Typically the goal is not to save R&D in the case of technology transfer agreements. Where costs on R&D can be saved is where you can access procedures, subject to the presence of ethical review boards, that allow the company to do clinical trials in developing countries. In developing countries you have many more patients who are available simply by virtue of the fact that these countries have not been very well-served because of lack of infrastructure, poverty, unaffordability of medicines, and colloquially they are called naïve populations, so you have naïve populations in many developing countries that are very hard to find in Europe and are simply less expensive.

Q780 Baroness Whitaker: The ethical considerations are presumably the same, are they?

Dr Bale: Yes, they are huge.

Q781 Baroness Whitaker: Identical with the ones in the West?

Dr Bale: The existence of ethical review boards is much more difficult in developing countries, where the standards have to be much more developed along the way to do many more clinical trials that are needed. A lot more development has to be done.

Mr Willis: A Dutch NGO did a study into this recently and found that most of the clinical trials that are taking place in developing countries are offshoots of clinical trials that are multi-centre clinical trials

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which are usually directed by companies or institutions in the developed world. The ethical standards that apply in the developed countries are, by extension, applied in the developing countries.

Q782 Baroness Whitaker: I just wanted to clarify that. What I want to ask is about generic drugs. I think you say that 95 per cent of pharmaceutical products on WHO's Essential Drugs List are not patented. Does this include the essential drugs for HIV/AIDS, Malaria, TB and influenza? Are they generic?

Dr Bale: That is a mix. They are patented in the UK, for example, and not patented typically in India or Bangladesh. A very interesting transformation took place in the Essential Drugs List. It takes a very long time to get a drug typically added to the list because of bureaucracy, questions about affordability, et cetera—

Q783 Baroness Whitaker: WHO bureaucracy?

Dr Bale: Yes, process. The Essential Drugs Committee, which was an observer, that meets twice a year, not very often—

Q784 Baroness Whitaker: So are you saying you might have to wait 12 months to get on the list?

Dr Bale: At least. The HIV/AIDS drugs were not added to the Essential Drugs List until, I think it was, 2001, 2002.

Dr Noehrenberg: 2002.

Dr Bale: For example, AZT has been around since 1987 and is now generic. AZT is the one drug in the HIV/AIDS class that is now generic. A large number of the others will become generic very soon. At the same time, because India and a number of other countries did not have patent laws until the early to mid-decade, at the beginning of 1995, you have a large number of the HIV/AIDS drugs available generically. Some of these drugs are good quality drugs. You cannot and should not associate a generic product with a substandard product. There are many substandard products available in developing countries, but there are also good quality generic products that are available. HIV/AIDS is kind of the big exception to that rule.

Q785 Baroness Whitaker: I think you also say that copies of products tend not to reach the poorest peoples. Could you just spell out all the reasons for this, because this is very crucial.

Dr Meredith: Where shall we start!

Q786 Baroness Whitaker: I can think of some, but you tell me your views.

Dr Bale: What is the statistic? How many millions of children die of diarrhoeal disease each year? The numbers are staggering, yet oral rehydration therapy costs pennies.

Q787 Baroness Whitaker: Indeed?

Dr Bale: If you go to basic antibiotics, one of the biggest killers in Africa today is respiratory disease, pneumonia, upper respiratory, lower respiratory; and antibiotics are cheap. A doctor will prescribe for me erythromycin and I will happily take it, it is a very cheap antibiotic. We cannot get this product into these countries.

Q788 Chairman: Why not?

Dr Bale: Because of the delivery systems. Let us start from the top and take the worst case example, Robert Mugabe, does he care? He is extreme; but, if you ask the WHO what is the biggest barrier to access to medicines today, they will tell you it is lack of sustained political commitment to public health.

Q789 Baroness Whitaker: So there might be entry restrictions on imports?

Mr Willis: Before you even get into that, it is simply the amount of money that they spend on healthcare.

Dr Bale: You are addressing just poverty, and that is a factor.

Q790 Baroness Whitaker: Poverty means you cannot afford the drugs if they cost something.

Mr Willis: It means that most sub-Saharan African countries are spending per capita, per person, per year less than \$5 (on medicines).

Q791 Baroness Whitaker: So there are two aspects to that, the individual cannot afford the drugs and the government cannot afford the health infrastructure, the transport?

Mr Willis: That is just talking about what the government spends. Typically in sub-Saharan Africa the ratio is 4:1 or 5:1. Out of pocket expenses are typically four or five times what the government spends, so total healthcare spending in Nigeria is in the order of \$50 per head, but 40 of that is coming out of the pocket of the individuals concerned. That is before you get into tariffs.

Dr Bale: There is a lady here in Geneva with the Global Fund who was the former drug regulatory chief in Gambia, who says that the quality control systems in Gambia have not been updated for over 20 years, so they do not have the capacity to even evaluate which drugs are good quality drugs and which are bad quality, let alone ensure that the good quality drugs get into the systems in remote areas.

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Dr Krause: During the first year of GAVI's activities they have agreed and decided to give free vaccines to 72 least developed countries around the world. It is not a matter of price. It was totally free and sent to individual countries in the proper way by UNICEF, but those countries that could have received free vaccines did not move forward in incorporating Hepatitis B and Hib vaccines in their immunisation schedules because they did not have any infrastructure for the cold chain, no delivery system and no healthcare system. They had no structure or system to implement vaccination campaign where infants and children to be vaccinated. For each vaccine, even when it is a zero cost or one cent, additional costs of about \$8 to \$14 per dose may be needed to implement vaccinations. The amount of additional cost depends on the level of infrastructure in those countries. That is the reason why GAVI Phase 2, which started in 2006, is focusing on how to strengthen the health care system and to make each government committed to the vaccination programs. Some countries immunised the children only when it was free and, if it became a few cents, they decided to stop immunisation programmes on those particular vaccines and did not care about the children who were dying. Now they are requesting GAVI recipient country to contribute in paying a small amount for each dose the country receives so that no government will receive free vaccines. Receiving free materials does not link to the recipient government's commitment. GAVI now focuses much more on the infrastructure, healthcare system strengthening and are not giving out the free vaccines any more.

Dr Meredith: I will give you some examples. I have spent most of my life working in Africa and I am really committed to seeing something different. You can go to the central stores in, let us take Tanzania or Rwanda, and the drugs are there, there are the basic essential drugs; but, when you are in a health post that is 1,000km from Dar es Salaam, there is nothing there. The whole supply chain management is a problem. It is a problem because the person at the health post actually has no training in how to keep an inventory and order. But, even worse, if he does have the training and the capacity, and some of them do, the road has been washed away during the rainy season, the landline telephone does not work. Nowadays, with mobile phones things are changing and there is the possibility; but, if there is no transport from Dar es Salaam to Mahengi, you do not get your drugs for three months and there is nothing there. For me, one of the major problems is also trying to address building capacity for much better infrastructure and supply chain management. The same is true in Rwanda, which had \$90 million when I was working there in 2006 just for HIV/AIDS alone for a population of a round seven million, and

at that point about 3.5 per cent of the population was infected with HIV. \$90 million is vastly over, in fact 300 per cent more than was actually needed, but still at the health posts there were not the drugs. They had the HIV drugs but none of the other essential drugs because there had been vertical training. That is infrastructure, lack of integrated policies and we need a broad sectorial approach to improving that.

Q792 Baroness Whitaker: I absolutely endorse what you are saying.

Dr Bale: We are happy if you stay for another hour!

Q793 Baroness Whitaker: It is our job to make recommendations to bear on the UK Government. With the best will in the world they have not too much influence on the range of tariff regimes, infrastructure, they have to choose where they can influence. To remedy this situation, to enable poor people to get generic drugs, what is the most useful thing, or things, that the UK Government can do, either at the political level or the aid level?

Dr Bale: We are starting a dialogue now with DFID. By the way, I think your Government is really a stand-out leader in this regard. Between DFID, USAID and a few other aid agencies focusing on health, this is enormous. First of all, I do think that the British Government should encourage institutions like the World Bank to focus more on these infrastructure issues. Instead of big mega-projects, like dams and telecoms and all that, that is fine but there is a bit of advocacy needed, because the UK Government is very influential in World Bank circles, and there needs to be more multilateral focus in this whole field of health. There are two issues. Not just supplying drugs—everybody seems to be keen about supplying drugs, UNITAID, et cetera. But let us get the infrastructure in place, let us build quality, let us keep counterfeits out. There needs to be a lot more focus on quality control, just as Stefanie, Eric and others have indicated. We have got to do that bilaterally, besides advocacy at the multilateral level, focusing against some of the programmes. We would love to work with DFID, for example, on this Gambia project. We would like to set up a model, in effect an exemplar, a project, a pilot, to use the Gambia, which is a small country of a million people, but still lots of problems, poor health quality control facilities, almost none. We are going to try to go in there and help. We have the skills and expertise but are not typically in a position to provide financing on a sustainable basis for 20-30 countries. It is a combination of public-private partnerships. We will bring the skills, we will put the resources in there and help get people there, companies committed, and it will cost them money. This is what we do with MMV, we get companies who are willing to devote

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laboratory resources to help develop a new anti-malarial drug, and it has spun on, most recently in the case of Ranbaxy in India, who picked this up to develop the drug further. It is a combination of what we call PPP, public-private partnerships.

Q794 Lord Avebury: Is it DFID which is in the lead in the Gambia model?

Dr Bale: Right now we are at an early stage on Gambia, but DFID certainly seems to be in the lead on a number of health-related issues in developing countries. We hope to work with DFID. I would suggest DFID is a good natural partner in the case of the Gambia.

Q795 Lord Jay of Ewelme: This is a question, following up what Stefanie Meredith was saying. I guess we have all been to rural areas and seen the shops and stores where there are not the drugs but there is, let us say, Coca-Cola. My question is! is there scope for the pharmaceutical companies to work with private sector distribution networks to get the drugs through to places where at the moment other goods get through but drugs do not?

Dr Meredith: It is unfortunate that many people bring up the whole thing with Coca-Cola, including Margaret Chan of WHO, because it is completely different.

Q796 Baroness Whitaker: Why?

Dr Meredith: In the health posts that I am talking about, it is public sector. In the small private sector shops the profit margins are very small, but in Coke the profit margins are larger. They are all bottled in-country, these are local products and the cold chain is local. We should also add that, unlike the majority of medicines, you don't need a doctor to prescribe Coca-Cola.

Dr Bale: Coca-Cola controls it from A-Z. Coke is in charge.

Lord Jay of Ewelme: It is just that there are private sector mechanisms for getting products from Dar es Salaam to the rural areas. If that exists, why can it not be used in some way for other products?

Lord Desai: Forget Coca-Cola, heroin always gets there!

Q797 Chairman: Do not go there!

Dr Bale: Again, in that case it is the drug lords who control the chain. Our role in this is frequently we are at a disadvantage. Even if we have companies in the countries—and we have companies in Kenya, Nigeria, South Africa—they cannot get out and direct the public health authorities to do this and this. What we are hoping we can do is train them. This is where we think the value of what we can do in

Gambia comes into play. At the end of the day we cannot own those health outlets.

Dr Meredith: What you are talking about is better and more innovation in distribution.

Q798 Lord Jay of Ewelme: Yes.

Dr Meredith: In fact, there are some innovative examples of essential drug franchise stores that were started in Kenya which were using something very much like this. I would recommend very strongly that we look more at expanding these franchises.

Q799 Chairman: A final word from Dr Noehrenberg.

Dr Noehrenberg: Thank you very much. Lord Jay raises a very important point. When I came to IFPMA from UNAIDS, where I was responsible for our relations with the private sector, this question was posed to me quite often: why is it that the private sector can reach out there. As Harvey and Stefanie have noted, every step along that chain in the private sector, every single person, makes a significant profit until the final end user, even out in the rural areas. What the private sector can do, and has done through organisations such as the Global Business Council or Global Business Coalition on HIV/AIDS, is to offer the private sector expertise on distribution, storage, management, in a way to get a more effective outreach into the rural areas. If you look through the printed copies of the book—that is the advance version and we are going to come out with the official printed copy in coming weeks—you will see specific initiatives which go to that exact issue, how to work with governments to reach out there. Your point is very well taken, your Lordship. The fact of the matter is that the public sector does not have the same incentives for each step along the way to get out to the people there in the rural areas, but by true collaboration and exchanging experiences it can become more effective. That is something that could be used to promote partnerships. May I make one last point? One of the most effective ways of getting AIDS drugs out to people in sub-Saharan Africa and the least developed countries is by what is called the Accelerating Access to AIDS Drugs Initiative. It was started in 2000 by a group of five companies, including GSK of the UK, and works with five UN agencies: WHO, UNDP, UNAIDS, the World Bank and UNPF. That now reaches to well over 800,000 people living with AIDS in sub-Saharan Africa and other developing countries with quality triple therapy treatment. Furthermore, the second-line antiretrovirals offered through that programme by the companies is lower in cost than those offered by generic copiers from India and other countries. That

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is proven if you do analysis of statistics on prices collected by *Médicins Sans Frontières* and WHO. The companies we represent are committed to expanding access, to offer drugs at cost, low cost, even for free, as appropriate. Furthermore, they also cover the costs of transportation, insurance, et cetera, to the purchaser, whereas many of the copiers of products do not do so. This goes to questions raised by Lady Whitaker, Lord Jay, Lord Avebury and others. We are committed to making access a reality and we are doing what we can to make it possible. Where we can do it alone, it does work, but it is even more effective through partnerships with the public sector, NGOs, faith-based organisations in many places. We are

trying to do our best to make it possible, so whatever can be done would be very helpful.

Chairman: Thank you very much indeed, that has been extremely helpful. There are one or two points you have raised which we will look at further that will bear further examination—the infrastructure one in a way being the most important one that we need to give some more thought to. If you do get any more ideas or thoughts, or want to elaborate one or two points more specifically, please do so, and if you write to Mr Preston in the House of Lords it will come to all of us. Once again, thank you for your hospitality but also for your very clear answers to our questions. Thank you very much.

TUESDAY 22 APRIL 2008

Present: Avebury, L
Desai, L

Soley, L (Chairman)
Whitaker, B

Memorandum by GAVI Alliance

INTRODUCTION

1. This submission includes a brief background on GAVI and addresses four of the issues listed in the Committee's Call for Evidence: points 1, 5, 6, 18 and 19.

BACKGROUND

2. The Global Alliance for Vaccines and Immunisation was established in 2000. GAVI's mission is to save children's lives and improve people's health by increasing access to immunisation in poor countries. GAVI has quickly established itself as a significant actor in global health: by the end of 2007, total support committed to poor countries in the period 2000 to 2015 was \$3.5 billion and we had received funds and long-term pledges from donors exceeding US\$7.5 billion. Our largest donors are the United Kingdom, France, Norway, Italy and the Bill and Melinda Gates Foundation.

3. The World Health Organization (WHO) estimates that in the first seven years of our existence, GAVI support has averted 2.9 million future deaths. Major successes include reversing the falling coverage rates of basic childhood vaccines, introducing immunisation safety practices and accelerating the uptake and use of new and under used vaccines, such as vaccines against hepatitis B and yellow fever. GAVI also offers vaccines against *Haemophilus influenzae* type b and pneumococcal disease (against pneumonia) and rotavirus (against diarrhea) thereby protecting children against the two biggest infectious disease killers.

4. Recognising poor health service delivery systems as an impediment to rolling out immunisation programs, in 2006 GAVI launched a Health Systems Strengthening (HSS) programme. GAVI's HSS has attracted the attention of WHO, the World Bank and others who see it as a potential model approach for supporting developing country's national health plans.

5. A feature of GAVI's success has been in developing and piloting innovative approaches to development financing. For example, the International Finance Facility for Immunisation (IFFIm) has seen donors make long-term (up to 20 year) commitments, and leveraged the strength of the capital markets to frontload assistance.

6. A less quantifiable success is reflected in GAVI's business model and approach to development assistance. GAVI represents a new model for international development cooperation in global health that positions developing countries at the centre of decision-making and draws on the relative strengths of both the public and private sectors. GAVI is currently restructuring its governance arrangements and the two main Boards are being brought together in a single governing body. This will include representatives of all of the major players relevant to the success of our mission: the developing countries, the donor governments, the main multilateral agencies (WHO, UNICEF, World Bank), the Gates Foundation, civil society and the vaccine industry; critically it will also include a significant number of non-affiliated individuals with private sector backgrounds.

7. There are not yet any licensed and available vaccines for the four infectious diseases that are the particular focus of the Committee's inquiry. The lessons that GAVI has learned and the approaches that we have put in place for introducing and accelerating vaccine supply and uptake will be useful and can be put into action when vaccines for malaria, tuberculosis and AIDS become available.

8. More information on GAVI, including details of our most recent performance results are available at www.gavialliance.org

SPECIFIC COMMENTS AGAINST THE COMMITTEE'S IDENTIFIED ISSUES

Point 1: status of global progress against communicable diseases

9. After some initial successes (eg smallpox and polio) routine vaccination in resource poor settings became a neglected issue and coverage fell in the early 1990s. GAVI was created in 2000 in response to falling coverage and the recognition of potential benefits in new and emerging vaccines. GAVI's early results demonstrate how a deteriorating situation can be addressed. For example, coverage rates for the basic childhood vaccines of diphtheria, tetanus and pertussis in Africa have risen from less than 50% in 1999 to over 70% today; and an additional 158.6 million children have been immunised against hepatitis B liver disease in the past seven years.

10. In regard to vaccines against the diseases that are the focus of the Committee's inquiry, a recent preliminary study conducted for GAVI by WHO ranked malaria as the highest public health priority in terms of a disease for which a vaccine is likely to be available in the near term. HIV/AIDS and second generation tuberculosis fell into the category of diseases for which vaccines are under development but unlikely to be licensed or available in the near future.

Point 5: blockages to achieving progress

11. GAVI's experience increasing access to immunisation demonstrates that more financial resources are needed for the research and development of new vaccines and that the right incentives need to be in place to spur development. That said there remains a basic lack of scientific knowledge that needs to be overcome if the world is to develop a vaccine against, for example, HIV/AIDS.

12. There are a relatively small number of established vaccine manufacturers but a growing number in the developing world. Vaccine production is a complex and expensive operation (relative, for example, to drugs) and better demand forecasting is an important ingredient in ensuring plant capacity. It is therefore essential that a long-term focus is maintained on market dynamics to ensure adequate supply.

13. Innovations in vaccines are insufficient if there is neither the finance nor the delivery platform to ensure that they reach the people who need them. A historic and long-standing neglect of basic health service systems (by the national governments, bilateral donors and the international development institutions) has left a legacy of failing and dramatically under-resourced health systems in many of the world's developing countries. Recent international initiatives, such as the International Health Partnership launched in London in September 2007, are commendable and demonstrate a high-level recognition of the problem but urgent and long-term action including a significant scaling up of resources will be required to overcome it.

Point 6: role of GAVI in combating the four diseases

14. GAVI brings together the relevant actors in vaccine and immunisation, plus effective non-affiliated private sector expertise, in a collective effort to leverage skills and attributes to accelerate action against vaccine preventable diseases. Lessons from our public-private partnership business model could be useful to others working to fight the diseases that are subject of the Committee's focus.

15. GAVI has also broken new ground with innovative financing approaches to development aid and can contribute experience and ideas to the broader effort required to increase financial resources and the predictability of aid.

16. HIV/AIDS related organisations, such as the International AIDS Vaccine Initiative, have shown strong interest in GAVI's experience as they recognize that having the vaccine technology is not enough—there are significant challenges in introducing and accelerating the uptake of new vaccines. GAVI's work is seen as a pathfinder in this regard.

17. GAVI is very engaged in advancing the broader global health development agenda, in particular pursuing efforts with other global health organizations to better coordinate our collective work and to ensure international efforts are aligned with developing countries own priorities. In addition to our alliance partners we work increasingly closely with the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Point 18. potential other infectious diseases

18. Diseases such as measles, polio and yellow fever could all require global control strategies that must be sustained. With increasing movement of people, outbreaks in any part of the world could have global implications.

Point 19. resources committed by the UK Government

19. The UK Government was one of GAVI's founding donors and has committed significant funds. Direct contributions to GAVI from UK total over US\$115 million and in addition the UK has committed £1.38 billion over twenty years for the International Finance Facility for Immunisation. GAVI has valued the UK Government's policy engagement with GAVI as well as both the quantum of funding and the long-term nature of the commitments.

25 January 2008

Examination of Witnesses

Witnesses: DR JULIAN LOB-LEVYT, Executive Secretary, MR GEOFF ADLIDE, Head, Advocacy & Public Policy, External Relations, Ms LINDA BIFANI, Head, Programme Funding Team, External Relations, and MS MAGDALENA ROBERT, Programme Officer, Anglophone Countries, Programme Funding Team, External Relations, GAVI, examined.

Q800 Chairman: Good morning. Thank you very much for your time in this rather splendid building, if I might say, which is rather admirable. We have about an hour today. As you know, we are the Select Committee on Intergovernmental Organisations looking at the question of communicable diseases and the way that intergovernmental organisations deal with them and the British Government's contribution to that. As you can see, there will be a full note taken of the exchanges at this meeting. That will be sent to you and you can check the transcript before it is published in the normal way if there are any factual matters you want to change. I would like to encourage a very full exchange, so please feel free to intervene on the various questions that will be asked. I also want to say that within one hour you cannot always get in all the things that matter; so, if you feel strongly that we have missed something out or you want to expand on something, you can write to the Clerk at the House of Lords. Perhaps I could ask you to introduce yourselves first so we have an idea of your roles. We have obviously read your brief.

Dr Lob-Levyt: I am Julian Lob-Levyt. I head up GAVI as the Executive Secretary. I will ask my colleagues to introduce themselves.

Ms Robert: My name is Magdalena Robert, I am in the Programme Funding Team within GAVI and am responsible for the UK.

Ms Bifani: I am Linda Bifani. I am the Head of the Programme Funding Team.

Mr Adlide: I am Geoff Adlide. I head the Advocacy & Public Policy Team here in the GAVI Secretariat.

Q801 Chairman: Thank you very much indeed. Can I start with one of our main interests, which is your health system strengthening programme. In fact, we have just come from a meeting with the pharmaceutical industry, who have been talking to us about the difficulties of getting drugs through on the ground and the infrastructure on the ground. One of the issues we have been struggling with a bit is the problem between the horizontal, as it is called, and the vertical of disease treatment options. I suppose what I would like you to do first is to ask if you could

tell us a bit more about what you are doing on that, how you see it working and any of the strengths and weaknesses. That would be very helpful to start us off.

Dr Lob-Levyt: Welcome to GAVI, it is nice to have you here. After the first five years of GAVI, two years ago, we consulted with stakeholders and principally developing countries and spoke in quite a structured way to 40 Ministers of Health of the 73 countries that we support, asking them what did they think about GAVI. There were positive things and negative things, but the consistent and very strong message was that, if we wished to achieve sustainability with introductions of vaccines, GAVI had to address health system strengthening. We listened to that very carefully and then ran a process of design with stakeholders and developing countries as to what might be most suitable for GAVI to do. This year we have introduced our new policy of opening up a window for health system support. The overall balance of funding in GAVI is structured as 70 per cent of our funding is still for our core mission around vaccines, about 30 per cent of our money is for systems building. I personally come from a health systems background, so this is a direction that personally I think is absolutely necessary. The debate has moved on a little bit from talking about vertical and horizontal programmes to trying to avoid saying that from now on and conceptually to think about service delivery platforms in the public-private and civil society sectors and defining the outputs they need to deliver, which will vary from country-to-country determined by the robustness of the system. The outputs of the system will be things like TB treatment, HIV treatment and prevention, malaria bednets and vaccinating children. That is the way we have taken it and that is the way we have structured this window. We asked countries to put their proposals to us, demonstrating how they fit within the national health strategy and what part of that strategy we would be funding, and we asked them to tackle critical bottlenecks in a way that would strengthen not only immunisation, which still has to be measured, but broader maternal and child health

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services. We have had the first year of funding proposals. The demand was far greater than we anticipated and we had to go back to our Board to ask for additional funding. There is a huge pent-up demand for health system funding. We were also pleased to see that most of these proposals, certainly those that were successful, were carefully designed with national partners at a country level and around national strategies and partnership. We have some quite good evidence that our finance catalysed the working together of key partners. The quality of the proposals was high and a greater proportion was approved than had been the case when GAVI first started with just vaccines. This is a reflection of the very good work that, in particular, WHO undertook working with countries in helping them to prepare quality proposals. That is another very positive development. It is too early to see the results and the outcomes, but the majority of the funding has been for peripheral activities and has focused a lot on human resource capacity, development and retention of staff. For example, the proposal in Ethiopia is part of a programme to train up to 35,000 health extension workers, linked into the health system to provide maternal and child health services and immunisation services out into the community, a programme that has been strongly endorsed by the World Bank and Partners at the country level. In a nutshell, that is where we are. We are also very clear that GAVI is a tiny slice of the necessary financing that will be required. The World Bank, the Global Fund, ourselves and others, are very clear that no single institution can deliver this, we all need to play our role collectively in a well-coordinated framework, and a coordinated effort will only work if it is country-driven. If we can work around country-driven strategies, I think it will have a lot of success in playing to what our institutions can deliver. For GAVI it is more about the catalytic finance, and then you will be looking to WHO for some of the normative work and standards and to the World Bank probably more for the capacity building, long-term institutional financial mechanisms at country level. It is challenging but, with in particular the creation of the International Health Partnership (IHP), a collaborative framework led by UK, France, Norway and others, at the country level I see that increasingly GAVI will have a framework into which our finance can fit, that we will not need separate approval processes, we will not need separate monitoring processes, we will have a collective process against which our finance can flow and against which we can measure our results.

Q802 Chairman: Can you expand on that a little in relation to the country-led bit. I can understand that in terms of a country that is functioning tolerably

well, but you have straight away got the problem that an awful lot of countries' governmental structures do not reach out beyond the capital or whatever. How do you deal with that?

Dr Lob-Levyt: You are absolutely right, it would be a minority of countries where you have a robust IHP well led by the government. We are beginning to see the first wave of those countries coming forward this year and next year. In those countries where you can rely less on the government financial systems in particular, we would be looking more to intermediaries to provide some of that function. For example, the World Bank would take on much more of a financial stewardship role at the country level and transfer the finances to the programmes until the capacity in those countries has been built to operate through national budgetary systems. We also work in fragile states and some quite politically difficult countries, such as North Korea or Burma, where there are real political concerns and concerns as to how that finance might be used. In these cases we work directly through the UN, WHO and UNICEF to monitor programmes. You can have a spectrum of funding modalities between these extremes. The goal should be to build increasingly along the model of the collaborative framework of an IHP type process and have that as the developmental goal which puts the countries in charge. In my experience, because I have spent most of my working career working in some of the poorest countries in the world and with different organisations, we constantly under-estimate the capacities of countries in sub-Saharan Africa and South Asia that, with well-thought through financial support, can really use that in an effective way. I happen to be a very firm believer that, if you can deliver the finance at the periphery to district managers, by and large they will do a very excellent job as long as you measure the outcomes against which they are delivering.

Q803 Chairman: I would like to pursue that if I could because one of the interesting points that was put to us a short while ago was about the role for the World Bank in supporting infrastructure. I hear what you say, that no single institution can deliver it, but the World Bank's involvement is pretty crucial?

Dr Lob-Levyt: Yes.

Q804 Chairman: I am also aware that, in a developing country, just because you do not have a functioning government, when dealing with a common enemy, for example disease, it does not follow that the informal structures do not necessarily work and work tolerably well. Would it be possible to use that, if you like, informal structure in these countries, perhaps a bit along the lines you were suggesting, I am not sure, and having the World

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Bank funding that infrastructure? Or is it the sort of infrastructure where the World Bank would throw up its hands in horror and say, "This is not something we can measure, it is not something we can see and identify the right sort of investment"? Is that a problem?

Dr Lob-Levyt: I would say that the Global Fund, the Global Fund to fight AIDS, TB and Malaria, and GAVI, in a positive way have challenged the status quo as to how you can operate in those circumstances and that has enabled governments to make more innovative and flexible responses, including involving civil society and the private sector more, NGOs for example, as routes and mechanisms for programme delivery. In part, it is challenging WHO, the World Bank and others to think about how they need to better engage with those other parts of the system in a way that traditionally they have not done before. That is a very healthy thing about the growth of Global Health Partnerships which is sometimes seen as a problem. I think it is a natural development of a heightened political commitment and interest in development. When you have Prime Ministers of the UK, Norway and an increasing number of Presidents committed to development in the G8 and more finance flowing, you are going to get a mushrooming of effort and initiatives, partly as a reflection of the lack of progress made in the past and that you have an urgency to deliver. We are in this rather exciting stage that I have never been in in my 25-year career in development, of more money, enthusiasm, incredible political leadership and great pressure to deliver. I think we are now at the stage of how we bring this rather challenging process together. This is a natural progression and we should not be frightened by it, we should be concerned to make it effective. Part of that is challenging existing institutions to think how they move into the 21st Century. Fundamentally, it is really about recognising the increasing and sophisticated capacity of some of the poorest countries in the world and how we need to tailor our assistance to support that, and many institutions have yet to fully move in that direction.

Q805 Chairman: What you are describing is not just bringing people into the 21st Century, it is requiring some established institutions which, for good reason, have got set ways of dealing with financial investment, which require, for example, very good accountancy to avoid the corruption problem. You actually need, do you not, the invention of a system that either takes account of the corruption or the misuse of funds in some way because, although I am sure you right, if you use the local network, it can often work very well but we also know it can work incredibly badly and, particularly where there has been conflict, drugs might end up with patients on

one side of the conflict but not on the other side of the conflict. You are asking a lot, and maybe the World Bank is a classic example where you are asking them to put money into something where you cannot see a structure which measures the use of that money.

Dr Lob-Levyt: Let me be very clear: unless we can have accountability for results, we are in a really difficult position because we will lose the confidence of governments and electorates that vote the monies for development. The way that GAVI has come to this is by focusing on results, so that we can measure independently through audit and UN institutions the performance against immunisation and health system delivery. If we are satisfied with those results, we can also have greater confidence in the finances being used in that direction. We also have the ability to bring in an external audit when we need to, either on a random basis or when we suspect there is an issue. All of the governments we work with fully understand this. It is a partnership, so it has to be worked out that we are both strengthening and supporting national systems and not undermining them, but there is accountability, this is a two-way process.

Q806 Lord Desai: Have you had any cases where you have had to say, "Enough is enough"?

Dr Lob-Levyt: Yes, we have. We suspended finance to Uganda because we became aware that there was a misappropriation of funds by the Minister of Health. We raised it directly with the government, the Minister of Health was brought to account and replace, and we have just come to an agreement with the government. We used their national audit processes, we were satisfied that they had found the problem and that they will repay the money to us. That is about to be officially announced.

Q807 Baroness Whitaker: I just wondered, when you evaluate results, are you talking about the delivery of vaccine to a clinic or organisation? Or are you talking about lowered prevalence, actual change, as the real eventual outcome?

Dr Lob-Levyt: The relationship between vaccination coverage and the impact on the disease is quite well understood and fairly well measured so that we know, for example, in the case of sub-Saharan Africa that by increasing the vaccination coverage from just over 40 per cent to over 75 per cent coverage in the life of GAVI we can model a significant impact on disease, and WHO has advised us that GAVI has now prevented some 2.9 million future deaths as a result.

Q808 Baroness Whitaker: Because they have noticed the absence of illness? Or because the vaccines are in the clinics?

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Dr Lob-Levyt: Because the vaccines are in the arms of the children, and that can be measured, we have had the coverage. We also have sentinel surveillance studies which take place to see what has happened to disease. There has just been an independent article published with the work of WHO and others in Uganda, where vaccinating against the disease of Haemophilus Influenza B, supported by GAVI, a very nasty disease—meningitis—has been eradicated from that country because that coverage is there. You are testing by measuring the disease burden and the secondary check is that a good quality vaccine got into the arm of a child. We are very confident of the impact that we are having and the sophistication of our surveillance through WHO and others allows us to have that confidence.

Q809 Chairman: Before we move on to the incentives for vaccine development, can I just clarify how do you use the investment in a way that ensures the vaccines or inoculations get to the place in a satisfactory state to be used? Presumably you need some equipment for that? Are they travelling vehicles, clinics, what are they?

Dr Lob-Levyt: The vaccines have to be internationally tendered. UNICEF undertakes the purchasing of GAVI vaccines out of Copenhagen, they are shipped to an African coast and get to a remote village. Vaccines need a cold chain to do that; a chain that keeps them within a specific temperature range, and we provide some of the finance that is necessary to sustain that cold chain to the village as part of the programme, as part of the system of support.

Q810 Chairman: That would be a driver and a vehicle?

Dr Lob-Levyt: A country may decide to use our finance to do that, or other finance. They mostly use their own budgets, of course. Most of health, and the necessary staffing, as we always forget, is funded by African national budgets, it is not just by donors. It has got pretty sophisticated now. There is very careful monitoring of the temperature. The vaccines that we supply now all have to have a little monitor on them, which is a colour-sensitive chemical strip that changes colour if it falls out of the temperature range, it is thrown away. This is constantly audited and measured. The quality of the vaccines when they arrive at these remote villages is very good on the whole. It is a remarkable story.

Q811 Chairman: I hear your enthusiasm. When it gets to this village, there is a person there trained who understands and knows to throw it away if the strip has changed colour? And they know how to inject?

Dr Lob-Levyt: Yes.

Q812 Chairman: Who has paid for that? Is that the healthcare system of the country? Or is it you?

Dr Lob-Levyt: It is the healthcare system of the country. Increasingly, we are saying that, to extend coverage to the remotest and poorest communities, you need to expand the human resource workforce. That is probably the biggest challenge for sub-Saharan Africa—the shortage of doctors, nurses, paramedics and community health workers. That is one of the ways in which our finance is being used, this new health system finance, to increase and strengthen that capacity. No vaccine is ever given except by a well-trained person, that is part of the system. The people who give it know how to do it and know how to monitor.

Q813 Chairman: Supposing the World Bank did say, “OK, we are going to put more money into the infrastructure to ensure vaccines and inoculations get through”, how would they do that? Would it be a matter of giving it to the health authority in the country? What would it be?

Dr Lob-Levyt: Again, it would depend on the country but it would be by providing the finance to budgets for training and capacity building. It is fairly simple. At the end of the day you need a well-trained, probably locally-based person in a reasonable clinic that is clean, is assured that they are well supervised and supported and their drugs and vaccines arrive regularly and on time. It is simple if you look at it from that end, but to put that infrastructure in place is very challenging. If we keep our minds focused—on what you need at that community level, or somebody who visits the villages on a regular basis, and work backwards from there, you can begin to put that system in place, and many of the countries I have worked in have done that, some of the poorest countries.

Q814 Lord Avebury: You mentioned incentives to spur development and I wonder if you could illustrate that by talking about the successes in Hepatitis and Yellow Fever. What were the incentives that worked there? They were not purely intellectual property incentives that applied across the board, there were some additional ones that you put in place. I think you developed the Advance Market Commitment?

Dr Lob-Levyt: Yes.

Q815 Lord Avebury: I wonder if that applied in the case of those two particular vaccines and if you could go on to say something about the current work you are doing on Pneumococcal Disease where, again, the Advance Market Commitment (AMC) is the tool of preference, as I understand it.

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Dr Lob-Levyt: The introduction of Hepatitis B probably represented the perfect situation. It was a vaccine that had been around for 15 or 20 years, well-used in the West but denied to the poorest countries on the basis of cost. When GAVI arrived, it said, “We have five years of financing, we are prepared to buy it”. There was a lot of competition out there, a lot of producers. Our volume of financing and our ability to finance over a number of years to some of the poorest countries and the demand from countries meant that Hepatitis B has gone from almost no coverage in the life of GAVI to almost 70 per cent coverage across some of the poorest parts of the world, so a significant increase very quickly. The price of the vaccine has dropped because of the competition. That is the perfect world that you would want to be in, it is off-patent and many manufacturers secure financing and demand from the countries. That is where you want to be. In other areas we are not in that situation. Let me step back from that for a moment. We learnt that five years of financing is desirable but not sufficient. What has changed and become a really important dynamic is that GAVI has a track record now of longer than five years, industry sees we are not fly-by-night, countries see we are not fly-by-night, Countries have the confidence that we will not let them down financially, and we have a better instrument. We have countries such as Norway and organisations like the Gates Foundation that have pledged ten years of financing. The International Financing Facility, for Immunisation (IFFIm), in which the UK Government was a major driver, allows us to have ten years of legally binding finances. We can go to countries and say, “We can enter into ten-year programmes to support you, so that you can build your budgets, the co-financing of these new products,” and industry responds well when they see a market where there was not a market before and come into it. So we see the competition build up as more companies come in, but it takes longer than the five years we first thought for newer vaccines, it takes five to ten years. The next step beyond that is the Advance Market Commitment, which is basically saying, at its simplest, “If you produce a vaccine in this disease area with this effectiveness and at a price at the end of the day that is affordable” and we will set that price, “we will buy it”. In the early years we will heavily subsidise that vaccine because it is an effective vaccine and it will generate demand from countries. But at the end of the day we know this is going to be affordable because we are going to get it at the rock bottom price. We used an independent committee to identify which disease and which vaccine would be most appropriate to test this concept, and that was against Pneumonia, the Pneumococcal vaccine, and then we worked with six governments, together with the

World Bank, to design and build the legally-binding framework that would mean that US\$1.5 billion would be there when the vaccine became available. Probably the biggest challenge was getting a multinational agreement that was sufficiently legally secure that industry would have confidence that, if they did this, it would happen. It is also designed in such a way that, if somebody comes up with a better vaccine, it is not the winner takes all the prizes as it were. If another company comes in with another vaccine further downstream, we have segmented it such that we can also take up that other vaccine to promote competition to get more than one industry coming in. The worst thing would be if it remained with that monopoly situation; we want to move to that situation where we have the hepatitis B with more people coming into this market.

Q816 Lord Avebury: Is that US\$1.5 billion in place? Have you got that money?

Dr Lob-Levyt: We have now got the US\$1.5 billion secured. We are finalising the legal documents. We are pretty confident we will have that by September of this year.

Q817 Lord Avebury: Is it PneumoADIP you are talking about?

Dr Lob-Levyt: The PneumoADIP was a separate mechanism that GAVI developed. We recognised that for new vaccines there was not a well-coordinated and appropriately funded mechanism to do the other pieces of work that are necessary, the safety trials in countries, Africa in particular, the other clinical studies, some of the practical operational work that we needed. So we set up the ADIP Committee, which was almost a contracted-out mechanism for GAVI, because even though this looks like a big conference room we are quite a small organisation, and with institutes, WHO and other experts, they oversaw the process of the necessary fieldwork that would need to be done to accelerate the introduction by having the results we would need—is it safe in Africa? What happens when you give it to HIV/AIDS populations? So we could get those answers faster. If you just leave it to the market, it takes ten years, so we deliberately targeted certain areas which were more on the operational side to speed up the answers we would need for when the vaccine was available. That was done for pneumonia and it was done for diarrhoea, Rotavirus.

Q818 Lord Avebury: Do you think this is a model which applies more generally than to particular diseases?

Dr Lob-Levyt: Yes, I think so. We have learnt a lot of things in GAVI which are applicable elsewhere and for other diseases.

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Q819 Baroness Whitaker: Lord Avebury and I are both members of the All-Party Parliamentary Group on Pneumococcal Disease, so we are very interested to hear your evidence on this. I was very interested to hear that you got long-term funding from the US Government, because one of the problems with making the International Financing Facility cover more than vaccines, and it was meant to be general, was that the US Government said, "We cannot commit ourselves so long in advance because Congress likes to renew our arrangements every year". How did you get around this?

Dr Lob-Levyt: Sadly we did not. I am sorry if I was not clear. It is from the Gates Foundation as a philanthropic organisation that we have had ten years of committed financing. Having said that, the US Government has remained very interested in the AMC, which is another form of securitised financing, so we are still working on that and hoping that, with the new Administration, we might make even better progress, but we shall see. Having said all that, the US has been a very committed supporter of GAVI. They provide US\$70 million a year and have funded at an increasing level since the beginning of GAVI. Although they appropriate their funds annually, we see them as a very committed donor, and an important one.

Q820 Chairman: Amongst others, we have seen the International Federation of Pharmaceutical Manufacturers & Associations. Do you feel they are doing enough? And could they do more? What is your feeling about them? And how closely do you work with them?

Dr Lob-Levyt: We have on our Board two seats for the pharmaceutical industry, that from the north and that representing the south. We now buy between 30 and 40 per cent of our vaccines from manufacturers from emerging markets, countries such as India, Brazil and elsewhere. We used to purchase everything from the north. This is a very healthy dynamic. I was in India not so long ago visiting the Serum Institute of India. And as you go into their facilities, you could be in Geneva, it is the latest state of the art equipment, high quality, and this is really very encouraging. We work very closely with industry through our Board. I can truthfully say that, at least in the vaccines area, a space has been created by GAVI where we can have a fairly open debate about some of the issues, and it is less confrontational. Particularly in drugs, there has been a lot of controversy over antiretrovirals which has made debate quite challenging and difficult and, to some extent, has caused industry to shy away from those debates. In vaccines we have not had that problem, and GAVI has created a space where we can have quite healthy debates about getting to the best prices,

getting products, and we are able to hear views that are different from emerging industry and existing industry as to what the issues are. I hope we preserve that in GAVI. We are also witnessing in the pharmaceutical industry writ-wide that less of the big blockbuster drugs are emerging from which they are making their big profits on the drugs side, and there is a lot more attention now on the vaccines side, a lot of new and exciting vaccines coming through. That may change the nature of debate in time as profits become more dependent upon profits made on the vaccines side. However, with vaccines we have the tiered pricing concept whereby we in the UK, or in Europe, are prepared to pay a higher price, middle income countries a lower price and with industry we can get fairly close to basic manufacturing prices. If we can preserve that tiering for the poorest parts of the world, that is a very healthy part of it. Could industry do more? Yes, they could, and for example we are encouraging and working with industry to support more of the clinical trials at a country level. Industry is quite often able to provide some of the finance provision of vaccines for free, say, whilst we are going through the testing phase.

Q821 Chairman: What about developing some production facilities in the area? I know that is difficult in Africa particularly, but it is not difficult in many other areas and it is happening, is it not?

Dr Lob-Levyt: GAVI has made a decision to mostly use our finance around what we call "market shaping", so that our ability to purchase, our long-term financing and innovative financing is used as the pull mechanism that encourages industry to invest itself in what needs to be done. We do not invest in the basic research, for example. We do not see that we have the competence or would get returns in that way, nor would we invest in establishing plant in, say, India or elsewhere. We would rather see, and we are seeing this and have had an independent study which has confirmed this, industry coming in forming partnerships in India and elsewhere, and there is a transfer of technology and joint ventures now being set up. The only competence of GAVI's is its money is to incentivise that.

Q822 Chairman: I am not making myself quite clear. My question was whether in your discussions with the pharmaceutical manufacturers you discussed the setting up of production facilities in that country, not you yourselves doing it.

Dr Lob-Levyt: That is something that we are interested in and we discuss that with industry. One of our concerns is always about having sufficient capacity across the world. It is a really difficult situation to be in when you are at marginal capacity

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because, if one plant closes down, it can close down for a year or two because of biological safety issues. We are concerned to have sufficient capacity and competition. We talk a lot with industry about what their plans are and what is happening, but I would not say this is something we have a very strong influence over through that discussion, it is more about understanding what is happening.

Q823 Lord Desai: Basically, we have been talking to quite a lot of people giving evidence, and one of the points has been the overlapping of bodies. We have talked to UNITAID, the Global Fund and others, and the question was what were they doing that others were not doing. I ask the same question of you. Is there scope for some kind of rationalisation of what you do and UNITAID and the Global Fund do, or maybe not?

Dr Lob-Levyt: I think, as I said before, that in this rather exciting and welcome situation where a thousand flowers have bloomed as a response, which I think is a healthy thing because it promotes different ideas and competition, from a developing country perspective this complex situation is really challenging. You will be aware of those studies that show Tanzania had 300 visits to the Ministry of Health in one year from NGOs, the Global Fund, a whole plethora of different organisations. We have to change that. The solution are country led frameworks to do that. Having said that, I think we need to better categorise the different kinds of Global Health Partnerships that now exist and understand where there is advantage in that distinction and where there is advantage in bringing some of those together. So you have largely advocacy initiatives, some about product development at the more basic end, and others that are principally financing instruments. We and the Global Fund are probably more of the last nature although, unlike the Global Fund, we use our finance in a more innovative way to get more product into market as a market-shaping initiative. I see that there is potential for merging some of these partnerships, maybe some of those in product development or advocacy, and I do not rule out eventual merger of GAVI and the Global Fund, for example. These kinds of things need to be thought through. We are very different from the Global Fund, in the way that we are organised. We are a much broader public-private dynamic and our Board is made up of private sector individuals as well as institutions, which brings a very exciting challenge dynamic whilst the Global Fund is more of a classical partnership of institutional representation. We need to understand those different dynamics which generate different benefits.

Q824 Lord Desai: Another issue was about aligning international efforts with national priorities. Who assesses these priorities? Do you assess the priorities? Do you have partnerships with the countries?

Dr Lob-Levyt: Basically, the priorities should be set by countries themselves and we should try and work behind those priorities, no question. In some areas in order to ensure that there is informed decision-making and priority-setting, information is needed, and I think we rely on the normative role of agencies such as WHO and others to ensure that the correct information is available to the country to make those decisions. A good example would be HPV vaccine, the vaccine against cervical cancer, recently introduced in the UK and certainly in other countries. That vaccine is less well-known and understood in the poorest countries in the world. Many of the poorest countries in the world would probably not be aware of the disease burden of cervical cancer amongst women in some of the poorest parts of their communities. Until that information is known, they may not prioritise that vaccine just giving this as an example but there will be others. Because we are now in a situation of new vaccines coming in against diseases which before we considered untreatable in the poorest parts of the world, part of this is about information-sharing to get that informed decision-making. Where we have to be very careful, and it is a challenge, is the distorting effects that we as global programmers can impose on national budgetary systems. If, through our enthusiasm and our advocacy, we are causing a country to take on a new and expensive vaccine that they have to pay for at the end of the day, there has to be a trade-off against another disease intervention. In GAVI, I think we have now got over that, because we insist on seeing how this fits into the national strategies over a long period of time. We are now talking about 10, 15, 20 year time horizons. We also have a much better understanding of how vaccine prices are declining and national budgets are growing. We did some interesting work, again through independent consultants, which showed that a package of vaccines, (including a theoretical malaria vaccine that we do not have yet), and given our long-term time horizons—it is clear that this long-term financing is so key in the way we introduce, co-financing and understanding how vaccine prices are declining and economies are growing. In all but perhaps five of the poorest countries in the world, that package of vaccines would never rise above between two or five per cent of a national health budget—provided we take this long-term time horizon. We are confident that what we are doing, if we take the long-term view, is not distorting. GAVI is prepared to heavily subsidise in these early years to ensure that we do not distort budgets. There will

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always be four, five or more countries where you cannot imagine, for various reasons of conflict or lack of resources, that their economies are ever going to grow. That is a humanitarian situation which we have to accept.

Q825 Baroness Whitaker: To return briefly to your synergy with other parts of the international system, how do you manage your relationships with the regional and country offices of the WHO? Are you going to be comfortable with one UN office?

Dr Lob-Levyt: I think the reform of the UN is absolutely vital if these institutions are going to survive; and, if they do not survive, that would be a disaster, because they are absolutely necessary. Maybe not all, but there are many that we would consider to be necessary, WHO is vital. It is a vital normative agency, particularly for the poorest countries in the world, where they do not have those capacities. We work not only with WHO headquarters—and they are an active member of our Board and provide us with a lot of the technical advice and support—but we also work down through the regions as well. We have WHO regional committees working with us and we rely particularly heavily on the Country Offices to support countries with the introduction of new vaccines.

Q826 Baroness Whitaker: How would that work technically? Would you be on their committees? Would they be on your committees?

Dr Lob-Levyt: WHO has its own committees that set normative standards, and we just accept and follow those.

Q827 Baroness Whitaker: At country level?

Dr Lob-Levyt: At the global level on the normative side. Sometimes we come up with a new vaccine and we ask WHO, with others, to advise us, “How should this be packaged? How should it be delivered”, and they come back to our Board and tell us how it should be done. They would consult with the Regions and the Country Offices to do that. The Country Offices are mostly about implementation, whereas the normative, standard-setting work and related thinking happens mostly at the Headquarters and goes down to the regions.

Q828 Chairman: Before we move on, I just want to pursue a little further this question of the number of organisations. You indicated there might be a need to merge in due course. What puzzles me is that, if you come here to Geneva or talk to the senior managing groups of these organisations, they are all determined to make it work. They are very able people, very committed, have a very clear focus on eliminating key diseases, and you can see why it works well, simply

because it is driven by people who have a very clear, specific aim and want to work together. I am not convinced that translates to ground level, where you might find many of these organisations doing slightly different things and, despite the best efforts of the leadership of all of these organisations, who if they were all put in a room would agree about everything almost instantly, that might not happen down on the ground. Does that make sense?

Dr Lob-Levyt: I think that is absolutely correct. You have a fairly unique moment in time, with some great leadership of different institutions who are very committed Margaret Chan at WHO and others, which provides a great opportunity. You are quite correct, these are large institutions and providing the internal institutional incentives to change behaviours takes time and is challenging, but we are beginning to see that happen. Again, I think the key is to make this country-driven. The IHP I am very enthusiastic about, because it can help us do that. What the IHP has committed itself to do, and I think this is really important, is to convene annually with that very high-profile global leadership and say, “Well, Julian, what did GAVI do at the country level? Did you change your behaviour?” So the Minister of Health from Ethiopia will be provided with an accountability framework that goes from the country level up to the global level and that says, “This was promised. It did happen” or “It did not happen”. I think that would provide a powerful incentive to all these institutions. There is another dynamic, not only that top-down dynamic but a bottom-up dynamic, which is very often found at the country level with development partners, WHO and others. There can be a local agreement on how to do things, and people are working well together. But, when it goes up to headquarters, for example even the UK, US or France, what happens can be rather different from what happens down at the country level. If you speak to most ministers of health in developing countries, it varies they currently feel there is quite a lot of traction about what happens at the country level but very little accountability up into the global level and that is what they would like to see happening. I think the IHP will help us get there.

Q829 Chairman: I understand your enthusiasm for the IHP. If you have a situation, which presumably must exist in some areas, where you have got a number of these organisations and you have not got a good country organisation, how does a national government like the UK or an organisation like WHO justify the use of the money? In other words, do you say, “Right, it is not working, we will stop it” after having tried to make it work? What do you do? There is always a danger, and you touched on it yourself, that if the electorates in the paying country

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begin to feel that money is not being well-used they turn against aid. That would not be the first time it has happened, although at the moment the political leadership on the right and left is much better than it has been in the past on all accounts, funnily enough. There must be a danger that some of these organisations are not functioning so well at the ground level, that gets noticed. Is it maybe a case where you say that some of these organisations ought to be merged, in other words the health architecture is too diverse? What are your comments on that?

Dr Lob-Levyt: There are two parts to that. One is where governments themselves in sub-Saharan Africa or elsewhere are not functioning well enough and where the institutions that are supporting them are not functioning well. We have to be driven by the results, and donors and those who sit on the boards of global institutions, multilateral or others, have a responsibility to ensure there is accountability to performance. Where it is not being delivered, no more money should be pumped into it, or the problem needs to be resolved. If you look broadly where systems are functioning well, national systems together with development partners at the country level, a lot of money does flow and it flows effectively. Where it is dysfunctional, you will see a lot less money flowing because countries cannot absorb that finance.

Q830 *Chairman:* Are there organisations operating in the countries of various types in delivering the aid systems which you think would be better merged? I am not necessarily asking you to name names, but do you think they would be better merged now because it is too diverse, it is too cluttered?

Dr Lob-Levyt: I would have to honestly say that I think we do need to think about respective roles and strengths in the long-term and simplify the world for some of the poorest countries.

Q831 *Chairman:* There is no mechanism for doing that, is there?

Dr Lob-Levyt: No, I think it extremely difficult. Have you have got any good ideas?

Q832 *Chairman:* Should it be a task for the World Health Organisation as a coordinator, if you like?

Dr Lob-Levyt: I think the World Health Organisation's strength is its normative agendas, setting normative standards, and less on the implementation side. On the normative areas, yes. In terms of coordination, it is national governments that should be put in charge through their development frameworks. There is a huge risk in putting one institution in charge of all coordination, one global institution. You really risk lack of fresh ideas, being in a situation of limited change, limited

accountability. I think it is fundamentally healthy to have a bit of competition, as it were, at the country level. Many developing countries are quite adept at managing that situation, but it is too complicated. Again, we need to work to national strategies and frameworks and agree to abide by them. Bilaterals are as much a part of the problem as are multilaterals, as are Global Health Partnerships. This is a collective responsibility.

Chairman: Yes. There is a theory that says democracy works best when it is messy and worst when it is well-organised. There might be an element of similarity here. I would not like to push the analogy too far, but you know what I mean. I would not like to push it too far in politics either!

Q833 *Baroness Whitaker:* Do you think that International Health Partnerships is the best way to simplify as much as is good?

Dr Lob-Levyt: It is one way of doing this, but I do not think it is the only way. Again, you need a WHO that works with partnerships but works as an institution with its own legitimacy and independence.

Q834 *Baroness Whitaker:* You mentioned collaborating much more closely with the Global Fund. But what about UNITAID. Is that not much closer to your kind of operation?

Dr Lob-Levyt: We will be having some meetings with UNITAID in the near future. They have been focusing mostly on the drugs side.

Q835 *Baroness Whitaker:* Sure, but drugs and vaccines are not a million miles apart?

Dr Lob-Levyt: Absolutely. Now that they are established, they have approached us and we are going to have some discussions with them about where we could be collaborating together.

Q836 *Lord Avebury:* Could there be particular collaboration on an Advance Market Commitment? If that was something that worked in vaccines, why should it not be equally effective in the wider field of drugs?

Dr Lob-Levyt: I think that is absolutely right. The Pneumococcal vaccine is a pilot, it is about to be set up—institutionally it can be done, financially is it efficient, does it work—and then it should be tested elsewhere.

Q837 *Lord Avebury:* But, because you have the expertise, you could transfer that to UNITAID?

Dr Lob-Levyt: Absolutely, if necessary.

Ms Bifani: On the advocacy and donor relations outreach side, we are certainly working together with UNITAID. We have just had people from UNITAID and GAVI in Brazil to meet with

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Brazilian Members of Parliament, because there is a bill in Brazilian legislation for support to UNITAID and GAVI. It was a verbal IFFIm commitment that was made from Lula to Tony Blair that we are following up in collaboration with the UK Embassy. This week, with UNITAID, we are in Senegal at a conference on global leadership and innovative financing, where we are both presenting UNITAID's model and GAVI's pilots on IFFIm and AMC together. On the advocacy side we do things together.

Q838 Baroness Whitaker: I think that very neatly leads into what is probably our last question area. You say that lessons from your public-private partnership business model could be useful to others, and you have obviously broken the ground on innovating financing, as you have said. We have heard quite a lot about that already, but if you have anything to add it would be helpful. As you know, we have to make recommendations and it may be that we should give a little bit of airtime to some of the innovations. Perhaps you would like to angle your remarks in that way. Could you also tell me if your Service Delivery Platform, which is a very interesting idea to get rid of the horizontal/vertical, is the same as WHO's diagonal structure. Or is one a subset of the other?

Dr Lob-Levyt: I will answer the second part first. We have agreed with WHO and the H8—leaders of the 8 major health agencies, which is another form of collaboration that is developing—that we will not use the term diagonal any more. We found it just as confusing as vertical and horizontal.

Q839 Baroness Whitaker: Service Delivery Platforms?

Dr Lob-Levyt: Very often, when you talk about health systems, that can be quite confusing for many people as well. That is what we try and use the term “service delivery platforms” to get over this, and it seems to work for us. You hear a lot about the “public-private” dynamic in health and development at the moment, and it is a term used very loosely. We have thought about this quite deep and hard and what does it really mean for GAVI. There is no question in my mind that, by having a Board and a philosophy that is driven by recognising there are values in the public and private sectors, where in development you mostly use public sector types of values, it is very useful to infect us with private sector thinking. On the new Board that we are creating at the moment, one-third of the seats will be reserved for individuals who do not represent institutions but come with particular skills out of the private sector to challenge us to do better. So when I report to the Board and say “We prevented 2.9 million deaths for \$1 billion” or whatever it might be, the traditional

public health community, among which I count myself, would normally feel delighted and very happy with that and we would move on. But the first and instant question from my private sector Board members will be “Well, Julian, why was it not 3.9 million? And why did you not do it for half the cost?” I think that is a very healthy question because development finance is so scarce. It is the most valuable of dollars and has got to be made to work most efficiently. I have learnt a lot working over the past three years with this different community, who want crisp decision-making, evidence of results and the want to understand how much it is costing and why can we cannot do it differently. Challenging the status quo is a huge value-added, but you need a Board with people who can do that. Having been in the development business for a long time, I can assure you that the boards of most other organisations do not self-challenge, it is quite a cosy relationship. In GAVI we do not have that, we have a very dynamic tension which is really important to preserve, and I have learnt a lot from that personally.

Baroness Whitaker: How would we frame that as a recommendation?

Chairman: With difficulty!

Q840 Baroness Whitaker: It is a very sound idea, something that a government can say is a good thing. But is there more in the WHO general machinery that our representatives should be pushing for?

Dr Lob-Levyt: I think there is openness in the leadership of WHO and they do recruit people from the private sector to some extent. There are also quite deep-seated sets of values within the multilateral system that perceives, in my view quite incorrectly, that there are not positive values to the private sector. It is seen in a very old-fashioned model. We need to recognise that there are strengths and weaknesses in the public sector, strengths and weaknesses in the private sector, and let us try and bring out the strengths of both and be clear about what we are trying to achieve and what skills are needed. In GAVI we desperately need experts in procurement, experts in working the markets. We could never have delivered the IFFIm (The International Financing Facility for Immunisation) without having a board member from Goldman Sachs who enabled us to be in contact with the markets, with the financial whiz kids in London and New York who helped us design IFFIm. You do not find that, quite frankly, in the public health community or in the multilateral system. When we went to the capital markets to raise our first US\$1 billion on bonds, they got the market stuff fairly quickly, they were pretty fascinated by how you do this with eight countries and make it legally binding and AAA rated, and they were rather impressed. They had to be convinced, but they got it

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fast. They wanted to spend all their time then asking the same questions you have been asking me: how do you make sure you get quality vaccines to children. For them, this was a fantastic ethical investment. We have made contact with a completely different community that is very interested in development now, because they have an ethical portfolio target that they have to make for the pension funds when they buy our bonds and they need to be able to understand and sell that. We are going to bring a completely different community into the development world. The private sector is a whole part of our society, the largest part of our society, that needs to be brought into development.

Q841 Chairman: You have obviously got a lot of knowledge and experience in the whole area of development now and you have heard our questions about the infrastructure and the whole strata of systems. If you were suddenly taken out of your present job and placed in the job of being adviser to the President of the World Bank, what would be the advice you would give on this? I would quite like to hear from your colleagues also, who have been fairly quiet, to see if we can get some creative tension here! Who wants to start?

Dr Lob-Levyt: I will go off the top of my head and give my colleagues a chance to come in. I would probably ask for three things. One is they need to spend more in the social sectors. They have been spending less and less in health for various reasons, so we want to turn that juggernaut around. For them to be able to do that requires them to simplify their systems so that they are less onerous on developing countries, because traditionally it can take them years to negotiate a loan with the World Bank. We need to change the dynamic of developing countries to be prepared to request wider loans for the social sectors because at the moment they are reluctant to do that.

Q842 Chairman: Why?

Dr Lob-Levyt: There is a feeling that loans should only be taken for other sorts of infrastructure, roads, dams, construction, rather than for the social sectors. We need to change that dynamic so that developing countries themselves see the value of taking a loan in the social sectors. We need to create a World Bank that perhaps in a more listening mode and is able to really carefully listen to what developing countries say. Rightly or wrongly, it has a reputation of top-down expertise and a certain approach, which developing countries may not appreciate. They may not naturally turn to the World Bank for advice because of perceptions of what it has stood for in the past, but that is changing. Let me be clear that the World Bank is an amazing technical resource and, as

I have said before, it is absolutely vital that the World Bank engages 100 per cent on the health sector, otherwise we will never get the development goals. They have great expertise and their niche is clear, but they need to be supported to do that.

Mr Adlide: I will jump in! I would say a few things. One is creating a comparative advantage, and the comparative advantage of the World Bank is large-scale financing, so it does not seek to be all things to everyone in every country. The problem that we have with the World Bank one they share with others, is what I heard a Cambodian Health Secretary say, which was, "Please close the gap between the rhetoric at head office and what we see in the field", which was what Julian was just speaking to. The people in head office are all saying, "We are all working together, we are part of the IHP", and in the field a team comes in from the World Bank and studies in a narrow context. To me, that speaks to the issue of perhaps moving to a knowledge-based approach rather than evidence-based approach, because the evidence-based approach seems to be a global evidence picture—it can be top-down, one-size-fits-all, whereas if you start talking about a knowledge—and contextualised-based approach you are able to put the country more in the driver's seat in that relationship and able to listen, as Julian said, and able to draw the lessons from that context that would be most appropriate. On financing, the issue is both volume but also long-term financing. This is the lesson, I think, we have learnt in GAVI. If I were to take your challenge and provide some advice to the World Bank, it would be about how we can extend the frameworks that we are talking about in terms of grants and loans to countries and set up some confidence there by being able to commit for 15 or 20 years. We have always been scrambling in development to say, "Let us get some real results, let us prove that this can work" and sometimes it can be in an election cycle with donor governments, it is quite short-term. The Millennium Development Goals reached out to 2015. It is pretty obvious that we are not going to have solved the world's development problems by 2015, but one of the things we have learnt is that by giving a longer-term timeframe there is potential to do it, both because it gives the countries themselves some confidence on the extent of that external support but also because it has that market-shaping effect too so that other players, the private sector which is so critical to sustainable development, is able to be conscious of the fact that there is something out there, there is a development market out there that we can be an active player in.

Chairman: Anyone else? No? Thank you very much. That was very useful. If you do have any more thoughts or ideas that you want to spell out in more

detail, do write to Mr Preston at the House of Lords and we will take that on board. We hope to have our report in July at some stage, and you will no doubt

see it. The evidence from the session will be on the website in a week or two's time. Thank you very much.

TUESDAY 22 APRIL 2008

Present: Avebury, L.
Desai, L.

Soley, L. (Chairman)
Whitaker, B.

Examination of Witnesses

Witnesses: MR PHILIPPE PETIT, Deputy Director General, and MR ANTONY TAUBMAN, Acting Director and Head of Global Intellectual Property Issues Division, World Intellectual Property Organisation, examined.

Q843 Chairman: Welcome. Thank you very much for your time and for coming here today. As you know, this is the Committee on Intergovernmental Organisations and in this particular study we are looking at the way the intergovernmental organisations address the issue of contagious diseases and the UK's financing of those organisations, its involvement with them, and how it might or should change. The events here are being recorded, as you can see. You will have an opportunity to see the record in draft form before it is finalised and published, so if you want to make any factual corrections you will be free to do so. We would very much like you to treat this as an exchange of views. So, if either of you want to answer questions, please do so. After we have finished, if there are things that we have not covered that you think we ought to have, or you want to clarify, then please feel free to write to the Clerk at the House of Lords. Perhaps I could start by asking you to introduce yourselves in terms of what your job roles are, your positions in the organisation, and then I want to ask about the organisation itself.

Mr Petit: Thank you very much. Good afternoon, my Lords. It is a pleasure to meet you today. I am Philippe Petit, Deputy-Director-General of the World Intellectual Property Organisation, after having been a diplomat and ambassador. Tony Taubman is the Head of the Global Intellectual Property Issues in the organisation. Before starting, I would say that, as members of the Secretariat, we can only express the informal views of the Secretariat which are not officially confirmed positions of the organisation. That being said, and please note it, we are at your disposal to provide any information that you might find useful for your mission.

Q844 Chairman: Mr Taubman, would you like to add anything? You are in Global Intellectual Property Issues.

Mr Taubman: It is an awkward division name, it is called the Global Intellectual Property Issues Division. That is long shorthand for a cluster of related issues, ranging from traditional knowledge, genetic resources and folklore, through to such issues that you are touching on—public health, human rights and issues related to biotechnology, life sciences, innovation, food security and so on.

Q845 Chairman: To help me understand this a bit, by background are you both lawyers? Is that the background you expect in a job like yours? Is that right?

Mr Petit: It is not contradictory with being a diplomat!

Q846 Chairman: Obviously, we have a particular interest in the TRIPS Agreement and you administer a number of the international agreements, but TRIPS is very much the WTO one as well. There is an obvious question here for us as to who calls the shots, in a way—WTO or WIPO. Perhaps you could start by talking us through the relationship between the WTO and WIPO, particularly in relation to TRIPS.

Mr Petit: In the questions we received there is mention of this relation operating as a tandem between the two organisations. The question is: is it fair to suggest that. I would say it is neither fair nor unfair, it is not exactly accurate. The TRIPS Agreement is a compendium of the 21 WIPO Treaties which existed in 1995 when WTO was formed and the TRIPS Agreement was concluded. It does not integrate the most recent WIPO Treaties, like the two Internet Treaties and the Singapore Treaty on trademarks. TRIPS and WIPO have different roles. WTO has the capacity to sanction violations of intellectual property protection as established in the TRIPS Agreement at the time of international commercial transactions. The WIPO mission is to help each country to enhance its own innovation and creation capacity through intellectual property and make the national intellectual property systems more compatible and user-friendly around the world. If you would keep the image of a tandem in your minds, you would have to consider that the tandem is ridden by an elderly teacher and a much younger policeman. Of course, as in your question, the young policeman with his weaponry attracts much more attention and is more visible than the elderly teacher.

Q847 Chairman: That is a rather nice analogy.

Mr Petit: The other part of the question was with which other international governmental organisations does WIPO collaborate in the public health arena. I think Tony can answer that directly.

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Mr Taubman: We have a wide range of collaboration with the World Health Organisation. Again, I think there is a tendency to see these forms of collaboration in power terms, as you say, in terms of who calls the shots or who is on top. Certainly, at the practical level, the desk level I work on, it is simply a natural collaboration. We are working with the WHO on a range of issues which I can touch on in more detail later. There is an absolute hunger for more focused, practical, technical information to provide a factual foundation for policy-making and the kinds of choices that WHO has to make on public health issues. We do not see our role as contending with them or offering a competing vision of the world, but rather providing what we can in terms of technical information, whether it is about the legal issues or the practical impact of patenting activity, that kind of thing. I have Exhibit A here, which is a number of the studies we have prepared for the WHO. We are scrupulous to respond to the needs expressed by the WHO as the organisation formulating the policy at the international level on public health. We do not attempt to second-guess their judgments. We respond to the needs expressed and try to fulfil them with factual input. There is a specific focus, of course, on certain TRIPS mechanisms in relation to access to medicines. Again, our approach, as you say, has been as lawyers to provide practical advice at that functional level rather than saying who has got it wrong, who has got it right or who is in charge here. It is hard to convey, but it is a more practical collaboration.

Q848 Chairman: Could you give us some examples, particularly in relation to WHO and public health. What sort of things would give us a picture of the way you are working with them?

Mr Taubman: For example, in the area of neglected diseases, which was a concern of the WHO Commission on Intellectual Property Rights, Innovation and Public Health, we have developed a set of what we call patent landscapes, which provide snapshots of relevant patenting activity in these fields. For example, on some of the rare diseases, what is the pattern of activity in relation to research on leishmaniasis, leprosy, TB or malaria; what is actually going on out there; who are the new players; what are the established players doing; and geographically what is going on? The experience in Europe is very different from the experience in sub-Saharan Africa. To get a practical picture. There is a tendency to see the world through a single lens but, of course, patents are territorial rights, they are very different in different jurisdictions. To break the issues down in a practical way is one of the means of clarifying options.

Q849 Chairman: You say “in a practical way” in order to do what—help the WHO allow a country to do something which it thinks it would not otherwise be allowed to do? Is that what you mean?

Mr Taubman: It goes in two directions. One is looking at the overall trends, so from a broader policy perspective, what are the innovation patterns relating to neglected diseases. That is one of the broad issues. It is more of an overview, a macro—

Q850 Chairman: That is the overview bit which says that these rules or these laws might apply in this situation in that country. But what about the more focused bit?

Mr Taubman: We have indeed been working with the WHO on a more focused question, which is, put simply: is this patent in force or is it not, in relation, say, to Kenya or to Ghana. It is a technical matter: that is simply a piece of factual information about the presence or absence of a patent in that country, and its legal status there. Because the information is far easier to get for the big jurisdictions, US, Europe and Japan, there is a tendency to focus in those areas, but legally the situation of a patent in the US is irrelevant if you are in South Africa or Venezuela. It is a matter of matching up the available information with policy need. It does get down to very practical matters, such as in relation to specific antiretroviral drugs and whether there is a patent in force in this country or not. Ultimately, that is a strictly legal matter. We do not give legal advice because that would be a judgment about the law of Ghana or Kenya, but the broader information is vitally needed. Essentially it is a technical question as to how you get access to the information and get it in front of the policy-makers in usable form.

Q851 Chairman: Could you give me an example of where you have been able to help the WHO interpret or relax, whatever the appropriate word is, relevant rules in order to enable them to get the drugs or vaccines through to the people who need them? Have you got any examples of that where they would have said, “Look, we need help on this. We know the drugs are needed there but we cannot get them through, there is a legal blockage to do with either the WTO or WIPO, please help us”? Can you give me an example of that?

Mr Taubman: Not yet, unfortunately, because this programme I have mentioned is just ramping up at the present. Literally two weeks ago we had a workshop exercise bringing in WHO to look at methodology, to look at policy needs, and to match them up a lot more. I cannot point to a specific outcome from that point of view.

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Q852 Chairman: Then put it the other way around: have you had situations where the World Health Organisation has said, "We need this help but, in so many words, you have not been able to help us"?

Mr Taubman: No, I do not think so. As I said earlier, we have been concerned not to step into their area of competence, which is setting their priorities on public health, so our work has been tracking the policies set by their Commission, by the Intergovernmental Working Group, so we take the lead from them. It is currently a matter of ramping things up. If you think of this from a global perspective, these are not easy questions to answer. There is a temptation to skim the surface and get a quick answer, but it is almost always misleading. We are deliberately taking a bit of time to ramp it up in the expectation that this will ensure that the answers will be better and quicker, more responsive next time.

Q853 Chairman: Perhaps I could put this question to Mr Petit. We have been told that both WIPO and WTO at times have got in the way, not necessarily intentionally, of delivering drugs to people who, if they do not get them, die; and they would say somehow or other we need to clear this blockage. What would you say to that?

Mr Petit: There is simplification, where some people consider that intellectual property is the obstacle against access to medicines. This is a very serious accusation, because it would mean intellectual property would be an obstacle to the right to health and the right to life. Intellectual property is one thing and access is something different. Intellectual property is one of many elements which intervene in the access. Other elements are price, health services, availability of the medicines and so on. Intellectual property is one of the elements and that is why they are having these negotiations in WTO about intellectual property for medicines. The TRIPS Agreement has now been amended so that the developing countries which are able to produce generic medicines can produce them under a compulsory licence, not only for their own needs but also for the needs of least developed countries which are not able to produce these generics. This helps, but it does not solve the problem of access to medicines when there are many other aspects, including the price policy by pharmaceutical companies. There has been a big evolution in that regard since the famous case in South Africa where pharmaceutical companies got the feeling that their image was becoming very bad and they had to change it. I repeat, it is not only a matter of intellectual property, although intellectual property is one of the elements.

Q854 Chairman: I do not think any of the organisations would say that it is just that, I think they all say the major problems are about the

infrastructure, the health structure and so on. But obviously we have an interest in finding out what blockages there are, whatever they are and wherever they are. My colleagues might want to come in in a moment. I liked your image of the tandem, but I just want to ask how much clout, how much influence do you have with the WTO? If you feel that something in the WTO's approach to this does make it more difficult for developing countries to get or use the drugs, or create the drugs that they need, how much influence would you have on them?

Mr Petit: I do not think we have any kind of influence. We have different governing bodies. The WTO has its own governing body which defines their policy and we have our own governing body, the Assembly of the Member States, which decides ours.

Q855 Chairman: You do not talk to them?

Mr Petit: I cannot say that we have an influence. The influence at the beginning, as I mentioned, was the fact that the TRIPS Agreement integrated all the previous WIPO Treaties. One may think that in the future TRIPS Agreement will progressively integrate other treaties negotiated in the framework of WIPO, that is the main link. There is also a cooperation agreement between WTO and WIPO, which was concluded in 1995 at the beginning of the TRIPS Agreement, according to which the two organisations cooperate mostly in technical assistance and capacity-building for developing countries. In advising on the legislation of developing countries, WIPO has to advise the countries on conformity of their draft legislation with the TRIPS dispositions. It is an agreement between the two organisations that WIPO has to advise them on the compatibility of their legislation with the dispositions of the TRIPS Agreement. Of course, we do not decide for the developing countries, but we are in a position to tell them: "If you draft your legislation in this way, it is compatible with TRIPS. If you draft it another way, it will be open to interpretation. If you draft it another way, it will not be compatible with TRIPS". That is the main relation between the two organisations. We can advise the country on the compatibility of their legislation with TRIPS, but we do not advise the WTO on the implementation of TRIPS and their interpretation of the TRIPS Agreement. There is a TRIPS Council which is in charge of that, and it is not WIPO.

Q856 Chairman: I fully understand they are separate organisations and there are separate Boards for WTO and WIPO, I am just puzzled in a way. I do not know whether I am picking up the right impression, but you are giving the impression you do not particularly have any liaison with your equivalent offices in WTO, that you do not discuss matters of common concern that might come up. Or do you?

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Mr Petit: Yes we do. Two years ago we created, by an informal agreement between the two Directors-General, a working group which meets from time to time, comprising members close to the heads of the two institutions. They meet and exchange views on the pending problems. This is quite new, two years old, and it does not meet very often.

Q857 Chairman: Would that be a committee where maybe one or more of the intergovernmental organisations operating in the field who feel that intellectual property rights are getting in the way of the supply of drugs could say to that organisation, "Look, we want you to look at this"? Who would they go to?

Mr Petit: The problem is more a question of sanctions by WTO than a problem of the role of WIPO, which is advising the countries. We advise the countries, but we have no sanctions capacity. One should bear in mind also that intellectual property protection is not an absolute monopoly, as many have a tendency to think. The aim of intellectual property protection is to promote innovation and creation, to promote, reward and support innovation and creation. To do this we have mostly to avoid that the innovator is dispossessed of his or her invention by a third party. If the creator or inventor agrees to give his invention for free, to have the technology transferred to anybody, put it in the public domain, if he agrees, we have no objection at all. What we want to avoid is that he or she would be dispossessed of their innovation or invention. We may have the possibility of talking about genetic resources and traditional knowledge, on which Tony Taubman is a great specialist. There the question is to protect the knowledge of an indigenous community, for example, from the exploitation by a major company of a third country without their agreement. It is the same for innovators and creators. If they agree to transfer their knowledge, put it in the public domain, transfer the licence, a licence which is sold and they can fix the price as they wish, it can be a very low price or a high price, or transfer it with a contract for receiving royalties in exchange, all of this is possible; it is not contrary to intellectual property protection. What we are looking for is to make sure that nobody is dispossessed of his or her invention, so that creation and innovation are supported and promoted.

Q858 Baroness Whitaker: To return a little bit to your organisation, I think you say that you have got some 250 NGOs and IGOs with official observer status. There are some who say that the majority of these are trade or industry organisations and, in fact, you do not have much representation at your meetings of public health or social NGOs. What is the situation?

Mr Petit: I have prepared a copy of the list of these 250 non-governmental organisations which are accredited to the General Assembly.

Baroness Whitaker: Thank you.

Q859 Chairman: That is helpful.

Mr Petit: Others are accredited to particular committees, and maybe Tony will give you more information on this. I can leave it to you to qualify these non-governmental organisations as you wish. For instance, you may appreciate which are trade or industry organisations from wealthy countries and which are in favour of public health and humanitarian interests. You will see that it is not always very clear. For instance, there is an NGO called the Generic Pharmaceutical Association, so it is an industry organisation. But you may consider that generic industry is favourable from the humanitarian point of view. There are very vocal associations speaking in the name of developing countries which, in fact, are representing the interests of consumers associations in rich countries. Consumers do not like to pay for any rights, so they are fighting intellectual property rights; but they think it is better to present it as a defence of developing countries than being as a defence of consumer associations of rich countries. In fact, all NGOs which request accreditation are accepted. We do not remember any case of an NGO accreditation which had been rejected. The Member States decide, but it is a formality: we give them the list of NGOs requesting accreditation and they always accept it. The door is wide open. In this list you will see an NGO like the Civil Society Coalition, which is a coalition of many NGOs, some of them very well-known, like *Médecins Sans Frontières* or Oxfam. They belong to a coalition which is the spokesman of these different NGOs, and coalitions like this are very active in our meetings and debates, which is not the case for all of these 250 NGOs; some do not participate much in our meetings. There are also NGOs especially accredited to our Intergovernmental Committee on Traditional Knowledge and Genetic Resources, for instance, or some are especially accredited for the Development Agenda. Tony can tell you a bit more on this.

Mr Taubman: Perhaps the image that is presented here is subject to a bit of time lag. The most striking phenomenon in the last eight to ten years in intellectual property has been a massive broadening of the stakeholders involved, the range of interests engaged. For me, the most striking example of that, essentially because it is part of my day job, is the work we have done on traditional knowledge which literally did not exist ten years ago. There is a dedicated intergovernmental committee working precisely on this issue, working towards international outcomes. It accredits many NGOs, in fact about

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200, directly to that process because they have a specific interest in this area. The majority of them are indigenous communities or local communities; they represent traditional knowledge-holders.

Q860 Baroness Whitaker: This is to protect the ownership of a certain plant growing in an area that might be used for a medicinal purpose? Is it that sort of thing?

Mr Taubman: That kind of thing. It is more the knowledge about the distinctive medical uses of the plant than just the plant itself.

Q861 Baroness Whitaker: The process?

Mr Taubman: There are concerns that knowledge may have been used inequitably and that there is insufficient recognition of the community that has nurtured this knowledge in the first place. That is the nature of the work. In terms of the process it is entirely driven by that concern and perspective. When you think of accreditation and active involvement, we have indigenous communities from across the globe now taking part in our work. One aspect is the formal process of accreditation, but the other aspect is concern about effective participation. We were told again and again that indigenous communities particularly did not have the means, the resources, to come to a meeting in Geneva. So a fund has been set up specifically to support their participation here. I must say, that has really changed the flavour of the work. Apart from the formal accreditation side, it is a matter of their active participation as well.

Q862 Baroness Whitaker: That is very helpful. Would you nevertheless say that the majority of non-governmental organisations which are there at your meetings still tend to be trade and industry? Or do you think it is evenly balanced now? Most of these, from a very quick look, look to me to be trade and industry.

Mr Petit: It is more a matter of impression. I will give you my impression. In the debates, those who actively take part are in favour of the defence of human rights, they are active, they are militant, they defend the interests of developing countries and humanitarian causes. Others are present, it is difficult to say in which proportion, it is difficult to qualify them sometimes, but they are not so active, not so vocal. I think they may have other means of lobbying. They follow the debates but do not intervene that much.

Q863 Baroness Whitaker: There are two developments which also fit in with your organisational role. I see that the new WIPO Committee on Development and Intellectual Property, according to my briefing, had its first

meeting on implementation in March. I would like to know if that will usher in any changes to your activity. I also understand that you are soon going to have an election for a new Director-General. Do you anticipate changes in regime? Are we going to hear some more good news now?

Mr Petit: In fact, there is a link between your two questions because the organisation for a short period is in a situation of transition between the former direction and the new one. A new Director-General will be elected soon. This has a consequence on the Development Agenda. The Development Agenda was adopted unanimously by the General Assembly of the organisation last September, but at the same time there was a crisis linked with the leadership of the organisation. The Development Agenda went somewhat unnoticed because everyone was concerned with the crisis and not so much with the Development Agenda. I think one of the first responsibilities of a new Director-General will be to promote this Development Agenda, which has remained almost unnoticed since last September, and then to implement it. The essential idea of the Development Agenda is not only to approve the 45 recommendations which were negotiated between the Member States but to have a global approach to development in all the activities of the organisation, a bit like the Doha Round has been baptized the highest development round in WTO. It is a global approach for us to put the accent on the fact that intellectual property is not an end in itself. Its end is to promote innovation and creation, which is as important for developing countries as it is for industrialised countries and is a factor of growth and development. This is the main idea of the Development Agenda, that it should inspire all the activities of the organisation and not only implement practically each one of the 45 recommendations.

Q864 Baroness Whitaker: I understand, it will be a sort of mission statement. What might be the practical outcome in the way you go about your business or your priorities or activities?

Mr Taubman: I can give two very recent examples. Two weeks ago I was in India, where the WTO was holding a regional workshop on implementing TRIPS in the interests of developing countries, so a strong focus of that was not the legalities in isolation but the practicalities of giving effect to the flexibilities that we covered earlier. Our role was to provide technical support, advice, input on a range of issues from access to medicines through to the recognition of indigenous knowledge, for example. That is routine. It does not get reported because it is so much embedded in what we do. As a second example, last week I was in South Africa working with the Indigenous Knowledge Systems Policy Group, who are looking at practical ways of building on the

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indigenous knowledge of South African communities and building that into their research and development systems in the pharmaceutical area. This program combines the goal of greater recognition, in a legal sense, of traditional knowledge with meeting the pressing health needs of the community. Again, it was entirely practical in character but was infused by the kind of policy settings espoused by the WIPO Development Agenda, a focus on social and economic development and a much more flexible look at what intellectual property is and does and how to apply it to real needs of developing countries. It is difficult to report on that globally because it is so infused in what we do. These two examples were literally in the last three weeks.

Q865 Baroness Whitaker: If I could ask one final question to try and clarify this. If you have a local community, quite poor, which has some useful plant medicine which they prepare and use, and a big company from outside wants to come in and exploit this a little bit more commercially and not deal in the local community with a fair deal, whose side would you be on? Would you be assisting the local community to protect its quasi-ownership, although it is not a very scientific one? Or would you be protecting the sophisticated scientific exploiter for the common good of this? How would you operate in that circumstance if you were called in?

Mr Taubman: You can look at it on two levels. The first is at the political level. Plainly, those who are in need of support from a UN agency, those who are lacking in resources, lacking in practical legal know-how, are the ones in need. The important point is that we are directed by the Member State concerned, we are not a free agent here. The Member State concerned would be guiding us as to what their overall needs were.

Q866 Baroness Whitaker: Which of these two alternatives do you prefer? The national government might prefer the big company, they might get themselves a good deal out of that.

Mr Taubman: At the practical level, it really depends on what the needs are. At the legal policy level, I would offer maybe a slightly casuistic response. I genuinely believe it is a matter of developing beneficial partnerships, because it has been shown not to work if there is a zero sum winner-takes-all approach. The problem is that the needs, the cultures, the ways of viewing the world, can be so disparate between potential partners. One of the difficulties is to see these kinds of complex partnerships squeezed into the question of what is a fair royalty rate. Indigenous communities can resent that approach because it suggests they are reducing what may be sacred traditional knowledge to a kind of cash-crop. It is a matter of building a stronger partnership which

involves community capacity-building, bringing traditional healers into the research and development community and letting their interests and values infuse the whole process. It is not such an arm's length arrangement.

Q867 Lord Avebury: Can I just take up where you left off, Lady Whitaker. To me this is a very fascinating question. If you try to enter into bargains with indigenous people to say, "You let us have your knowledge and we will assist in your development", that would interfere with the transition of their product into a useful pharmaceutical, because you would have all the lawyers coming down and arguing about how to couch an agreement that would be fair to both sides. As Lady Whitaker has indicated, that may be a very difficult process. Whereas if you said, "Let us consider how to develop the indigenous communities" and as a totally separate matter how you turn the products into useful pharmaceuticals and you do not try and enter into some equation between the two, you might more rapidly develop products which they have obviously got in very rudimentary form because they do not process them. Is not the attempt to put these processes together a mechanism for causing serious delay and injecting a lot of financial cost into the process?

Mr Taubman: I would respectfully suggest that that is not the case for several reasons. Perhaps the most interesting one is that we are not talking about traditional knowledge as a litany of interesting facts, but rather as established bodies of knowledge and innovation systems in themselves. A lot of what is important knowledge about traditional medicine is not that this or that herb is potentially useful for arthritis, but rather that there are synergistic effects that a plant, when harvested in such a way and combined with such other herbs, in the light of these observed symptoms, has this effect. That means that to get the full benefit from this knowledge you need to step inside that knowledge system and work with it. There is no alternative to bringing the community in as part of the overall arrangement. A second reason is an argument from the point of view of overall equity. That has been pushed very forcefully at the political level by indigenous groups themselves, but also by developing countries, who argue that it is simply inequitable to view traditional knowledge as simply just out there for anyone to use.

Q868 Lord Avebury: Public domain?

Mr Taubman: Public domain, and just a resource for the nimble to help themselves to, because that tends to occlude the genuine contribution made by indigenous communities. There is a broader equitable argument. These two rationales converge if you look at the practicalities of bringing a new pharmaceutical through the whole R&D pipeline.

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Very few companies would be willing to invest in that risk and that difficulty not only with that technical uncertainty, but also with this extra political layer. In short, it is not good business to be branded a bio-pirate while you are already going through the risky R&D process. You do not need to buy yourself yet another area of uncertainty and risk and political difficulty at that stage. I think it is a much more sustainable, effective package to look at it holistically, rather than to try to separate the knowledge providers and users, but obviously we are talking about very, very diverse scenarios. As a broad proposition I would suggest it is a way that works better. One final observation is that developing countries are increasingly looking to indigenous medical knowledge to be integrated with their health policy overall, as it is obviously more affordable, more accessible than waiting for the next miracle drug to drop off the pipeline from the developed world. There is a broader social interest in bringing traditional medicine into the mainstream because there are all sorts of regulatory issues and so on, but as a discernible trend that is very clear for the most pragmatic reasons and also for these broader questions of equity and cultural recognition that lie behind this movement.

Q869 Lord Avebury: It would be very interesting to me, I must say, to have an example of where this process has led to a successful development. Although one is aware of cases where people have capitalised on indigenous knowledge and not given anything to the originators of it, I am not informed of any process where there has been a reciprocal benefit to the indigenous people. If we had a little note on that, I think it would be very interesting. Can I ask you a second question about what you said on genetic resources. I do worry that a lot of genetic information, including genome sequencing, is being taken out of the public domain and made the exclusive property of big companies, which then take out patents and deny them for the benefit of the wider community. Is that within your terms of reference?

Mr Taubman: Yes, at two levels. I have brought a draft we have been working on on the interplay between intellectual property and bioethics. We work with an inter-agency group within the UN on these issues. As you well know, this has been a persistent concern: how to reconcile bioethics with intellectual property law. We are working through it from a policy point of view, not in terms of passing judgment to say, "You are right and you are wrong", but rather to help frame the issues, to sift them through. For instance, the observation has been made that a certain proportion of the human genome has been patented and is in private hands.

Q870 Lord Avebury: Yes.

Mr Taubman: But what does that mean in practice? There is a very big difference between using a shred of my DNA to code for an artificial form of insulin, as against asserting a claim against the DNA integral within my own cells. It gets very technical very quickly, but I think it needs to be, just to sort out these concerns. In this area, too, we are working with our UN partners to sift through patent information, because perhaps the biggest problem is making sense of mounds of patent information, and distilling out useful observations for policymakers. For example, we have commissioned an investigation, in the agricultural field, of patenting on the rice genome. This helps to prepare for more difficult work on the human genome. This research found that around 74 per cent of the rice genome is covered by patent applications but only 0.26 per cent is covered by granted patents. There is a technical distinction, if you like, between what the original applicant puts in as an ambit claim, as a broad claim, and what is actually permitted by the Patent Office. We see this dramatic narrowing. That might be seen as good news or bad news, but it is certainly valuable information to get a grip on exactly the concern about patenting the genome.

Q871 Lord Avebury: Is it part of your remit to prevent the gradual narrowing of the public domain through this process of people doing work on genetic sequencing and then removing it by means of patent applications or patent successes?

Mr Taubman: Yes, indeed. Not in terms of intervening—we would not shoulder aside a British patent examiner and say, "You have got it wrong here"—but by systemic improvements, because it is simply a very demanding task to sift through this data and make a genuine assessment of whether this claimed invention is real contribution to human know-how; or whether they have made an opportunistic claim after applying a very routine way to sequence a gene. There are real systemic demands that come into play in answering those questions. We have done work, particularly in relation to genetic resources that are typically held by biodiverse countries, to ensure that patent examiners are more able to assess, if I am claiming this is a new way of creating a therapeutic protein, that I have genuinely added something to what is already known and what is already available in nature. To a large extent, it is a matter of getting good useable information literally on the screen of the patent examiner. Once again, it becomes very technical very quickly. That is a large part of getting it right. Very few people ultimately are quarrelling with the broad principles of patenting, and we see convergence of understanding there, not a formal convergence but a convergence in practice. But it is a long step between the principle and the

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actual practice when you are a patent examiner faced with a desk piled high with sequence listings and making sense of them. It is at that systemic level that we are trying to develop more effective mechanisms, not to pre-empt or pre-judge what are sovereign findings of national Patent Offices, but to build up the platform of support for their decision making.

Q872 Lord Avebury: And also to examine the consistency between the national Patents Offices, is that part of your remit?

Mr Taubman: Certainly not any legal remit, that would make us a court of appeal, if you like, against sovereign national processes, and there is an understandable sensitivity about that. Once again, it is more of supporting offices that we are seeking to cooperate with and strengthen their own operations rather than making a precise assessment on our part. I think there would be a lot of sensitivity about that.

Q873 Lord Avebury: If I may turn very briefly to another question. On the TRIPS Agreement it has been suggested that the flexibilities which are built into it are in danger of being eroded because of bilateral free trade agreements. Have you any comment to make on that?

Mr Petit: I would say that this question might be addressed to WTO in the first place. Bilateral free trade agreements are in contradiction with the multilateral approach promoted by WTO, which is their mission. To answer your question, in my own view there is little doubt that bilateral or regional trade agreements may be dangerous for the flexibilities and exceptions in the TRIPS Agreement, since the strongest partner may impose its conditions more easily than would be the case in a multilateral agreement and in the framework of WTO. Bilateral trade agreements may contain what is called TRIPS-plus clauses, with more stringent clauses than the TRIPS Agreement itself. WTO is trying to say that there should not be such bilateral or even regional trade agreements, that the whole multilateral trade process should take place in the framework of WTO. But, as long as the Doha Round does not find an agreement, there is a development of these bilateral and regional trade agreements.

Q874 Lord Avebury: My second question concerns the technical assistance that you provide to developing countries. I think you have already partially responded to this in a previous question, where you said that there had been a recent international meeting on the practicalities of giving effect to the flexibility of TRIPS. The suggestion that has been made by some of our witnesses is that more emphasis is being placed on the obligations that States have under TRIPS and less on the flexibility,

and I would be grateful if you would comment on that.

Mr Petit: Certainly. I have already mentioned that there is a cooperation agreement between the two organisations, WTO and WIPO, that was concluded in 1995. Article 4 stipulates that the two organisations shall enhance cooperation in their legal technical assistance and technical cooperation activities relating to the TRIPS Agreement for developing countries so as to maximise the usefulness of those activities and ensure they are of a mutually supportive nature. In fact, WIPO gives legislative advice to developing countries and the organisation has a duty to inform them on the conformity of their draft legislation with their TRIPS obligations. WIPO would say whether it is in line, or open to interpretation, or not in line with their TRIPS obligations. It means that we have to help them and advise them on the conformity of their draft legislation with all the dispositions of TRIPS, which are not only the regulations but also the flexibilities and exceptions. We advise them on conformity with the TRIPS Agreement, not with TRIPS-plus. Maybe more important, our organisation advises the developing countries' governments and countries in transition as well, on national intellectual property strategies so that they define their own national strategies in the field of intellectual property. We advise them to define strategies which are adapted to the special conditions of each country, taking into account its level of development, its own culture and national characteristics. All of this is enhanced by the Development Agenda. We could summarise this by saying it is not one-size-fits-all, which is the expression that has been used in discussions on the Development Agenda. We have to advise on all dispositions of the TRIPS, including flexibilities and exceptions, but also we try to take into account the national characteristics of each country. Maybe Tony would like to add something.

Mr Taubman: Thank you, yes. Perhaps, again, this is an area where there has been a historic shift. The TRIPS Agreement came into effect for developing countries in 2000 for the large part, and I can tell you that in other guises—unrelated to my current position—I was personally involved in this process from 1995-2000, when there was something of a scramble in many developing countries as they took on a really formidable, imposing legislative task. That was one reason why there was an emphasis on implementation as such. As practical legislators yourselves, you could imagine us advising a national Government having to introduce eight parallel major intellectual property bills to comply with TRIPS. That in itself is an enormous task. That legislative effort was something of a concentration in that period from 1995-2000. However, since that time, and noticeably with the Doha Declaration of 2001,

we have seen a major shift in emphasis. It is not my area in WIPO, but I know the people working in that area are increasingly being asked by Member States, (and it is exclusively demand-driven) to advise on areas of flexibility. In the area of medicines this includes strategies for parallel importation, alternatives for protection of clinical trial data, implementation of the compulsory licensing mechanism established following Doha, and so on. It is a matter of putting before the Member States, “This is your range of options, these are your flexibilities” and ultimately the question is how do you want to flex them. That is a matter of national sovereignty—“Here is your space to work in”. We help to identify and define the options. Then it is a matter for national policymakers to go through the sovereign legislative process—“This is the formula we have worked out, this is applicable to us”. It is not our role to second-guess the national process but to lay out the range of options. I think my colleagues would say with confidence and pride that they do indeed lay out the full range of options right up to the very edges of that flexibility.

Lord Avebury: Can you get as far as laying out the range of options in a series of models without contradicting the one-size-does-not-fit-all? Is it possible to think in terms of the preliminaries to legislation, such as the instructions to counsel on what we would call a preliminary document that goes to the lawyers who draft the legislation in terms of the series of options that you mentioned? Similarly, in the national strategies on IP, can you lay out the series of options in a standard document which, while offering choices to sovereign states, allows them to pick from a menu, as it were?

Q875 Chairman: If you could answer that fairly briefly, it is a complex and important question but we are getting quite tight on time. I do not know if you can give a brief answer, or maybe write in if you cannot.

Mr Taubman: I can give a very precise example in the area of parallel importation, for example. There is a range of options from strict national exhaustion, as it is called, to entirely open international exhaustion, and the options set out are a spectrum between those. That is what would be given to reflect upon.

Q876 Lord Desai: A brief question about this episode in 2005 when there was this flu pandemic and at the time it was critical. Did you have any power to compel the pharmaceutical company to allow more production? Or, in general, do you think there are problems of IP preventing this sort of generic development?

Mr Taubman: Once again, we do not have express power to do that, it would be a matter of intruding in domestic processes, because the patents concerned

are held within national legal systems. However, it is an area where information has been desperately needed. I was in one country that year where there was a huge debate about this question. The question arose whether it would be appropriate to issue a compulsory licence for a flu drug but it turned out there was no patent on the drug in that country. We are talking therefore about a fundamental need for factual information which perhaps we take for granted in the developed world but is desperately needed elsewhere. Such information has important practical implications. For example, in this case the pharmaceutical firm Roche was not the patent holder (though it was often assumed to be), but rather was the licensee. The patent was held by a firm called Gilead, which was in the middle of re-negotiating its licence with Roche. This changed the whole complexion of how you practically deal with this situation. Once again, we would seek to provide information about what your options are, but to intrude in a domestic policy-making process or a choice over what—

Q877 Lord Desai: Is that sort of knowledge not in the public domain? You cannot just go to WIPO and find out?

Mr Taubman: In principle, it is in the public domain; in practice, in many countries it is very difficult to obtain. Once again, it is part of the background support we are doing, going from country-to-country and bringing this material into accessible digital form.

Q878 Chairman: Is it difficult to get in the public domain because it is not in one place? Or because you would need a legal interpretation? Or what?

Mr Taubman: There are two aspects. There is actual access to the patent document concerned, and in countries with limited resources and overworked bureaucracies the files are not in very good shape. It resembles my office, to some extent, with random piles of paper. It is difficult to get the information in a systematic way.

Q879 Lord Avebury: You could put it on the web?

Mr Taubman: To turn that pile of paper into something you can access, that is the very objective and we have a programme of progressively doing that right now. In time the problem will be solved. It is not a matter of unwillingness, it is quite a technical task to go back 20 years and digitise these paper files. The second aspect is the legal question, interpreting this patent under national law, and that is difficult. In the UK there are hundreds of years of patent law, there is some predictability about what is the exact scope of the exclusive right; but for a country that has recently introduced patent law there is no background of jurisprudence, so, unfortunately, it is inherently

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uncertain and that is something that will have to work its way through the system over time. It is difficult to assess in the short term.

Q880 Lord Desai: Even if I have signed the WTO and I am subject to TRIPS and whatever the patent is, it is under the old TRIPS, there is still no way of finding out whether I am subject to that patent or not as a country?

Mr Taubman: It is ultimately possible, it is just very resource intensive. When we work with civil society on these issues, they point out that the private sector does have the resources to pay people to spend a long time going through the documents, but an NGO looking to procure drugs for their humanitarian aid does not have the resources. It is about evening up access to information. But in principle it is there, it is a public document.

Q881 Lord Desai: I thought a patent was granted for all countries?

Mr Taubman: No, they are strictly territorial. This is one of the major difficulties in understanding that we find. For example some key patents are in force in the US and Europe but not in many developing countries, so it is impossible to legally assert patent rights in those countries.

Q882 Baroness Whitaker: Quite a lot of anti-malarials are fake and the WHO is concerned about this and uses the words “global public health crisis”. Whose responsibility is it to deal with counterfeit medicines? Is it yours or WTO’s? Is it Interpol’s? If there is more than one, who is the conductor of the orchestra?

Mr Petit: Counterfeiters are no longer isolated craftsmen, but more and more large international mafias counterfeiting medicines as well as cosmetics, agro-food products, automotive and aircraft spare parts. As far as medicines are concerned, we fully agree with WTO that the problem of counterfeit drugs is a global public health crisis. Under the aegis of WHO and the International Medical Products Anti-Counterfeiting Taskforce—IMPACT—which was created in 2006 led by WHO (and our organisation is an active participant in this taskforce with other international institutions, such as the World Customs Organisation and Interpol and other governmental and non-governmental institutions) WIPO contributes with legislative assistance, education, capacity-building and awareness-raising on this task of fighting counterfeit medicines, which are a large danger for health and sometimes for life. We have an action of capacity-building for judges, which we are the only organisation to do. Sometimes judges are not very happy to receive lessons from international organisations, but we organise seminars with some judges who are already very

competent who discuss with their colleagues and train them in intellectual property matters and fighting against counterfeiting. In the framework of this IMPACT taskforce, led by WHO, there are draft principles for national legislation against counterfeit medical products, which should be approved by the next World Health Assembly in May, next month. We contribute to this with the other organisations.

Q883 Baroness Whitaker: That is very helpful. As you see, the brief wonders if there are tensions between the work of your Advisory Committee on Enforcement and your Development Agenda. I have to say that I am not absolutely sure what tensions these might be, but maybe you can think of some tensions.

Mr Petit: There is no tension between the work on counterfeiting and the Development Agenda. There is one recommendation, which in fact is the last of the 45 recommendations of the Development Agenda, which deals with this matter and it is taken from the terms of Article 7 of the TRIPS Agreement. It is in full accord with the TRIPS Agreement, there is no contradiction and tension. What is more important is that developing countries know that counterfeit medicines are particularly bad for them. In fact, the proportion of counterfeit drugs is higher in Africa than anywhere else.

Q884 Baroness Whitaker: Indeed?

Mr Petit: It is a threat to the health and lives of the population. As a consequence of counterfeiting, companies in industrialised countries may lose money but in developing countries people may lose their lives, that is the difference. Developing countries’ governments are fully conscious of that. There is nothing against development in combating counterfeiting for medicines; on the contrary, it is part of it.

Q885 Baroness Whitaker: I agree with you.

Mr Petit: The authorities of developing countries need support to be able to control this plague.

Q886 Lord Desai: This is about the structure of your income derived from registration fees. People say that you do not have either the resources or the incentives to deal with public interest matters and help. Is that the case? Or do you feel that is not right, not a restriction on your activities, your self-financing methods?

Mr Petit: Well, there is no contradiction between our registration services which generate income and the rest of the activities of the organisation, which are more classical UN institution tasks contributing to the Millennium Development Goals. There is no contradiction because the mandate of WIPO in its funding convention is to promote the protection of

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intellectual property and also to maintain services facilitating the international protection of intellectual property and, where appropriate, providing for registration in this field and publication of data concerning this registration. That is Article 4. In fact, the international systems of patents and trademarks, managed by the organisation, are facilitating the international protection of intellectual property. Through this system it is much easier and cheaper to obtain an international patent or trademark protection. We should remind you that at the beginning the Patent Cooperation Treaty, commonly called the PCT, was not beneficial. It was supported by the contributions of the Member States, but fortunately, or unfortunately if you consider that was not the right thing, it has been a great success, and now 48 per cent of all international patents in the world go through our system. The fact is that the two systems of registration now provide more than 90 per cent of the budget of the organisation, even after a reduction of fees in the last ten years of 30 per cent and an additional reduction of five per cent in the last few weeks. The income is not growing as fast as it had been for several years during the time of the expansion of the PCT system. There are 138 country members of the PCT system and it has achieved its full development. As we have reduced the fees, the growth of income has become very, very limited every year. To be very transparent, there is a dispute between the Member States about the possible use of additional income. In the past we have had five per cent growth of income. Some Member States consider that there should not be such a growth: most of the international organisations are financed by Member States' contributions and are imposed as zero growth in their budgets. For us, nobody decides in advance what the income of the organisation will be, if we work well, we earn more. That is a problem for some who consider that instead of having an increased income we should reduce the fees so that there is no growth in income. These are industrialised countries, of course. Some other industrialised countries consider that, if there is an income growth, it should be used for improving the registration systems which generate the income. The developing countries, quite naturally, consider that an additional income is very welcome and should be used to finance more technical assistance and more cooperation for development. We could say there is no contradiction; on the contrary, developing countries are in favour of more income to be used for more technical assistance and cooperation. This is a debate which is not solved but which is for the Member States to decide. In fact, innovative sources of financing, other than Member States' contributions, are sought for by other UN institutions. Maybe WIPO has inspired some jealousy by giving an example, which may explain

some of the difficulties of the organisation, because it has been too successful in a way. I should also mention that developing countries are growing users of the system.

Q887 Lord Desai: I have accessed your data system and it is very, very good.

Mr Petit: Korea has just passed France as the fourth user of the PCT, our patent system, and China is presently seventh after the UK, but every year China's participation grows between 30 and 50 per cent, when the UK grows between three and six per cent, so I suppose in 2008 China will pass the UK as a user of the system. It shows that developing countries are not opposed to the system of financing of the organisation. There is also special financing for activities like the IGC, and you mentioned that indigenous community delegates are financed, their travel is paid, they are paid to come and participate at our meetings.

Q888 Chairman: A final question. I am sure you are aware of the Indonesian case, where they withheld the virus because of fear of exploitation by pharmaceutical companies. What can you tell us about that? Do you think that is going to happen again? Is that going to be a perennial problem? Or is it one can we can deal with?

Mr Taubman: I know you are pressed for time so, in that memorable phrase, here's one I prepared earlier!

Q889 Chairman: You are giving us something to read on the plane?

Mr Taubman: Yes, indeed.

Q890 Chairman: That is fine.

Mr Taubman: Some excess luggage for you! We have done an enormous amount of work on the flu question for two reasons: the first one being that it concerns the availability of vaccines for the bulk of the community, so it could not be more important; secondly, regrettably, once again, there are complex technical questions that need to be worked through. We have done that work for the WHO, having been commissioned by the WHO by the Intergovernmental Committee that is working on these questions. The basic questions, once again, filter down to what are the specific patents of concern? Is there a pattern of taking the wild flu strain and patenting it directly since there was a concern about a misappropriation of the genetic resources (a flu virus is viewed as a genetic resource, even though we want to get rid of it) is that being taken and just patented as it is; if not, then what is going on within the patent system? Then, at the other end of the pipeline, there is a question, should a pandemic hit us, what are the structures, the arrangements, for generating the vaccine that will be

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needed in a blinding hurry? And what resources and infrastructure are needed to respond; what patents apply to these technologies? These two questions are quite distinct, but they were conflated in the broad debate, understandably because there is a lot of passionate concern about it. What we have done is to essentially distinguish the issues and say, firstly, this is what is going on in terms of who is patenting genetic materials taken straight from the virus; and, secondly, these are the main technologies used to produce vaccines, of course using the genetic material as one input, and this is where they are held and these are the obstacles to fast-track implementation of those technologies. They are distinct issues. We have reported on that in great detail to the WHO. You would not go to WIPO, to patent lawyers, to advise you on your personal health. Equally, it is up to the WHO to work out what technologies are going to be vital for vaccine production in the future and what innovation structures are necessary to plug the genetic material from the flu virus into the vaccine

innovation pipeline. It would be very foolish to ask us about what vaccine technologies are needed. We provide the factual information about what is going on in the patent system, what the legal implications are, and what the options are for the patent system. We have done a paper saying that these are the six or seven major models you could look at; it is the job of health policymakers, appropriately, to match that information to their needs.

Q891 Chairman: Have you put that in the papers you have given us, these six or seven options?

Mr Taubman: Yes.

Chairman: That is very useful. Thank you very much indeed. We have kept you longer than anticipated, we are very grateful. It is a complex area and it is very helpful to have that background. As I say, you will get a transcript and do make any factual corrections you wish to pick up or, if you want to clarify or extend any information, please let us know. Thank you very much again for coming along today.

MONDAY 28 APRIL 2008

Present:	Avebury, L Desai, L Eccles of Moulton, B Geddes, L Hannay of Chiswick, L	Hooper, B Howarth of Newport, L Jay of Ewelme, L Soley, L (Chairman) Whitaker, B
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Memorandum by the European Centre for Disease Prevention and Control

INTRODUCTION

1. The European Centre for Disease Prevention and Control (ECDC) is a European Union (EU) agency tasked with monitoring, assessing and communicating threats to human health from communicable diseases. The Centre is based in Stockholm and became operational in May 2005.

While public health remains primarily a Member State competence in the EU ECDC supports the work of Europe's national disease control agencies and coordinates EU level activities, but does not centralise power or resources. The Centre does not have policy or regulatory powers, and key assets such as laboratories continue to be located in national institutes. The core functions of the Centre can be summarized as follows: reinforce and develop Europe's system of an EU-wide disease surveillance, reinforce Europe's rapid alert systems against disease outbreaks, support the EU and its Member States in strengthening preparedness and response against epidemics, provide authoritative scientific advice on infectious diseases and the risks they pose, work closely with Member States and other partners to prevent and control such diseases, and not least to communicate all its findings to the European public health community and to a larger European public.

2. In the context of the EU, with economic integration and open frontiers, cooperation on public health issues is becoming more important. While the idea of creating a European CDC had been around for quite some time amongst public health experts in the EU, the outbreak of SARS in 2003 and its rapid spread across countries confirmed the urgency of the creation of an institution dedicated to EU-level cooperation on public health issues. ECDC was set up in record time for an EU agency: the European Commission presented draft legislation in July 2003,³ by the spring of 2004 ECDC's Founding Regulation had been passed⁴ and by the spring of 2005 the Centre started operating. As it started its activities, another threat—H5N1 avian influenza arriving in the EU's neighbourhood and the fear that it could adapt or mutate into a pandemic strain of human influenza—confirmed the relevance of its mission. Though ECDC's primary focus is on health in the EU rather than global health, it is indisputable that disease control policy in the EU has an impact on the international picture—and vice-versa. Several organisations that have already given evidence have mentioned ECDC in their submissions. Because of this, the ECDC is keen to outline its role in the EU system.

3. ECDC's written evidence is divided into two sections:

- (a) Description of ECDC and its role in strengthening Europe's defences against communicable diseases
- (b) Answers to the questions posed by the Committee

In describing ECDC's role in communicable disease surveillance, early warning and response (ie part (a) of our written evidence) we address the key comments about ECDC made in written evidence from other organisations.

STRENGTHENING EUROPE'S DEFENCES AGAINST COMMUNICABLE DISEASES

4. ECDC's core tasks are:

- (a) Provision of scientific advice to EU Institutions and Member States
- (b) EU-level surveillance of communicable diseases

³ Proposal for a regulation of the European Parliament and of the Council establishing a European Centre for Disease Prevention and Control COM(2003) 441.

⁴ Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control. OJ L 142, 30.4. 2004: 1–11.

- (c) Enhancing EU-wide preparedness and response
- (d) Communicating the results of its work

5. ECDC's capacity to produce risk assessments and scientific advice to inform EU level decision making is a relatively new development in Europe's health security. In 2003, when SARS became an issue of concern globally and to all EU countries, there was no mechanism in place to produce a common assessment of the risk posed to Europe or to advise on the level of response needed. Countries took differing views on issues such as whether people entering the EU from affected countries should be screened for SARS, and whether EU citizens should be advised against travelling to the Far East. The relevance of reaching a common EU view on such measures is this: given the open borders between EU countries, screening of people entering the EU can only be effective if it is done by all Member States. Though an ad hoc EU scientific group was created to build a scientific consensus on control measures needed against SARS, it took several weeks to reach a conclusion. In contrast to this, in October 2005 when the arrival of H5N1 on the borders of the EU caused concern in all Member States, ECDC was able to produce an assessment of the risk to human health within a matter of days. Expert scientific advice an EU-wide consensus was reached on a number of issues including the risk groups (people working or living with poultry) was rapidly reached, along with EU-wide guidance on the measures needed to protect these groups (for more information on this topic see: the ECDC Avian Influenza Portfolio <http://www.ecdc.europa.eu/Health—topics/Avian—Influenza/Guidance.html>)

6. To fulfil its mandate to monitor, detect and assess emerging threats related to communicable diseases or of unknown origin, ECDC developed a database for tracking events requiring a thorough assessment. Since May 2005, this Threat Tracking Tool (TTT) is monitoring EU domestic threats as well as threat from international origin and is used by ECDC to produce the Communicable Disease Threat Bulletin shared with a restricted list of experts from the Member States.

7. The existence, since the creation of ECDC, of dedicated EU-level resources available to assist in the response to communicable disease incidents of international concern is also a new development. In the few years since ECDC became operational, this capacity has also proved its worth. For example, in January 2006 a cluster of human cases of H5N1 avian influenza in Eastern Turkey caused concern that the H5N1 virus might be becoming more transmissible to humans. An ECDC epidemiologist, along with an expert from WHO Europe and a veterinarian from the European Commission, were the first representatives of the international response team to reach the villages in Eastern Turkey where the cases occurred. ECDC experts played a key role in coordinating for WHO the international team assisting the Turkish authorities in investigating the incident, and were able to ensure all EU Member States were briefed of developments. In the summer of 2007 an outbreak of the tropical disease chikungunya fever occurred in Ravenna district in Italy, spread by local *Aedes albopictus* mosquitoes. Though the Italian authorities ably contained this outbreak, the *Aedes albopictus* mosquito is present in several other European countries so this event was of international interest. An ECDC led team (including members from WHO and national public health institutes) visited Ravenna district and produced an assessment of the risk to Europe from chikungunya fever, which concluded that there is indeed potential for outbreaks in other parts of Europe. ECDC's work on chikungunya fever—which already began in 2006—was intensified as a result of this (for more information on this topic see: http://ecdc.europa.eu/Health_topics/Chikungunya_Fever/Chikungunya_Fever.html).

8. In the area of disease surveillance, however, ECDC did not start with a “blank sheet of paper”. As far back as the 1990s, public health authorities across the EU realised that the opening of Europe's internal borders would make the control of communicable diseases on a purely national basis increasingly difficult. Because of this, a system of EU-wide disease surveillance evolved, along with an EU Early Warning and Response System (EWRS) on public health threats. EWRS is a secure messaging network linking public health authorities in the EU Member States, ECDC and the European Commission. If a disease outbreak occurs that has potential to spread across borders then a Member States is obliged to post an alert on the system. EWRS pre-dates the WHO's revised International Health Regulations (IHR) by many years, but mirrors in many ways the IHR requirements in the area of communicable diseases.

9. It is worth making a distinction between “surveillance systems” and “early warning systems”. Surveillance has traditionally meant the routine collection of data from health care providers about the occurrence of predefined diseases or conditions—for example, HIV or tuberculosis. This can be contrasted with “early warning” systems that seek to identify public health events—acute outbreaks of diseases (including new or emerging diseases) that may require urgent action to contain them.

10. By the time ECDC became operational in 2005 the EU had one main network focused on public health events (the EWRS network) and a total of 17 Designated Surveillance Networks (DSNs) collecting surveillance data on different diseases and groups of diseases.

11. The DSNs were financed as projects under the EU's Public Health Programme, while EWRS was managed directly by the European Commission. The system of DSNs relied on consortiums of national public health institutions proposing the creation of networks and submitting proposals for EU funding. The bulk of the EU funding to support the DSNs was routed through the various national public health institutions which acted as project leaders for the different DSN consortiums. In 2005, when ECDC became operational, a total of six DSN consortiums were led by British institutions. One of these (the EuroCJD network) was led by the National CJD Surveillance Unit in Edinburgh, while the other five were led by the Health Protection Agency.

12. Each of the 17 DSNs had made substantial contributions in their respective areas, but there were also some important drawbacks with this decentralised system of DSNs. The DSNs evolved and developed in an uncoordinated way. They each had different Standard Operating Procedures (SOPs), different organisational structures, different methods for collecting data and different reporting formats. Some DSNs collected data on only one disease, while other collected data on several. Some covered all EU Member States, some only a limited number, while two (EuroHIV and EuroTB) covered the whole of Europe including the states of the former Soviet Union. Very good European level data was available for some diseases (eg tuberculosis and HIV/AIDS), but for other important diseases (eg viral hepatitis) the data available was patchy. In addition, each DSN had its own website, its own database and its own scientific publications. All of this made life very difficult for any user of the DSN data who wanted to get an overall picture of the state of communicable diseases in the EU.

As well as being sub-optimal for users of surveillance data, the previous system placed an unnecessarily heavy burden on data providers in Member States, who had to report to numerous different systems in different formats. The system was financially precarious in that each DSN was financed from year to year as an EU funded project, with the project leaders having to periodically submit bids to the EU Public Health Programme for further funding. The DSNs were funded as time limited projects so they were always in danger of having their funding not renewed, as happened in the case of one of the most successful and largest DSNs, the EuroHIV surveillance network. At one point it was decided that this network was not a priority for funding and it was not re-funded in time to maintain continuity. The whole network was in danger of collapsing until the host hub, the French Institut de veille sanitaire (INVS), came up with emergency funds to keep the activities alive for about a year. These problems with ensuring continuity and sustainability of funding were eliminated once the coordination activities were transferred to ECDC. In the second public health programme of the EU surveillance is no longer a priority and therefore funding is not available. As ECDC uses the EU taxpayers' money, it has to keep its financial and human resources constantly under scrutiny and ensure the most cost-effective investment of resources. Therefore the integrated surveillance in Europe with one database to provide for a "One Stop Shop" approach for policymakers and public health institutions and continuous improvement of the quality and comparability of data and link to the decision making process is the most justified way forward. The evaluation and assessment of the DSN's, inspite of all the achievements—have clearly demonstrated the weaknesses of that system including the excess use of resources.

13. One of ECDC's first tasks on becoming operational was to conduct an evaluation of the DSNs and make recommendations to its Management Board for a short/medium and long term strategy for a coordinated EU surveillance setup. Evaluations and reviews took place for individual DSNs while an extensive consultation took place with public health institutions in the Member States as to the overall strategy for surveillance. The conclusion reached was that collection of data should be standardised and simplified, with all surveillance data being fed into a single database hosted by ECDC. ECDC would progressively integrate into its own activities the surveillance previously conducted by the DSNs. However, a guiding principle of this process is that ECDC will only "take over" a specific DSN's surveillance activities if and when it has capacity to provide at least the same level of service as the DSN.

14. As of February 2008, one DSN has been discontinued, while the surveillance activities of a further five DSNs have been transferred to ECDC. Of the five DSNs whose surveillance activities have been transferred to ECDC, two were DSNs formerly led by the Health Protection Agency: the EU Invasive Bacterial Infections Surveillance Network (EU-IBIS) and the International surveillance network for the enteric infections Salmonella, Campylobacter and VTEC O157 (ENTER-NET).

15. When ECDC became operational in May 2005 the start up team was about a dozen people. By the end of 2007 ECDC had recruited nearly 200 staff, and this figure will rise to nearly 300 by the end of 2008. Overall, the creation of ECDC represents a significant increase in the EU-level capacity to monitor, evaluate and respond to communicable disease threats.

16. Though the development of an integrated system of EU-wide disease surveillance is still a work in progress, ECDC is convinced that this is the right goal to aim for. We also believe we are on course to achieve this goal. A database capable of capturing all the key variables for some 50 communicable diseases has been created by ECDC and is now being used as the repository for all EU surveillance data from 2006 onwards.

New, more standardised, case definitions for diseases under surveillance have been developed and agreed and will shortly be published in the EU's Official Journal. Work begun by DSNs on quality standards for laboratory testing for various communicable diseases is being continued. ECDC has recruited top quality experts, and is capable of both gathering and analysing data on key diseases.

17. One clear added value from ECDC's integrated approach to communicable diseases is that in 2007 we were able to publish an Annual Epidemiological Report analysing 10 year's worth of data from 27 European countries covering over 50 different diseases and disease groups. In this report we were able to give a comparative analysis of the magnitude of the threat posed by these different diseases. This report can be viewed online at: http://ecdc.europa.eu/pdf/ECDC_epi_report_2007.pdf. Hard copies of the report have also been sent to the Committee secretariat. Our next Annual Epidemiological Report will be published later this year. In future, as national disease surveillance institutes get used to reporting into ECDC's surveillance database in "real time" rather than as part of an annual data collection cycle, it should be possible to produce reports quarterly or even monthly. An on-going challenge is to link the European surveillance system to the public health decision making process. This consultation is ongoing with the European Commission.

ECDC ACTIVITIES ON AVIAN INFLUENZA, HIV/AIDS, MALARIA AND TUBERCULOSIS

18. As mentioned in paragraph 15 above, ECDC started in 2005 with just a handful of staff. ECDC has grown steadily since then, but we are still a young organisation and still small relative to partners such as WHO or the US Centres for Disease Prevention and Control. ECDC has a staff of almost 200 people from 25 different nationalities. We have therefore had to prioritise in the start up of our disease specific activities. The ECDC is at the heart of a network of 80 competent bodies employing over 8000 people from all EU Member States, Norway, Iceland and Liechtenstein, including all national organisations involved in the fight against communicable diseases such as the Health Protection Agency.

19. Influenza became an early priority of ECDC, given the concern about H5N1 avian influenza in the summer and autumn of 2005. As mentioned already at paragraph 5, ECDC produced a risk assessment on the human health implications of the arrival of H5N1 avian influenza in the European region and produced a significant body of technical guidance on protection measures. Having started on pandemic preparedness in 2005 the completion of the bulk of work on avian influenza meant that, during 2006 and 2007 ECDC could shift its focus to enhancing preparedness against a possible future influenza pandemic be it based on avian influenza or another strain. ECDC has also been reinforcing the public health response to seasonal influenza. Surveillance of seasonal influenza in Europe will be integrated into ECDC as from September 2008. For more information on ECDC's activities concerning influenza see http://ecdc.europa.eu/Health_topics/influenza/Index.html

20. ECDC's activities in relation to HIV/AIDS and tuberculosis began in 2006. An agenda for ECDC's activities on HIV/AIDS was agreed at a meeting of national HIV/AIDS coordinators in October 2006. An Action Plan to address tuberculosis in the EU is currently being finalised by ECDC and will be published in the coming months. From the beginning of 2008 the surveillance of both HIV/AIDS and tuberculosis in the EU has been integrated into ECDC, with surveillance of these diseases in the wider Europe (including the countries of the former Soviet Union) is being undertaken in collaboration with WHO Europe. For further information on ECDC's activities in relation to HIV/AIDS see: <http://ecdc.europa.eu/Health—topics/AIDS/Index.html>. For further information on ECDC's activities in relation to tuberculosis see: http://ecdc.europa.eu/Health_topics/Tuberculosis/Tuberculosis.html

21. ECDC has a programme that covers vector born diseases such as malaria (see: http://ecdc.europa.eu/About_us/projects/env—zoon.html). Only a few thousand cases of malaria are reported each year in the EU, and these are generally imported from outside the EU. In contrast, a major outbreak of the mosquito born disease chikungunya fever occurred in the French Indian Ocean department of La Reunion in 2006 affecting 266,000 people. A risk assessment conducted by ECDC concluded in March 2006 that there was a potential risk of chikungunya being introduced to continental Europe in countries where the *Aedes albopictus* mosquito is present (this includes several Mediterranean and Adriatic countries). As a result, ECDC embarked in actions to strengthen preparedness of EU MS to tackle this potential threat: diagnostic capacity for chikungunya in the MS was reviewed and developed through the European Network for Imported Viral Diseases (ENIVD) and 2 one week training on management of the emergence of chikungunya fever were conducted. In the summer of 2007 an outbreak of chikungunya fever did in fact occur in Ravenna district in Italy, and ECDC conducted an assessment of the risk of further outbreaks in Europe. Given the emerging threat to Europe of chikungunya over the past 2 years, this has been a higher priority for ECDC's

vector born diseases team than malaria. Currently ECDC is finalising the review of the factors that would allow the establishment of *Aedes albopictus* in other part of the EU in order to allow a better targeting of preparedness activities regarding chikungunya fever.

EXPLANATORY STATEMENT ABOUT ECDC'S ANSWERS TO THE QUESTIONS POSED BY THE COMMITTEE

22. Response by ECDC to the questions posed by the Committee have been drafted with regard to the fact that:

- (a) The focus of ECDC's activities is the European Union and its immediate neighbourhood
- (b) ECDC's scientific activities started up in 2005, so we have not yet addressed in depth all the issues raised by the Committee in its questions.

ANSWERS TO QUESTIONS POSED BY THE COMMITTEE

1. *A recent report on Communicable Diseases by the UK Department of Health stated that "post-war optimism that their conquest was near has proved dramatically unfounded". What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis?*

23. The first two parts of the question are covered in a recent (December 2007) Eurosurveillance editorial *Why a burden of disease study?* by the Director of the ECDC. The full article is available via <http://www.eurosurveillance.org/em/v12n12/1212-221.asp>) and key aspects are reproduced below:

- although the public health community "knows" that Communicable Diseases (CD) have in general decreased substantially in Europe over the last century, it was also clear that new CDs have started to emerge and old ones re-emerge.⁵
- The success in tackling CDs, and hence their burden, has also changed the balance between Communicable and Non-Communicable Diseases (NCDs).
- the traditional boundaries between CDs and NCDs are also clearly changing, as present research indicates that many traditional NCDs have infections in their aetiology and should perhaps now be classified as CDs rather than NCDs.
- In addition, "success" in controlling SARS has in some quarters, especially the mass media, raised questions of "waving shrouds" and the necessity of the considerable expense that was involved. Such doubts may migrate to current avian influenza and pandemic preparedness. These perceptions also need to be rectified with the help of "evidence".

24. The editorial concluded by saying that "Forty years ago, the United States' Surgeon General, Dr William Stewart proposed that, with the advent of antibiotics and the broad use of vaccines, the war against infectious diseases had been essentially won, and that we now needed to pay attention to other important health issues, such as chronic diseases. However, it is clear today that we have only won a "battle": the "war" will surely continue. Turning to less aggressive vocabulary, perhaps it is a "never-ending dance" [With apologies to Adrian K Ong and David L Heyman. "Microbes and humans: the long dance". WHO bulletin volumes/85/6/06-0372200/en] in which the human race needs to constantly find new technologies and tools to keep "in step" with changing and new microbes!"

25. The human/microbe balance and evolutionary struggle is not new and has been recognised over the centuries [Hans Zinsser (*Rats Lice and History*), W.H. McNeill (*Plagues and People*)]. Although hard evidence is lacking in all cases, many aspects of the current "re-emergence" and "emergence" of "new" diseases are probably "man-made". Firstly through "developments" that have consequences on the balance such as agricultural and animal farming (majority of pathogens come to humans from animals), globalization, and climate change. Secondly through non-use, incorrect use and/or abuse of the very defensives developed (eg vaccines, poor adherence to TB treatment, indiscriminate use and abuse of antibiotics). Continuing success on the part of the human species in this struggle will remain dependent upon constant and continuous vigilance and commitment to take action irrespective of the consequences on the health or other sectors (including financial); transparency and avoidance of denial are other lessons learnt from past "battles" (SARS, BSE). Also since economic development will and must continue, investment in careful health impact assessments by all sectors, continued research; and strengthening the health sector remain important elements of defense. Perhaps the most important being a strong health sector that recognizes the diseases early and is capable of

⁵ SARS, Legionella and Marburg Fever (some two dozen new pathogens have been discovered over last 25 years) and old ones re-emerge such as Tuberculosis, Chikungunya and Avian Influenza as potential threat to human health.

treating the diseases once detected. Amongst other things, this requires a clear recognition by all countries (even if current communicable disease figures are low) of the continued importance of communicable disease, its funding, on-going training and integration into relevant parts of the health sector (especially primary health care: the first point of detection/defense).

26. More specifically the following factors are important:

- the unanticipated emergence of resistance to antimicrobial or anti malarial drugs;
- the need to develop a global approach to the prevention and control of such threat, which proved to be:
 - (a) costly but effective for diseases such as smallpox because of existence of an effective vaccine and the absence of non-human reservoir, but
 - (b) ineffective for diseases of more complex nature, such as tuberculosis with a vaccine of limited efficacy and treatment subject to resistance, or malaria, requiring a global sustained approach for vector control and prone to the emergence of resistance to the first line cheap antimalarial drugs;

27. In the case of tuberculosis, the development of streptomycin and anti tuberculosis (TB) drugs enabled treatment of the disease and therefore a decrease in its transmission and dramatically lower incidence. However, the apparition of resistance to treatment, and the persistence of higher transmission rates in resource limited or unstable areas as well as specific risk groups (prisons, migrant worker) resulted in the persistence and in some instance re-emergence of TB and also multi-drug resistance/extremely drug resistance (MDR/XDR) TB (see also section 37,38 40 & 41). Little development of new drugs and tools to treat and rapidly detect TB and poor adherence to existing treatment have also been contributory factors. Many countries with the highest rates of MDR/XDR TB have “historical” connections to EU countries (and hence related “ethnic” communities in the host countries). This provides unique and cost efficient possibilities to help both the countries concerned whilst at same time protecting the host populations.

In the case of malaria, similar optimism was raised by initial good vector control attained through the wide use of insecticides and effectiveness of cheap treatment for malaria. The emergence of resistance, concerns about the wide usage of DDT and the instability in some endemic malaria area preventing control programme from being effective resulted in the persistence of malaria in most of its originally endemic areas.

HIV and avian influenza, being emerging threats, were not indeed concerned by the “post war optimism”.

28. ECDC would not qualify the overall situation regarding these four diseases as a crisis. While the situation has improved for some diseases in some areas, it has deteriorated in other, often in relation with profound societal changes, civil unrest and civil war often resulting in interruption of prevention and control programme, resurgence of diseases as well as migration of precarious populations contributing to further spread of the diseases. There is also the question of “crisis” for whom? In the UK for the population as a whole, it is probably not a crisis. However, for pockets (eg some urban areas and Boroughs, Prisons, high risk populations) where for example TB rates are higher than the highest rates in Eastern Europe, it probably is a crisis for the people concerned. These communities are perhaps the very ones whose socio-economic, poverty, housing profiles put them most at risk (including probably through lower immunity levels). Therefore the overall goal of reducing poverty will also most certainly help the battle against many communicable diseases.

2. What reliable data exist regarding the numbers of people infected globally with the four diseases⁶ on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?

29. A global system, led by WHO, exists for the worldwide surveillance of individual cases of H5N1 avian influenza. This system works relatively well, as this is still a very rare disease among humans with the number of confirmed cases totalling in the hundreds: latest figures are available online from the WHO and ECDC websites. For other strains of avian influenza (for example, H3N7), and for malaria, HIV and tuberculosis systems for reporting cases and compiling data do not exist in all parts of the world. The Health Protection Agency, UNAIDS and WHO have already commented on this limitation of the worldwide data.

30. What ECDC would like to point out is that within the European Union, and some of its neighbouring countries systematic reporting of the major infectious diseases does in fact take place. In June 2007 ECDC published an analysis of ten years’ worth of data on infectious diseases from the 25 countries that were Member States of the EU in 2005 plus Iceland and Norway. This report,⁷ which covers nearly 50 diseases,

⁶ HIV/AIDS, Tuberculosis, Malaria and Avian Influenza.

⁷ Annual Epidemiological Report on Communicable Diseases in Europe, ECDC, Stockholm, June 2007

is available on ECDC's website—see paragraph 17 above for more details. In addition, a short summary of European data on the four diseases the Committee has a particular interest in are given as an annex to this evidence.

3. What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? And what improvements might be made?

31. Please see paragraphs 8 to 17 above for an explanation of the systems of EU-wide disease surveillance and early warning, and ECDC's views on these systems.

32. ECDC has established working relationships with counterpart disease control organisations in the US, Canada and China and has close collaboration with WHO. There is also collaboration on health security issues within the G8. With these key international partners, ECDC and the European Commission are working to further strengthen international cooperation on epidemic intelligence and early warning. Successful implementation of the new International Health Regulations will be of key importance in achieving this—see answer to question 16 below.

4. Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years?

33. It is difficult to make predictions with any confidence and perhaps the only certainty with emerging infections is that Europe will certainly be surprised and need to respond to new threats such as the most recent emergence of oseltamivir resistant influenza viruses see http://www.ecdc.europa.eu/Health_topics/influenza/antivirals.html. HIV/AIDS and tuberculosis are preventable diseases, there is growing political commitment in the EU to addressing the challenges they pose, so our aspiration would be to see the number of new cases of these diseases in the EU fall over the coming decade. We believe this is achievable. Malaria is not currently an endemic disease in the EU. We believe the chances of it being reintroduced in Europe are low, but we cannot entirely exclude this possibility (see paragraphs 7 and 21 above). As long as H5N1 avian influenza is endemic in the continents of Africa and Asia, we will continue to see sporadic outbreaks among birds in Europe. Veterinary measures to contain these outbreaks in the EU have proved effective and we have no reason to believe they will not be effective in containing future outbreaks. The risk to human health from these outbreaks is low, as long as current guidance on human health protection is followed (see paragraph 5 above). There is a possibility—but by no means a certainty—that we will experience a pandemic of human influenza at some point in the next decade. It is impossible to quantify this risk as it depends on the mutation patterns of an unpredictable virus but this possibility must be prepared for.

5. What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?

34. Poverty, war and political instability and in many instances the lack of political commitment for the prevention and control of these diseases are clearly among the principle blockages to progress in rolling back these and other communicable diseases in the developing world. ECDC is not in a position to advise on how these blockages be removed, as our remit is to focus on the EU and its immediate neighbours. Lack of international cooperation, communication and transparency is another more tractable blockage and ECDC is committed to work to counter these blocks. It is clear, though, that the persistence of high rates of infection in some other parts of the world is a factor that hinders efforts to eliminate these diseases in the EU. Communicable diseases do not respect national borders and move swiftly. A chain is as strong as its weakest link and international efforts to control and prevent communicable disease require a concerted international effort in this regard.

6. What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?

35. The role of ECDC in relation to all of these diseases is to conduct EU-level disease surveillance, provide guidance on evidence-based public health interventions to the EU Institutions and Member States, and assist with the response to incidents, ECDC works closely with WHO EURO and WHO Headquarters in Geneva. There is excellent collaboration and synergy with the WHO and there is a Memorandum of Understanding in

place to ensure consistency and synergy. ECDC benefits from the placement of a WHO Liaison Officer who ensures constant contact and communication with WHO. ECDC benefits similarly from the placement of an officer from the US CDC who is placed in the ECDC Scientific Advice Unit. There is also an official from the European Environment Agency working in ECDC on the preparation of common indicators and databases. The ECDC has finalised Memorandums of Understanding with counterpart organisations in China, Canada and the US. ECDC has agreed Memorandum of Understanding with the European Food Safety Authority (EFSA), with the European Drug Monitoring Centre (EMSDDA). With the Joint Research Centre (JRC), Institute for the Protection of the Security of the Citizen (IPSC) and with the Swedish Rescue Agency (SRA). These reflect the main organisations with which ECDC currently has collaboration and co-operation apart from the EUECDC works in close collaboration with a number of similar organisations and European Union institutions which are the natural partners to ECDC. A day-to-day collaboration exists with the European Commission and a close one with the European Parliament and the currently rotating six monthly EU Presidencies. In addition ECDC has very close working relations with the Member States through the national Health Ministries based in the capitals, the national Health Protection Agencies, institutes, and surveillance agencies and the competent bodies. Many of these partners are represented on the governing bodies of ECDC including the Management Board and Advisory Forum. All EU Member States that we represented on work both the Management Board and Advisory Forum.

7. What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient 'joined-up' thinking in approaching the problem?

36. Poverty, war and political instability and lack of political commitment are clearly among the principle blockages to progress in rolling back these and other communicable diseases in the developing world. ECDC is not in a position to advise on how these blockages be removed in the developing world, as our remit is to focus on the EU and its immediate neighbours.

37. Looking at the situation within the EU, there is good evidence that individuals with lower socio-economic positions suffer disproportionately from communicable diseases (this is also true for chronic diseases such as cancer and health disease. Communicable diseases are distributed unevenly throughout society, with marginalized and vulnerable groups bearing a disproportionate burden. These groups are not only negatively impacted by a few "signature infections" such as TB or HIV but rather by a wide array of other communicable diseases. Thus, there seems to be a need to devise targeted interventions for a wide range of communicable diseases in marginalized and vulnerable groups. In its work on helping EU/EEA member states improve pandemic preparedness ECDC emphasises the need for "joined-up" whole society approaches see http://www.ecdc.europa.eu/Health_topics/Pandemic_Influenza/updates1.html and we are finding this message is being received and followed.

38. The four communicable diseases being examined by the Committee might not be directly linked to climate change in the EU; however, impending potential climate change-related threats should be monitored. 'Joined-up' thinking can proactively address the problem both for the short- and the long-term, and should address surveillance; policy; assurance; and research.

8. Cases of Tuberculosis fell progressively in the UK until the mid-1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of Tuberculosis infections in Britain? And how could intergovernmental action help to reverse the trend?

39. In most countries in the European Union incidence of tuberculosis has experienced a decline in the last 5 years (2.5% per year) after a period of increase or stagnation observed in several countries in the early 1990s. The increasing trend observed during the 1990s was due to a decrease in awareness and reduction of resources and services for TB prevention and control. In addition, the breaking down of Soviet Union and the whole Socialist system (including Health Care) in Europe occurred at that time.

40. In recent years some countries like the United Kingdom are experiencing again an increasing trend in tuberculosis. This is largely due to increase in TB cases of foreign origin especially in younger age groups (Source: Surveillance of Tuberculosis in Europe, EuroTB Annual Report, Paris 2007, available in: <http://www.eurotb.org/>). Tuberculosis in many EU countries and other developed countries is aggregating in vulnerable populations, such as migrants, prisoners, homeless and in poor areas in large cities among others.

Resources and actions should be addressed to these groups of the population in order to ensure appropriate access to health care and quality tuberculosis treatment.

41. As a request of the European Commission, ECDC has drafted a TB Action Plan to fight tuberculosis in the EU which describes a framework of actions to be implemented at national and at the EU level. Collaboration with countries in the wider European Region and in the world should be considered when developing strategies to fight TB since TB rates are much higher in those countries and the disease doesn't respect borders.

9. Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions—eg HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?

42. Other contributors have commented on the worldwide situation. ECDC would like to make some comments on the specific situation in the EU. In most EU countries the number of cases of tuberculosis being reported is low and has decreased in the last five years—see paragraphs above.

43. In countries such as the Baltic States, there is an important overlap between the TB and the HIV epidemics. Current antiretroviral regimen are extremely potent at reconstituting the immunity of HIV infected persons, and in the case of persons infected with TB causing bacteria, in preventing them from developing the disease TB. That a substantial proportion of HIV infected persons are not diagnosed, and hence cannot benefit from early antiretroviral therapy is a barrier to controlling both HIV and TB. MDR-TB and XDR-TB is a serious challenge in this context.

44. ECDC has developed an Action Plan for Tuberculosis in the EU—see paragraphs above.

10. To what extent do you believe that the 2004 Stockholm Convention limiting the use of DDT against Malaria-carrying mosquitoes has been a factor of increases in the spread of the disease? Has any risk analysis been carried out comparing the relative dangers to human health posed by DDT and Malaria?

45. A risk/benefit analysis of the use of DDT against malaria-carrying mosquitoes would need to look at issues of chemical safety, impact on the food chain, environmental impact and occupational health and safety impact, in addition to its effectiveness as a vector control intervention. ECDC is not in a position, at present, to conduct such an analysis as our mandate does not extend to all these areas. Our focus is exclusively on infectious diseases.

11. What intergovernmental action is planned or in hand for early detection of the transmission of Avian Flu from birds to humans and of human-to-human transmission in potential source countries? Is this proving sufficiently effective to prevent an Influenza pandemic? What more could be done?

46. The global lead on human aspects of pandemic preparedness/Avian Influenza is with WHO with OIE and FAO being responsible for the animal and food aspects respectively. UNSIC's role is to coordinate the various UN agencies. A series of Global International meetings (Washington, Geneva, Beijing, Vienna, Bamako and New Delhi as well as a technical meeting in Rome) have taken place since 2005. These were variously Ministerial, Pledging and Senior Officials Meetings that began immediately following the concern over Avian Influenza. Within the EU there have been specific meetings of health ministers in this topic in 2004, 2005, 2006. In addition, there have been joint meetings of Chief Medical Officers and Chief Veterinary Officers and also cross-sectoral meetings of veterinary, Consular, Foreign Ministry Cabinet Office and health officials at which ECDC has actively participated. ECDC also participates in the European Commission Health Security Committee on this work.

47. The key strategy for preventing H5N1 avian influenza becoming a human pandemic virus is to reduce, and if possible eradicate, circulation of H5N1 in the bird populations. Veterinary measures (including sometimes bird vaccination) implemented in Vietnam, China and Thailand have greatly reduced outbreaks in poultry population in those countries but have failed to eradicate. This in turn has reduced the number of cases of humans infected with H5N1 in these countries. However efforts to reduce circulation of H5N1 among birds have been unsuccessful in some other parts of the world notably Indonesia and Egypt and there are now indications of the infection becoming entrenched in India and Bangladesh.

48. An essential parallel strategy is to promote pandemic preparedness planning. Even if H5N1 does not turn out to be the virus that causes a pandemic, at some point—another influenza virus will. There were three influenza pandemics in the 20th century (starting in 1918, 1957 and 1968), so it's certain that we will face a pandemic at some point in the 21st century.

49. Considerable effort has been put into pandemic preparedness planning in EU countries. Between June 2005 and October 2007 ECDC led teams working with WHO and the European Commission that visited and helped all 27 EU Member States plus Norway, Iceland and Liechtenstein to assess and strengthen their plans and preparedness. A report on the state of pandemic preparedness in the EU was published by ECDC in December 2007. This concludes that considerable progress has been made since 2005, but a further 2 to 3 years of sustained effort is needed to complete the process of preparedness. For more information see: http://ecdc.europa.eu/Health_topics/Pandemic_Influenza/updates1.html
ECDC plans to have similar visits to Turkey, Croatia and the Former Yugoslav Republic of Macedonia during 2008.

12. *To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?*

50. Re-emergence of TB in the European Union has been fuelled by the HIV epidemic and the development of multidrug-resistant (MDR) TB strains. In many European countries, where the incidence of TB remains unacceptably high, resistance to the most effective anti-TB agents, ie isoniazid and rifampicin (MDR TB), as well as to second-line antibiotics (extensively drug-resistant TB, or XDR TB) poses a serious challenge to control.

51. MDR TB represented 15-20% of TB cases in Baltic States, whereas it only represented 0–6% of TB cases in other countries. MDR TB is generally more common in patients of foreign origin, especially coming from the Former Soviet Union. By 1st May 2007, 17 out of 30 EU plus EEA/EFTA countries and 4 Former Soviet Union countries had reported TB cases fitting the definition of XDR TB.

52. ECDC has developed an Action Plan for Tuberculosis in the EU—see paragraph 41 above. This contains a strand on addressing MDR-TB and XDR-TB.

53. Doxycycline—an antibiotic of the tetracycline class—is active against Plasmodium and is among the drugs recommended for malaria prophylaxis in areas of chloroquine resistance, eg sub-Saharan Africa. There is, to our knowledge, no report of doxycycline-resistant Plasmodium. However, malaria prophylaxis with doxycycline is a risk factor for infection with resistant bacteria, eg doxycycline-resistant Staphylococcus aureus.

54. Antibiotics, ie antibacterial agents, are not active against viruses such as avian influenza or HIV, so antibiotic resistance is not considered to be a factor in the rise of these infections.

13. *In a number of countries, including the UK, there is a problem with hospital-acquired infections. {What intergovernmental sharing of knowledge is taking place to help bring this problem under control?*

55. Prevention and control of hospital-acquired infections, as well as of infections due to antibiotic-resistant bacteria in hospitals and in the community, is a priority activity of ECDC.

56. Surveillance of these infections is performed via three dedicated European surveillance networks focusing on healthcare-associated infections (IPSE/HELICS), antibiotic-resistant bacteria (EARSS) and antimicrobial use (ESAC), respectively. These dedicated surveillance networks will be gradually integrated to the routine activities of the agency. ECDC is also financing a European network for the standardisation of antimicrobial susceptibility testing, EUCAST.

57. In addition to surveillance, an extensive work plan has been developed by ECDC to improve prevention and control of antimicrobial resistance and healthcare-associated infections in the European Union. These new activities that are gradually being implemented by ECDC and include:

- regular meetings of a network of national antimicrobial resistance focal points (one per country) to share experiences on how to control antimicrobial resistance, both in hospitals and in the community;
- country visits to evaluate the implementation of Council Recommendation 2002/77/EC on the prudent use of antimicrobial agents in human medicine and reporting on these visits (8 country visits performed, more planned in 2008);

- advice and guidance on key diseases such as MRSA and Clostridium difficile-associated disease (2007–08); and
- organisation of a European Antibiotic Day to increase awareness of Europeans about antibiotic resistance and the need to use antibiotics rationally. This will be an annual event, which will first focus on the general public and use of antibiotics by outpatients, but will gradually focus on other topics, including multidrug-resistant bacteria, antibiotic use and infection control in hospitals. The first European Antibiotic Day will be 18 November 2008.

14. *Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?*

58. ECDC's activities focus primarily on scientific data and analysis. Our work to date has not included an analysis of intellectual property issues, so we do not have any comments to make on in relation to this question.

15. *What interchange exists between States in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?*

59. Since the mid-1990s the EU has funded the European Programme for Intervention Epidemiology Training (EPIET). This is a two year fellowship scheme aimed at doctors and other public health professionals from across the EU. Ten percent of the time is taken up by formal training courses and the remainder by placement at a training site in a European country different from the fellow's country of origin. This scheme, which since 2006 has been financed by ECDC, has helped expand capacity across the EU in surveillance and control of communicable diseases, including (but not limited to) the four diseases the Committee is interested in. It has also fostered exchange of knowledge by creating a cadre of like-minded practice-oriented epidemiologists who have a European perspective on disease surveillance and outbreak investigation.

60. Fostering the pooling of knowledge on communicable disease prevention and control between EU Member States, and supporting specialised training programmes are core activities of ECDC. See paragraphs 4 to 17 for more about ECDC's general remit in this regard and 18 to 21 for further details of work done on the four diseases. See also paragraphs 43 and 44 regarding work done on preparedness against a possible influenza pandemic.

16. *The International Health Regulations 2005 are intended to provide a global framework for the rapid identification and containment of public health emergencies. How effective do you consider this response system to be? Do improvements need to be made?*

61. The revised International Health Regulations (IHR) are a major step forward for global health security. The new system, the revised IHR created, is still in its infancy. It is too soon to comment on the systems effectiveness: rather, the challenge at present is to make the new system work. Key to this will be ensuring national authorities have the capacity to meet the new obligations the revised IHR places on them. Though the IHR obligations mirror, to a large extent, the reporting requirements under the EU's Early Warning and Response System (EWRS) on public health threats (see paragraph 8 above), there may still be work for ECDC to do in providing technical support to some of the EU Member States in order to help them implement the revised IHR.

17. *What intergovernmental planning has been undertaken to cope with the impact of an outbreak of infectious disease caused by deliberate release of micro-organisms into the environment? Is there adequate liaison between the various agencies involved, including intelligence, law enforcement and health care professionals? How could action by intergovernmental bodies help further?*

62. An agenda for EU cooperation against the threat of deliberate release of micro-organisms was adopted by EU Health Ministers in November 2001. This included the creation of an EU Health Security Committee (HSC) to foster cooperation and joint planning in this area. The HSC continues to meet regularly and is hosted by the European Commission with technical input from ECDC. An updated agenda for EU cooperation in the area of Bio-Preparedness was outlined in a Green Paper issued by the European Commission in November 2007. For more information on EU cooperation in this field see: http://ec.europa.eu/health/ph—threats/Bioterrorisme/bioterrorisme_en.htm

18. *Though our remit is focused specifically on known infectious diseases, we would be interested to know how you view the global threat from new or previously unrecognised ones and from the transmission of infections from animals to humans.*

63. The emergence of completely new microbes, or the adaptation of existing microbes into new more dangerous forms, is one of the major threats we face in the area of communicable diseases. We discover new communicable diseases at the rate of about one every two years. These present particular challenges for prevention and control as—by definition—when a disease is new it can take some time to discover how it is transmitted, how it can best be prevented and what (if any) the treatment options are. New communicable diseases that have emerged in the past few decades include HIV/AIDS (in the 1980s), new variant Creutzfeldt-Jakob disease (in the 1990s) and SARS (2003). Of these three diseases, it is thought that all had their origins in animal diseases. However there are also other ones that are not clearly of animal origin. The most recent example for Europe is the emergence of oseltamivir resistant human influenza viruses where ECDC is working especially with the UK based part of the VIRGIL network see http://ecdc.europa.eu/Health_topics/influenza/antivirals.html

64. There are a number of existing animal diseases that can infect humans, including salmonella, campylobacter and rabies. ECDC and the European Food Safety Agency (EFSA) produce a joint annual report on the extent of these zoonoses in the EU. For more information see: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178671312912.htm

19. *What resources (subscriptions, staff, training, medicines etc) does the UK Government commit to intergovernmental bodies to help in the fight against the four diseases listed?*

65. There is one senior expert on secondment from the Health Protection Agency (Professor Angus Nicoll CBE) who works full time for ECDC. However, many UK government officials and Health Protection Agency (HPA) and other staff contribute their time and expertise to ECDC on a part time basis by attending meetings and sitting on expert panels. This input is highly valued by ECDC and should be acknowledged. A senior official from the UK Department of Health attends ECDC Management Board meetings, which take place three times a year. Senior experts from the HPA attend meetings of ECDC's Advisory Forum, which meets four times a year and the Editorial Board of our scientific journal Eurosurveillance, which meets once a year.

66. HPA experts also regularly contribute to ad hoc scientific panels convened by ECDC to address specific scientific questions. For example, in 2007 it was an HPA official who chaired ECDC's scientific panel looking at the likely effectiveness of using human H5N1 vaccines as so called "pre-pandemic" vaccines.

20. *Do you wish to provide any other relevant information in addition to what you have said in answer to the above?*

67. Please see paragraphs 1 to 22 above for an introduction to ECDC and its work on communicable disease. Please see also our website www.ecdc.europa.eu and our scientific journal Eurosurveillance www.eurosurveillance.org.

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Annex

KEY EUROPEAN DATA ON THE FOUR DISEASES

AVIAN INFLUENZA:

1. There have been no human cases of H5N1 avian influenza in the EU though there have been intermittent threats from outbreaks in poultry in the Europe and numbers of people needing assessment for possible infections. There have been human infections with other avian influenza taking place in the EU including in the UK which are a reminder that we could still see human cases of H5N1.

HIV/AIDS AND TUBERCULOSIS:

2. Relatively good data exists within the European Region on the number of new diagnosis of HIV and tuberculosis being reported each year. These data are based on cases diagnosed by health professionals and then reported to national public health authorities.
3. A limitation of this data is that the number of new diagnosis being reported in a given year does not necessarily equate with the amount of infection taking place in that year. This is because some of the infections reported may have occurred several years before diagnosis. Also, infections currently taking place may remain undiagnosed—and therefore unreported—for several years
4. People can be infected with HIV for months or years before becoming ill. Some people infected with TB causing bacteria may never actually develop the disease: others may not become ill for many years. ECDC estimates that around 30% of the people living with HIV in Europe are unaware of being infected. Another limitation worth noting is that a few European countries (including two in the EU) are unable to provide national data on HIV infections.
5. In the European region of 53 countries, 86 912 newly diagnosed cases of HIV infection were reported in 2006,⁸ giving an overall rate of 111.1 per million inhabitants. Four countries reported rates of more than 200 new HIV diagnoses per million inhabitants: Estonia (504), Ukraine (288), Russian Federation (275) and Portugal (205). Across Europe, the number of new diagnoses of HIV infections has continued to increase. This could be due to an increase in testing rates among HIV infected persons, an increase in the number of persons becoming infected in Europe, an increase in the number of HIV infected persons migrating to Europe, or a combination of these factors. The level and the nature of the epidemic and its implications for public health vary across Europe.
6. The East of Europe⁹ has reported the largest number of new cases, with 210.8 HIV diagnoses per million inhabitants. Although this rate is lower than the epidemic peak observed in 2001, the number of reported new HIV diagnoses has increased in recent years. In this region, injecting drug use remains the main mode of transmission. Over a quarter of the new HIV diagnoses were among young people aged 15-24 years and 41% of the cases were reported amongst females. Further spread into the general population through heterosexual contact is a potential risk.
7. In the West of Europe,¹⁰ the rate of new diagnoses was equal to 82.5 per million inhabitants and the nature of the epidemic reflects that of the EU, where the majority of persons diagnosed with HIV were infected through heterosexual contact. A substantial proportion of these however are among persons originating from sub-Saharan Africa, the majority of which are believed to have been infected in their country of origin. Therefore in many countries of Western Europe sex between men accounts for the majority of infections that take place in the country.
8. In the Centre,¹¹ the level of HIV epidemic remains low, with 9.4 new diagnoses per million inhabitants, representing a small increase since 1999. The most common transmission group was heterosexual contact (52%), with a quarter attributed to men having sex with men. The number of reported cases has increased since 1999 in both these groups, while a decline has been observed among injecting drugs users (16%).
9. WHO/UNAIDS estimates that, at end of 2007, 760,000 people were living with HIV in western and central Europe and 1.6 million in eastern Europe and central Asia.
10. TB rates in the EU decreased by 2.5% annually between 2001 and 2005.¹² Nonetheless, a total of 91,845 tuberculosis cases were reported in the 27 EU Member States in 2005. While the prevalence of TB in the EU is low by international standards, rates of infection have increased among certain vulnerable groups. These include HIV/AIDS infected persons and people of foreign origin. In addition, some EU countries are reporting a high rate of cases of drug resistant TB. In the Baltic States 18% of TB cases are from drug resistant strains (compared to 0% to 6% in other Member States).
11. Across the whole of the WHO European Region in 2005 there were 445 000 new cases of TB reported and 66 000 TB-related deaths.

⁸ EuroHIV Annual Report, Paris, November 2007.

⁹ 15 countries of the former Soviet Union: Armenia, Azerbaijan, Belarus, Estonia*, Georgia, Kazakhstan, Kyrgyzstan, Latvia*, Lithuania*, Republic of Moldova, Russian Federation, Tajikistan, Turkmenistan, Ukraine, Uzbekistan.

¹⁰ 23 countries: Andorra, Austria*, Belgium*, Denmark*, Finland*, France*, Germany*, Greece*, Iceland, Ireland*, Israel, Italy*, Luxembourg*, Malta*, Monaco, Netherlands*, Norway, Portugal*, San Marino, Spain*, Sweden*, Switzerland, United Kingdom*.

¹¹ 15 countries : Albania, Bosnia and Herzegovina, Bulgaria*, Croatia, Cyprus*, Czech Republic*, Hungary*, Former Yugoslav Republic of Macedonia, Montenegro, Poland*, Romania*, Serbia, Slovakia*, Slovenia*, Turkey.

¹² EuroTB Annual Report, Paris, March 2007.

MALARIA:

12. 4,271 cases of malaria were reported in the European Union in 2005, which equates to approximately 1.07 cases per 100,000 population.¹³ Malaria in the EU is almost always an imported disease: ie it is linked to persons travelling to countries where malaria is endemic. The potential for malaria to become established in Europe is addressed in more detail in our response to Question 7.

Examination of Witness

Witness: MRS ZSUZSANNA JAKAB, Director, European Centre for Disease Prevention and Control (ECDC), examined via video-link.

Chairman: Good afternoon and welcome. Thank you very much for your time this afternoon. I just have a couple of introductory points. The Intergovernmental Organisations Select Committee of the House of Lords is charged with looking at intergovernmental organisations, as it says, but in this case in relation to communicable diseases. You will probably be pleased to know that we are not looking at the internal workings of the European Union, which is covered by a separate Committee. I do want to say that the proceedings this afternoon will be recorded. You will be sent a transcript of the evidence to make any factual corrections, if necessary. Also, we would like you to contact us further if you have any views you want to add to what we discuss this afternoon. We may have a vote in the middle of these proceedings. If we do, we will try to resume as quickly as possible. With that, perhaps I could ask Lord Howarth to ask the first question, which is about WHO and the role of your organisation.

Q892 Lord Howarth of Newport: Good afternoon. May I ask you about the interface of your own organisation with the World Health Organisation's Regional Office for Europe? The WHO office covers 53 countries, including all the EU Member States, and the role of WHO Euro is to work to strengthen Europe's defences against infectious diseases. In what respects does the role of your organisation, ECDC, differ? Why should two organisations be needed which would appear to be dedicated to remarkably similar purposes?

Mrs Jakab: Good afternoon to the Committee. I am Zsuzsanna Jakab, Director of the ECDC, the European Centre for Disease Prevention and Control. It is a real honour for me to give oral evidence to your Committee on this highly important issue, and many thanks for the first question. I would like to say that the role of WHO and the role of ECDC are different but they are very much complementary. WHO is clearly an intergovernmental organisation that covers the whole world globally and regionally, including the Regional Office for Europe. It has a very strong policy mandate—it sets policy and targets; it has a very strong advocacy role, of course. On the other

hand, ECDC is a new agency of the European Union which was set up just three years ago in 2005. Our responsibility and our role have to be seen in the whole context of the EU structure and EU architecture. Our role is mainly for the detection of health threats, to protect EU citizens from emerging health threats, we have to analyse these threats, we have to come up with risk assessments, we have to come up with scientific advice to policy-makers at a European level and in the Member States. We have to promote the preparedness and advise to coordinated response in Europe. This works, of course, for the 27-plus EU countries. The WHO are responsible for 53 countries, as you pointed out, and for obvious reasons the WHO has to put high emphasis on the countries that are outside the European Union; and they have to put high emphasis also on the diseases that are not communicable diseases but are the major killers.

Q893 Chairman: Mrs Jakab, could I briefly interrupt? Your English is amazingly good but we have a slight echo here. If you could slow down slightly, I would be very grateful. Your English is remarkably good; let me compliment you on that. It seems funny for me to be asking you to go slower, but there is a slight echo and we are not getting everything.

Mrs Jakab: My conclusion is that there is no overlapping in the roles and in the mandate of WHO and ECDC. The roles are absolutely complementary; that is a very important point. This is one of the buzzwords that I would like to give you in my reply to this first question. The second buzzword is that we have to have synergy. We have to make sure that the strategies are coordinated and also established for the high-risk countries that WHO Euro has developed. The second important notion for WHO and ECDC is synergy. The third important issue is the partnership. I was myself in WHO Euro for several years before I went back to my own country, and I was leading the country health development programmes in WHO Euro. I really believe that WHO has a very important and significant role to play, which has to be supported. Collaboration and partnership are absolutely vital. In 2005 I signed a Memorandum of Understanding with WHO Euro, and once a year we

¹³ Annual Epidemiological Report on Communicable Diseases in Europe, ECDC, Stockholm, June 2007.

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have a meeting at the highest level. This year it was at the end of February which also included the Assistant Director-General from WHO Geneva. Once annually we have a high level meeting like this. This year we agreed that every three months we should have a video-conference in addition to that. At the political and at the strategic level we already have the on-going collaboration, and at the operational, technical level it has already been developed between our teams, WHO Euro and ECDC, so that is already in place. The synergy is very important and this is the way to ensure it. We also contribute to certain elements of the Commission's and the Council's decisions. In the European Union many of the important decisions are taken by the Council, with the Ministers sitting there. When an issue falls into the ECDC mandate, they ask for a contribution from ECDC to make sure that decisions are evidence-based. Therefore, we contribute through our advise both to the policies but we also contribute to the work of the European Commission when it comes to legal issues. ECDC has no policy mandate and no legal power, but we do have an advisory role here; and, whenever the Commission wants us to contribute, we do that. That is why I was saying that our role has to be seen in the context and in the light of the whole EU set up and EU infrastructure. We are not an intergovernmental organisation like WHO, but we are an EU agency—part of the family—with a responsibility to the EU and we bring the scientific evidence to ensure a sound decision is made.

Q894 Chairman: If you look down the line ten to 20 years, would you see this type of organisation being replicated in other regions of the world and replacing the role of the nation states to some extent? In other words, would you see other regions creating a regional organisation like this? Is that what you see happening?

Mrs Jakab: I think the PAHO initiative before and after the Second World War was something similar to what we have now in the European region. The European Union Member States are looking into that model, how it works and how we can ensure a partnership. Here the key issue is that WHO and the European institutions have to develop a very close partnership. In recent years we have gone a long way in Europe to bring WHO and the European institutions together and we have to go further and deeper in this exercise. That is why I would like to emphasise again that here the issue is not about ECDC and WHO; here the issue is about the EU and the WHO. In the EU important decisions are taken in the Council; DG SANCO has a very important public health programme which runs a number of programmes and takes important decisions for the health of the European Union citizens. In addition to that, we have the European CDC in the development

phase. All these issues together have to be looked at, and we have to see what is the best way to ensure a very strong and very deep collaboration between these institutions and WHO and I can assure you that this has been on the mind of the policy-makers in Europe in the past year.

Chairman: We are going to have to break now for the vote. I would ask all Members to come back as quickly as possible, and then we will start with Lord Hannay's question.

*The Committee suspended from
3.46 pm to 3.54 pm for a division in the House*

Q895 Lord Hannay of Chiswick: You spoke very eloquently about the interface with WHO. Could say just a little bit about the interface with the National Health Authorities who, after all, have huge budgets and are very big operators in this field, and also about your interface with the various research institutions around the European Union, who also are devoting big resources to all these problems? I just wondered whether you could say something about that, because I think the issue of potential duplication runs in both directions, upwards to the world level and downwards to the national and research level.

Mrs Jakab: This is a very important issue. I would like to emphasise that the European CDC was based and built up on a model that takes into consideration the fact that the European Member States have very strong national public health institutions very strong infrastructures and expertise. The founding fathers of ECDC took a very wise decision when they said that we should not duplicate. We do not want you to have research institutions belonging to ECDC directly; we do not want you to have laboratories linked to ECDC; we do not want you to follow the American model of the US CDC. What we want you to do is to network with the European institutions, network with the European nationals. This is the thought process behind ECDC. We have to link ourselves to the public health institutions in your country; we have to link ourselves with the research institutions and to the excellent expertise that you have. Therefore, if you look at the founding regulations of ECDC, it is very clear that we have to work with the Member States in many ways, and I would like to highlight at least three. One is that we are an independent institution, but we have a governing body which is our Management Board. In this Management Board we have the representatives of the Ministers of Council from all over the European Union countries. We have an Advisory Forum, where we have representatives from national public health institutions from all the EU countries, plus we have a list of competent bodies which are our collaborating institutions in the Member States. The Member States of the EU have compiled for us a list of competent bodies with which we have to

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collaborate. Therefore, please rest assured that there is no duplication, and we have a lot of interaction with the Member States to decide what are the European CDC priorities and programmes. We only engage on those issues where we can bring an added value into the European structure.

Q896 Lord Avebury: You mentioned that you did not want to replicate the CDC, although you do say somewhere in your evidence that the idea was to create a European CDC. I wondered in what sense you thought you were creating a European CDC and in what sense you differ from them?

Mrs Jakab: The American CDC, CDC Atlanta, was one of the first institutions that I visited when I took up this job. I wanted to see how they operate. There are clearly similarities and differences between these two institutions, CDC Atlanta and the European CDC. The similarities are the following. The decisions for health, health systems and organisation of health care and the financing is very similar in the United States to what it is in the European Union, because there are very strong national competencies. In the United States this is the same. There is a very strong responsibility at the State level for all the health issues and a limited responsibility at the Federal level for health issues. Therefore, in my view, the power and the mandate of the European CDC and the US CDC do not differ too much. I would not say that the CDC Atlanta and ECDC differ too much in this regard. The American CDC cannot do more at the Federal level than what it can do at the European level with due respect to the competencies. They have a huge budget and they use the “carrot approach”. I was told they use the carrot approach by putting out calls for tender to the States and they want them to apply and thus the Federal level of the CDC financing these activities. We do not have so much money here, therefore we compensate it through networking. We have a very, very close cooperation with the European Member States’ institutions. There are clearly differences, and one of the biggest difference I see is that the CDC Atlanta is a huge establishment; it has a number of centres together which is coordinated by a central place. They have a number of research institutions and a huge pool of international research centres and the laboratories. They also have a huge budget, but please bear in mind that they are not only covering communicable diseases but the full spectrum of public health, including communicable diseases, food safety, occupational health, NCD and determinant, etc plus they are not only covering the United States but also 40 countries outside the United States. Whenever I am travelling in India, for example, I see huge operations from the US CDC. These are clearly differences, but I would also say that the European model is a different model because of the European

specificities, the strong national public health capacity is there and should not be duplicated. The final comment on this is that the US CDC was set up about 60 years ago in 1946, something like that. We are a very young institution in the European Union, just operational in the last three years. We are very new; we are still in the development stage but, if we look again at this issue in a few decades from now we may find that a different situation has also developed in the European Union CDC. I personally believe that it was a very good decision of the founding fathers of the European CDC to set up this institution, because there is a big interest among the national public health institutes to have this coordination role in place which was not the case before ECDC was put in place.

Q897 Chairman: One obviously hopes there will not be, but if there were an outbreak of pandemic flu, for example, WHO Europe would have to coordinate with all the 53 countries in their region. Would they not then be duplicating things if they also have to go to you? The question, in a sense, is that WHO has got to liaise with all of these countries but also liaise with you, and there is a slight anxiety that that might cause confusion. What would you say to that?

Mrs Jakab: I would say that there cannot be enough coordination on such an important issue as an outbreak of pandemic flu. We have had several simulation exercises in Europe in the last two or three years since we were established. Some were organised by us, others by the Commission. We have had one big exercise on pandemic preparedness. The scenario was developed by the Health Protection Agency in the UK, and it was a very, very successful event. In that case the European Commission, ECDC and WHO and the MS’s participated in this exercise. We had Emergency Operation Centres and there was absolutely no confusion in the exercise; the roles and the mandate were very clear. In the European Union you have to look at this in the light of the division of roles and responsibilities between the different players. I said that the Member States had a very strong mandate in taking decisions on the risk management of health measures. This is coordinated by the European Commission, whereas ECDC contributes to this process through risk assessment. We have mainly a risk assessment role and an advisory role. In the EU the European Commission will coordinate the work of the Member States, with the input from ECDC, the adoption of any public health measures. It is therefore again not only an ECDC/WHO issue, this has to be rolled out also towards the European Commission, and other institutions of the European Union. There are many different players in this case.

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Q898 Lord Hannay of Chiswick: This is not entirely different from what we have been talking about, but in our evidence that we have been taking from a very wide range of research people, governmental representatives, international organisations, we are continually struck by the fact that you do have considerable difficulty in working out how all the bits fit together and whether the architecture is really designed to produce the maximum value for money and impact on dealing with communicable diseases. For example, one can see that the WHO is very heavily engaged in Malaria, and I do not imagine Malaria is a hugely important issue for the ECDC. In some of the other big communicable diseases, the balances between the WHO's role and that of other organisations will be different. We are always struck by the fact that everyone says that WHO is indispensable, but they also say that it is under-resourced; they also say that they wish it could give more of a lead. One is bound to ask the question: might it not give a bit more of a lead if the field were not so cluttered with other organisations?

Mrs Jakab: Thank you very much for this important question. I would like to approach it from two sides. First of all, I think it is a positive development that we are so many players, because this shows that health has really become a priority. It is a priority under the Development Agenda and basically we have reached what we wanted to reach, to have a number of players around and to involve both the community and civil society in the decision-making process. We have seen the flourishing of all these NGOs and civil initiatives, which is extremely positive. On the other hand, you are absolutely right that there are so many players on the ground and we need to have much more coordination and much more synergy. You are also absolutely right in saying that the WHO is under-resourced. I also believe it is, and this is why WHO has to accept a situation whereby a relatively-small regular budget on the one hand and rather large voluntary donations on the other, which sometimes support the priorities that are set by WHO, sometimes they are not. Sometimes WHO's priorities are driven by those organisations giving the voluntary donation. I would also suggest that WHO resources should be increased globally. It is true that we are not dealing with Malaria in the European Union, but with climate change this may come, so I cannot discount it. Having said this, the number of players needs a lot of coordination, and I think WHO has to be in a position to play this coordination function. I would not like to see new organisations coming up just to play this coordination role; I think WHO has to play it. Sometimes it plays it very well, like in the Member States where there is a large and well resourced WHO Country Office which links all the donors and the players together. It plays it extremely well. If the

WHO office is smaller due to the size of the country or the size of the budget, than it has a limited capacity. At the moment I think WHO has to be more resourced to play this coordination role more effectively together with its other global leadership functions. Beyond this, I also believe that the various players have to develop partnerships; from our perspective we are clearly doing that. We have Memoranda of Understanding with all of the important players, first of all with the European institutions obviously to develop close collaboration, but with all the important players. I think this is a very important issue also for the others to follow, that on one hand you have close bi-lateral arrangements between the players and on the other hand there is a body—in my mind this should be WHO—which plays a coordinating role and should be supported by resources. The best way to do that coordination is to have a policy and strategy that is agreed upon by the international fora which provides a very good platform for all the partners coming in and coordinating the activities.

Q899 Chairman: You can always send in more information if you wish to after the hearing. But do you now have access to the WHO International Health Regulation website? Do you or do you not have access to that now?

Mrs Jakab: Not yet but it is in the pipeline.

Q900 Chairman: Is it not agreed yet? Have you got access or is just not agreed yet?

Mrs Jakab: Not yet, but it is agreed. We had a high-level meeting of WHO leaders and this was on the agenda. The WHO headquarters staff told us that under Article 14 of the International Health Regulations they can give access to ECDC to the IHR website.

Q901 Chairman: The agreement is there in principle but it is not yet happening? Is that right?

Mrs Jakab: Yes, exactly. It has not yet happened, but the political levels of the WHO are seriously considering it and it will happen.

Q902 Lord Jay of Ewelme: To some extent this follows the answer you gave a moment or two ago to Lord Soley. You mention in your submission (which was extremely helpful) the Early Warning and Response System that the ECDC operates and you also talked about the EU Health and Security Committee that is in charge of pandemic planning. As I understand it, you also recently launched an Emergency Operations Centre which, on the face of it, seems a very sensible thing to do. I wonder if you could very briefly say how those organisations relate to each other and how they relate to the WHO's Global Outbreak Alert and Response Network, the

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GOARN, which we were hearing about in our visit to Geneva last week?

Mrs Jakab: First of all, I can say that there is close collaboration between ECDC, the European Commission and WHO. The Early Warning and Response System of the EU foreshadowed the IHR by about ten years when the IHR were put in place, the EWRS was already established. This is a communication platform among the EU Member States the Commission and ECDC to exchange information and coordinate the public health measures in case of an outbreak. Then there is the Health Security Committee which is an advisory committee of the European Commission looking at the health security perspective of the EU. Many times the WHO is invited to those meetings in its observer capacity. Then we have recently launched the Emergency Operations Centre, which is modelled on a similar emergency operation centre in WHO Geneva, which is called the Strategic Health Operation Centre. The leader of that Strategic Health Operation Centre was invited by us to contribute to the specifications of our Centre in very close collaboration. The GOARN, is a WHO network of institutions that can mobilise international expertise. ECDC is part of the GOARN. I think the coordination is in place and, as I said before, I do not think there can be too much coordination on this issue.

Q903 Baroness Whitaker: I want to stay with coordination but from a different perspective. Your evidence has pointed out that the majority of pathogens come to humans from animals, and we have heard evidence that that is about three quarters of the emergent infections but also that there is not enough coordination between the international organisations that monitor human and animal health. We would like to ask you: what is your view about the synergy at the moment between the WHO, FAO and OIE and also how your own organisation coordinates its work with these other bodies in respect of the jump from animal to human health.

Mrs Jakab: I think we need to have more coordination for sure, but I must say that with the avian influenza the coordination has improved to a great extent. In recent years there was a meeting in New Delhi for avian influenza and pandemic flu preparedness globally. This was the first time that the Director-Generals of WHO, FAO and OIE came to the same platform to address these issues. Also within the European Union the avian influenza outbreak brought in the collaboration between the Chief Medical Officers and the Chief Veterinary Officers in the Member States, coordinated by the European Commission. This has taken place a few times and we were discussing all these pandemic issues. Also, here in Uppsala we organised a conference on the

strengthening of pandemic flu preparedness to which we invited OIE, FAO and of course WHO. I think that is a positive start and positive progress. We are not there yet, but I think the progress is positive. From an ECDC perspective, we are working very closely with EFSA, because we are jointly preparing a zoonosis report every year. From our perspective we also collaborate with European Commission veterinary unit whenever there is a need for that.

Q904 Baroness Whitaker: Could I just take it for a minute to the operation level? If there were an outbreak among a group of animals which came to the attention of the FAO or the OIE, would you hear about it very rapidly from them? What leverage would you then operate? How would you then operate as ECDC to safeguard European citizens?

Mrs Jakab: This is the responsibility of the European Commission. If there is an outbreak in animal health or there is an animal issue, this is something which is very much coordinated by the European Commission. In case of an outbreak of this type, the European Commission would take action. We would only be involved if there were implications for human health. In the case of avian influenza, it was considered as an animal disease until we had the first human case: for example in Turkey we went there with WHO, the Commission and others to investigate the human cases of avian influenza.

Q905 Baroness Whitaker: Is that satisfactory in your view, that you only hear of the outbreak when it has finally made the jump into infecting humans? Are you happy with that?

Mrs Jakab: Our mandate comes from the founding regulation of ECDC, which gives us the mandate for human health issues. We do not have a mandate for animal health issues. We have to follow our mandate. There is always an update on the ECDC mandate taking place now for the next period of time. So, if the founding fathers want to change anything in our mandate, they will do so; but for the time being we do not have a mandate for animal health issues. EFSA have much more of a mandate than we do, that is the European Food Safety Agency of the European Union.

Q906 Baroness Hooper: Turning now to the wider picture, in your evidence you referred to the fact that economic development will and must continue. You have already touched on the area of research and strengthening the health sector in all this, but you also referred to continued investment in careful health impact assessments. Bearing in mind that environmental impact assessments were also a creature of the European Union, would you care to define a little more what you actually mean by health impact assessments and whether these are effective in

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other countries (or in certain countries) and whether in fact other intergovernmental organisations in sectors other than health use health impact assessments in deciding the relevance of their policies?

Mrs Jakab: I think that health impact assessment is a very important issue because, if you want to introduce a new policy or you want to introduce new legislation in any sector, it is extremely important to look at the health impact of this new legislation or new policy. This is mainly to safeguard the health of the citizen and to avoid any detrimental effect from policies that have been made. So this is the idea. The European Commission has been very strong on health impact assessments and this has been an initiative in health in all policies, which was strongly supported by the European Commission and later on it was picked up by WHO. Some Member States are also doing it, others are not, but on the whole our message is that the health impact assessment is a very healthy exercise. It really safeguards and protects the health of the citizens by looking at the health impact of various decisions before the decisions are taken.

Q907 Chairman: If the World Trade Organisation made a certain proposal on trade affecting animals, for example, and you saw a health risk, would you see it as your responsibility to approach the WTO and suggest a health impact assessment?

Mrs Jakab: No, it would not fall into the mandate of ECDC.

Q908 Chairman: The World Trade Organisation does obviously have views about trade in animals; trade in animals can then spill over into problems for human health. In circumstances where you feared that might happen, where you feared there might be a spill over, could you approach the WTO with the idea of a health impact assessment? Or would that not be something the ECDC could do?

Mrs Jakab: First of all, we would consider it ourselves, discuss it with partners like EFSA, if needed because they have a mandate for food safety whereas we have a mandate for human health. Then we would get in touch with the European Commission and inform the European Commission accordingly and the European Commission would be the one who would take it up with the WTO if it considers necessary.

Q909 Lord Desai: We have many people observing—and indeed you said in your evidence—that there is very little development of new drugs to treat TB, and the re-emergence of TB may be partly because of lack of new drugs. Some witnesses have argued that the lack of new drugs is a market failure instance. Do you share this view, that market failure causes this? Will initiatives like Advanced Market

Commitments or UNITAID or the International Finance Facility for Immunization help to speed up the invention of new drugs?

Mrs Jakab: That is an extremely important issue both for TB drugs and also for antibiotic development and drugs for other diseases. With regard to TB, I agree that it is a market failure that we do not have new drugs on the market. But I would like to add two comments. What I want to say is that the clinical trials for TB drugs development are very long: they have to be tested and they need another large trial period. In the past decade we have seen a number of TB drugs in the pipeline and there are at least seven drugs now in the development stage, and three of these are in clinical development, which is a very positive thing. Some of them are funded by different international donors and a number of them are funded by DG Research. This is also extremely positive that DG Research has considered this as a priority. Again, it is a long clinical and field-testing period on the drugs before they can be put into use. As said before the positive thing that is that they are in the pipeline whilst not yet ready for use because there is a lengthy testing period. I also want to add to this that there is a very specific feature of the research and development business model of the pharmaceutical industry, because they favour a large market where the consumer is able to afford a high market price. Therefore, these initiatives that you have also mentioned, the Advanced Market Commitments initiative, this is a very promising strategy which we have already seen on one or two occasions and it has to be tested more in the future. We have to experiment with similar approaches in order to start work on the development of TB drugs, but also the development of antibiotics because, with increasing antibiotic resistance not only in the UK but everywhere in Europe, there is a need to develop new antibiotics. Such initiatives as you mentioned are important. We are working with the EMEA and other partners on these issues.

Q910 Lord Geddes: I would like to address the possible links between international travel and the spread of infectious diseases. The Royal Society in this country said, in September of last year, that “the healthcare screening and treatment processes for migrants entering the European Union need to be better evaluated and coordinated across Member States to prevent the potential spread of infectious diseases such as TB and HIV”. Do you accept that comment? If so, what action is the ECDC taking to address the situation?

Mrs Jakab: It is very important that migrants benefit from healthcare and health assessments, of which the screening is one very important component. I also believe that the evaluation of such processes is very important and it is obvious that they take time. What

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we are doing currently is that, during the Portuguese Presidency, migration and health were high on the agenda and there was an important Council conclusion which referred to the ECDC to develop a report by ECDC, by the end of 2008 on migration and health. We are looking at these issues in various areas of TB, HIV and other diseases. We are in the process of compiling such a report which we would be very honoured to share with you.

Q911 Lord Geddes: When do you expect that report to be published?

Mrs Jakab: Not before the end of 2008, but of course certain elements will be ready before that. I would imagine that around early autumn we would have a

first draft, which we would be happy to share with you.

Chairman: Thank you very much, Mrs Jakab. Thank you for your time; my apologies for the interruption with the vote. If there is anything you want to add, please write to us. You indicated that in principle WHO Europe had agreed to allow you access to the website on IHR events. You might need to check this with them, but could you let us know why it is that there is a delay in doing that, given that the agreement in principle has been taken? Could I also ask you to let us know when you will have access to it? If you could write to us on that basis I would be very grateful. Meanwhile, thank you very much indeed; thank you for your time and your efforts.

TUESDAY 6 MAY 2008

Present:	Avebury, L	Howarth of Newport, L
	Eccles of Moulton, B	Jay of Ewelme, L
	Falkner of Margravine, B	Soley, L (Chairman)
	Hooper, B	Whitaker, B

Memorandum by Professor Harvey Rubin, University of Pennsylvania

The principal issues on which the Committee would welcome your views are:

1. *A recent report on Communicable Diseases by the UK Department of Health stated that “post-war optimism that their conquest was near has proved dramatically unfounded”. What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis?*

The Global Burden of Disease Study indicates that infectious diseases accounts for 22% of all deaths and 27% of disability adjusted life years (DALYs) with a disproportionate impact on the developing world where infectious diseases account for 52% of deaths and 50% DALYs in sub-Saharan Africa and only 11% of deaths and 5% of DALYs in established market economies (Globalization and Infectious Diseases: A review of the linkages. found at http://www.who.int/tdr/cd_publications/pdf/seb_topic3.pdf). While progress has been made on a number of fronts, especially at the basic science level in understanding the pathogenesis of many diseases, the overall situation in controlling infectious diseases has deteriorated for a number of interrelated reasons including: 1) the increase in antibiotic resistant bacterial infections, 2) the pipeline of new molecular entities that lead to effective anti-infective agents is quite sparse, 3) large pharmaceutical companies have, in many cases, abandoned anti-infective drug development and discovery, 4) while antiviral research and development is progressing, work developing antibacterial, anti-fungal and especially anti-parasitic agents lags far behind, 5) the absence of harmonized regulatory processes hinders rapid development of anti-infective agents, 6) in many parts of the world the distribution of anti-infective agents to clinics and to patients is woefully underdeveloped, 7) the infrastructure that is necessary for rapid and accurate diagnostic testing in the developing world is woefully inadequate, 8) global infectious disease surveillance and reporting is incomplete and shared, interoperable, real-time databases are also inadequate, 9) there are an insufficient number of well-trained medical workers that are necessary to ensure proper diagnosis, prescribing and monitoring practices, 10) zoonotic and foodborne infections must be taken into consideration in the increased incidence of the spread of infectious diseases, 11) the increased incidence of national insurgencies and of failed states worsens the global communicable disease situation, 12) individual nations have different motivations in generating policy for the use of first, second and third line anti-infective agents, 13) globalization-economic globalization, demographic globalization (urbanization and refugee movement), technological global changes and environmental/climate global changes, all contribute to altered patterns of communicable diseases, frequently in unpredictable ways, 14) agencies that work for increased access to anti-infective agents must coordinate goals and policies with agencies that work to limit the emergence of resistance to anti-infective agents, 15) increased number and availability of counterfeit drugs contribute substantially to the spread and emergence of drug resistance of communicable diseases, 16) the emergence of new research in synthetic biology generates an entirely new threat space with the synthetic creation of new infectious agents, the reintroduction of infectious agents that no longer exist in nature or in generating infectious agents that exist in nature but are hard to isolate.

Therefore it is not an exaggeration to speak of a crisis; on the contrary it is a moral, medical, economic and political imperative to raise these issues at the highest level of government.

2. What reliable data exist regarding the numbers of people infected globally with the four diseases¹⁴ on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?

1. HIV/AIDS

Global summary of the AIDS epidemic December 2007 (http://data.unaids.org/pub/EPISlides/2007/2007_epiupdate_en.pdf)

Total 33.2 million [30.6–36.1 million]
 Adults 30.8 million [28.2–33.6 million]
 Women 15.4 million [13.9–16.6 million]
 Children under 15 years 2.5 million [2.2–2.6 million]

People newly infected with HIV in 2007

Total 2.5 million [1.8–4.1 million]
 Adults 2.1 million [1.4–3.6 million]
 Children under 15 years 420,000 [350,000–540,000]

AIDS deaths in 2007 Number of people living with HIV in 2007

Total 2.1 million [1.9–2.4 million]
 Adults 1.7 million [1.6–2.1 million]
 Children under 15 years 330 000 [310,000–380,000]

The ranges around the estimates in this table define the boundaries within which the actual numbers lie, based on the best available information.

2. TUBERCULOSIS-FROM THE DATA COLLECTED BY THE WHO

(<http://www.who.int/mediacentre/factsheets/fs04/en/>)

Global and regional incidence

The World Health Organization (WHO) estimates that the largest number of new TB cases in 2005 occurred in the South-East Asia Region, which accounted for 34% of incident cases globally. However, the estimated incidence rate in sub-Saharan Africa is nearly twice that of the South-East Asia Region, at nearly 350 cases per 100,000 population.

It is estimated that 1.6 million deaths resulted from TB in 2005. Both the highest number of deaths and the highest mortality per capita are in the Africa Region. The TB epidemic in Africa grew rapidly during the 1990s, but this growth has been slowing each year, and incidence rates now appear to have stabilized or begun to fall.

In 2005, estimated per capita TB incidence was stable or falling in all six WHO regions. However, the slow decline in incidence rates per capita is offset by population growth. Consequently, the number of new cases arising each year is still increasing globally and in the WHO regions of Africa, the Eastern Mediterranean and South-East Asia.

Estimated TB incidence, prevalence and mortality, 2005

WHO region	Incidence ^a		Prevalence ^a		TB Mortality			
	All forms	Smear positive ^b	per number	per number	per number	per number		
	(thousands)	(thousands)	100,000	100,000	100,000	100,000		
	(% of global total)	pop	pop	pop	pop	pop		
Africa	2,529 (29)	343	1,088	147	3,773	511	544	74
The Americas	352 (4)	39	157	18	448	50	49	5.5
Eastern Mediterranean	565 (6)	104	253	47	881	163	112	21
Europe	445 (5)	50	199	23	525	60	66	7.4

¹⁴ HIV/AIDS, Tuberculosis and Avian Influenza.

WHO region	Incidence ^a		Prevalence ^a			TB Mortality		
	All forms		Smear positive ^b					
	number (thousands) (% of global total)	per 100,000 pop	number (thousands)	per 100,000 pop	number (thousands)	per 100,000 pop	number (thousands)	per 100,000 pop
South-East Asia	2,993 (34)	181	1,339	81	4,809	290	512	31
Western Pacific	1,927 (22)	110	866	49	3,616	206	295	17
Global	8,811 (100)	136	3,902	60	14,052	217	1,577	24

^a Incidence—new cases arising in given period; prevalence—the number of cases which exist in the population at a given point in time.

^b Smear-positive cases are those confirmed by smear microscopy, and are the most infectious cases. pop indicates population.

1. Pursuing high-quality DOTS expansion and enhancement. Making high-quality services widely available and accessible to all those who need them, including the poorest and most vulnerable, requires DOTS expansion to even the remotest areas. In 2004, 183 countries (including all 22 of the high-burden countries which account for 80% of the world's TB cases) were implementing DOTS in at least part of the country.
2. Addressing TB/HIV, MDR-TB and other challenges. Addressing TB/HIV, MDR-TB and other challenges requires much greater action and input than DOTS implementation and is essential to achieving the targets set for 2015, including the United Nations Millennium Development Goal relating to TB (Goal 6; Target 8).
3. Contributing to health system strengthening. National TB control programmes must contribute to overall strategies to advance financing, planning, management, information and supply systems and innovative service delivery scale-up.
4. Engaging all care providers. TB patients seek care from a wide array of public, private, corporate and voluntary health-care providers. To be able to reach all patients and ensure that they receive high-quality care, all types of health-care providers are to be engaged.
5. Empowering people with TB, and communities. Community TB care projects have shown how people and communities can undertake some essential TB control tasks. These networks can mobilize civil societies and also ensure political support and long-term sustainability for TB control programmes.
6. Enabling and promoting research. While current tools can control TB, improved practices and elimination will depend on new diagnostics, drugs and vaccines.

3. MALARIA

WHO collects the most comprehensive data

(http://rbm.who.int/wmr2005/tables/table_a21.pdf) with compilation and analysis carried out by Roll Back Malaria <http://www.rollbackmalaria.org/wmr2005/>

“As of 2004, 107 countries and territories have reported areas at risk of malaria transmission. Although this number is considerably less than in the 1950s, with 140 endemic countries or territories, 3.2 billion people are still at risk. Present estimates are that around 350–500 million clinical disease episodes occur annually. Around 60% of the cases of clinical malaria and over 80% of the deaths occur in Africa south of the Sahara. Of the more than one million Africans who die from malaria each year, most are children under five years of age. In addition to acute disease episodes and deaths in Africa, malaria also contributes significantly to anaemia in children and pregnant women, adverse birth outcomes such as spontaneous abortion, stillbirth, premature delivery and low birth weight, and overall child mortality. The disease is estimated to be responsible for an estimated average annual reduction of 1.3% in economic growth for those countries with the highest burden.

The wide variation seen in the burden of malaria between different regions of the world is driven by several factors. First, there is great variation in parasite- vector-human transmission dynamics that favour or limit the transmission of malaria infection and the associated risk of disease and death. Of the four species of *Plasmodium* that infect humans—*P. falciparum*, *P. vivax*, *P. malariae* and *P. ovale*—*P. falciparum* causes most of the severe disease and deaths attributable to malaria and is most prevalent in Africa south of the Sahara and in certain areas of South-East Asia and the Western Pacific. The second most common malaria species, *P. vivax*, is rarely fatal and commonly found in

most of Asia, and in parts of the Americas, Europe and North Africa. There are over 40 species of anopheline mosquitoes that transmit human malaria, which differ in their transmission potential. The most competent and efficient malaria vector, *Anopheles gambiae*, occurs exclusively in Africa and is also one of the most difficult to control. Climatic conditions determine the presence or absence of anopheline's vectors. Tropical areas of the world have the best combination of adequate rainfall, temperature and humidity allowing for breeding and survival of anophelines.

The second major factor contributing to regional and local variability in malaria burden is differences in levels of socioeconomic development. Determinants include general poverty, quality of housing and access to health care and health education, as well as the existence of active malaria control programmes providing access to malaria prevention and treatment measures. The poorest nations generally have the least resources for adequate control efforts. In many poor countries, exposure to malaria of vulnerable populations is enhanced by migrations enforced by poverty and/or conflict.”

AVIAN INFLUENZA

http://www.who.int/csr/disease/avian_influenza/country/cases_table_2008_01_24/en/index.html

Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO

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Country	2003		2004		2005		2006		2007		2008		Total	
	cases	deaths												
Azerbaijan	0	0	0	0	0	0	8	5	0	0	0	0	8	5
Cambodia	0	0	0	0	4	4	2	2	1	1	0	0	7	7
China	1	1	0	0	8	5	13	8	5	3	0	0	27	17
Djibouti	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Egypt	0	0	0	0	0	0	18	10	25	9	0	0	43	19
Indonesia	0	0	0	0	20	13	55	45	42	37	3	3	120	98
Iraq	0	0	0	0	0	0	3	2	0	0	0	0	3	2
Lao People's Democratic Republic	0	0	0	0	0	0	0	0	2	2	0	0	2	2
Myanmar	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Nigeria	0	0	0	0	0	0	0	0	1	1	0	0	1	1
Pakistan	0	0	0	0	0	0	0	0	1	1	0	0	1	1
Thailand	0	0	17	12	5	2	3	3	0	0	0	0	25	17
Turkey	0	0	0	0	0	0	12	4	0	0	0	0	12	4
Vietnam	3	3	29	20	61	19	0	0	8	5	1	1	102	48
Total	4	4	46	32	98	43	115	79	86	59	4	4	353	221

3. *What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? And what improvements might be made?*

Data is collected by a number of agencies including the:

1. World Health Organization, Global Outbreak Alert and Response Network (GOARN) <http://www.who.int/csr/outbreaknetwork/en/>
2. EuroTB (tuberculosis <http://www.eurotb.org/>)
3. EuroHIV (HIV/AIDS <http://www.eurohiv.org/>)
4. EISS (influenza <http://www.eiss.org/>)
5. EU-IBIS (N meningitidis and H influenzae <http://www.euibis.org/index.htm>)
6. EWGLINET (legionnaires disease <http://www.ewgli.org/ewglinet.htm>)
7. EuroCJD (Creutzfeldt-Jakob disease <http://www.eurocjd.ed.ac.uk/>)
8. DIVINE (foodborne enteric viral infections <http://www.eiss.org/>.http://www.rivm.nl/en/aboutrivm/projects/index/background_information_objectives.jsp#tcm:13-25598)
9. EARSS (antimicrobial resistance <http://vwww.rivm.nl/earss/>)
10. BSN (basic surveillance network <http://www.eurosurveillance.org/em/v09n07/0907-221.asp>)
11. ESAC (antimicrobial consumption) <http://www.esac.ua.ac.be/>

12. EUCAST (antimicrobial susceptibility testing http://www.escmid.org/sites/index_f.aspx?par=2.4)
13. ENIVD (imported viral diseases <http://www.eurosurveillance.org/em/v03n07/0307-223.asp>)
14. EUVACNET (vaccine preventable diseases <http://www.euvac.net/graphics/euvac/index.html>)
15. DIPNET (diphtheria <http://www.eurosurveillance.org/em/v12n12/1212-225.asp>)
16. ESSTI (sexually transmitted diseases <http://www.essti.org/epidemiology.php>)
17. US Centers for Disease Control (CDC) National Electronic Disease Surveillance System (NEDSS) <http://www.cdc.gov/nedss/>
18. US CDC Early Aberration Reporting System EARS <http://www.bt.cdc.gov/surveillance/ears/>
19. US CDC BIOSENSE <http://www.cdc.gov/biosense/>
20. US Department of Homeland Security BLOWATCH http://www.dhs.gov/xoig/assets/mgmt/rpts/OIG_07-22_Jan_07.pdf
21. Enter-net (enteric pathogens <http://www.cdc.gov/ncidod/eid/vol4no3/young.htm>)
22. Wild Bird Global Avian Influenza Network for Surveillance (GAINS) <http://www.gains.org/>
23. ESSENCE (US Military electronic Surveillance System for the Early Notification of Community-based Epidemics <http://www.geis.fhp.osd.mil/GEIS/SurveillanceActivities/ESSENCE/ESSENCEIV.asp>)
24. GEIS (US Department of Defense Global Emerging Infections Surveillance and Response System <http://www.geis.fhp.osd.mil/>)
25. ARGUS (integration of disparate data <http://biodefense.georgetown.edu/projects/argus.aspx>)

As one can tell from the sheer number of surveillance systems, integration is lacking as is interoperability, security, real time data collection and incentives to contribute data. In addition, these databases do not link in an operational sense to other databases such as clinical trial databases, drug discovery databases and regulatory databases. Furthermore, all databases are incomplete in collection and are limited by the inadequacy of the existing diagnostic infrastructure, the lack of adequately trained medical personnel and the lack of adequate death registries.

4. *Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years?*

The complexity of the system, makes it difficult to predict with any given level of certainty, however, judging from past and the circumstances enumerated in response to question 1, I would suggest that the situation will continue to worsen until the issues raised here are not only addressed but the problems solved.

I agree in most cases with the US Central Intelligence Agency's three scenarios in its assessment of the course of the infectious disease threat from 2000-2020: (<http://www.au.af.mil/au/awc/awcgate/cia/nie99-17d/index.htm>)

“1. Steady Progress

The least likely scenario projects steady progress whereby the aging of global populations and declining fertility rates, socioeconomic advances, and improvements in health care and medical breakthroughs hasten movement toward a ‘health transition’ in which such noninfectious diseases as heart disease and cancer would replace infectious diseases as the overarching global health challenge. We believe this scenario is unlikely primarily because it gives inadequate emphasis to persistent demographic and socioeconomic challenges in the developing countries, to increasing microbial resistance to existing antibiotics, and because related models have already underestimated the force of major killers such as HIV/AIDS, TB, and malaria.

2. Progress Stymied

A more pessimistic—and more plausible—scenario projects little or no progress in countering infectious diseases over the duration of this Estimate. Under this scenario, HIV/AIDS reaches catastrophic proportions as the virus spreads throughout the vast populations of India, China, the former Soviet Union, and Latin America, while multidrug treatments encounter microbial resistance and remain prohibitively expensive for developing countries. Multidrug resistant strains of TB, malaria, and other infectious diseases appear at a faster pace than new drugs and vaccines, wreaking havoc on world health. Although more likely than the ‘steady progress’ scenario, we judge that this scenario also is unlikely to prevail because it underestimates the prospects for socioeconomic

development, international collaboration, and medical and health care advances to constrain the spread of at least some widespread infectious diseases.

3. Deterioration, then Limited Improvement

The most likely scenario, in our view, is one in which the infectious disease threat—particularly from HIV/AIDS—worsens during the first half of our time frame, but decreases fitfully after that, owing to better prevention and control efforts, new drugs and vaccines, and socioeconomic improvements. In the next decade, under this scenario, negative demographic and social conditions in developing countries, such as continued urbanization and poor health care capacity, remain conducive to the spread of infectious diseases; persistent poverty sustains the least developed countries as reservoirs of infection; and microbial resistance continues to increase faster than the pace of new drug and vaccine development. During the subsequent decade, more positive demographic changes such as reduced fertility and aging populations; gradual socioeconomic improvement in most countries; medical advances against childhood and vaccine-preventable killers such as diarrheal diseases, neonatal tetanus, and measles, expanded international surveillance and response systems; and improvements in national health care capacities take hold in all but the least developed countries. Barring the appearance of a deadly and highly infectious new disease, a catastrophic upward lurch by HIV/AIDS, or the release of a highly contagious biological agent capable of rapid and widescale secondary spread, these developments produce at least limited gains against the overall infectious disease threat. However, the remaining group of virulent diseases, led by HIV/AIDS and TB, continue to take a significant toll.”

5. *What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?*

The principal blockages are enumerated in response to Question 1. The only way I see to overcome these issues will be to completely develop a Global Compact for Infectious Diseases as we describe here:

Making the Case for an Enforceable Global Compact for Infectious Diseases

We live in a world of pandemic, epidemic and endemic infectious diseases that threaten personal, national and international security. The current realities are overwhelming. Each year, 300 million cases of malaria kill two million people. An estimated 3% of the world's population-170 million people-is chronically infected with the hepatitis C virus. About four million people are newly infected each year, many of who will develop a chronic infection associated with cirrhosis and liver cancer. Hepatitis B infects one in three people worldwide, an estimated two billion people, and of the 400 million people chronically infected, approximately one million will die each year from complications associated with the virus. One third of the world is infected with M tuberculosis with 10 million cases each year accounting for two million deaths. About one third of the world's population is affected by schistosomiasis and soil-transmitted helminths, representing more than 40% of the disease burden due to all tropical diseases excluding malaria. Finally HIV, with over 40 million infected people worldwide, resulted in over three million deaths in 2005 and helps foster the growth of other dangerous diseases like MDR and XDR strains of tuberculosis. The total mortality from infectious diseases worldwide exceeds 18 million deaths each year-one third of all human deaths-including many that could be prevented by efforts to research, develop and distribute new pharmaceuticals.¹⁵ Casualties approach 50,000 each day, a number that, in light of the potential to prevent and treat these diseases, represents a global moral burden.

Beyond the undeniable moral significance of this state of affairs, our collective failure to give this problem the attention it deserves has implications for the economic wellbeing of both the developed and developing world.¹⁶ International development scholars have described the role that infectious diseases play in the perpetuation of poverty in the developing world: destroying family structures and limiting economic and educational opportunities. However, infectious diseases are not merely an “over there” problem but a symmetric threat that imperils the economic security of all nations. While the social disintegration that accompanies an epidemic has filtered into the public consciousness, the resulting economic disruption is less well-known. A few weeks after the identification of SARS, the disease had already cost nearly \$30 billion, an

¹⁵ TW Pogge, *Human Rights and Global Health: A Research Program*. *Metaphilosophy*, Vol 36, Nos 1–2, January 2005. pp. 1–2, LO Gostin. *Meeting Basic Survival Needs of the World's Least Healthy People Toward a Framework Convention on Global Health*; Inaugural Lecture for the Investiture of the Linda D and Timothy J O'Neill Professor of Global Health Law. April 19, 2007.

¹⁶ I Kickbusch. *A Wake-Up Call for Global Health*, *International Herald Tribune* April 29, 2003. Cited in M Selgelid, *Ethics and Infectious Disease*, *Bioethics* Vol 19, Number 3, 2005.

amount sufficient to prevent 8 million deaths from infectious disease worldwide.¹⁷ A potential H5N1 pandemic carries an even higher cost, with economic losses approaching 600 billion dollars in the United States alone, depending on the virulence and mortality rate of the pandemic strain.¹⁸ Even without an epidemic, the spread of antibiotic resistant strains of bacteria imposes a persistent cost in terms of both health and dollars. Medical and popular literature is replete with reports of life-threatening infections caused by bacteria that are increasingly resistant to existing antibiotics. The recent Infectious Diseases Society of America report observed that the CDC estimates that two million people in the United States will acquire a nosocomial bacterial infection accounting for 90,000 deaths and that “in a growing and frightening number of cases, these bacteria are resistant to many approved drugs, and patients have to be treated with new, investigational compounds or older, toxic alternatives.”¹⁹

Finally, the increasing prevalence of dangerous infections and antibiotic resistant strains impacts both national and international security. While dangerous pathogens will not mobilize armies nor annex land, if unchecked they create human costs rivaling those of armed conflict, while simultaneously restricting the freedom of policymakers to address other pressing concerns. A study of United States national security issues conducted by the Woodrow Wilson School of Public and International Affairs at Princeton University unequivocally states that, “American national security in the 21st century . . . is likely to be threatened by pathogens as much as people. New diseases and antibiotic-resistant strains of old ones are on the rise . . .”²⁰ Clearly, the problem of new and emerging infectious diseases is global.

What to do about it?—A Global Compact for Infectious Diseases

We propose a new approach, a strategy based on the creation of a unique, four-point International Compact²¹ for Infectious Diseases (the “Compact”:) distinguished by:

- *Compact Core Mission I:* Establish, maintain and monitor a shared international data and knowledge base for infectious diseases, including but not limited to biosurveillance information, basic research data, relevant pharmaceutical data and suites of services and skills.
- *Compact Core Mission II:* Establish, maintain and monitor a network of international basic science research centers that will support fundamental investigations into the pathophysiology of certain microbial threats to global health.
- *Compact Core Mission III:* Expand capabilities for the production of vaccines and therapeutics expressly for emerging and reemerging infections.
- *Compact Core Mission IV:* Establish, maintain and monitor international standards for best laboratory and regulatory practices.

Through the implementation of these four core missions, the Compact will minimize the impact of infectious diseases on national and international health, social and economic development and international security. The key benefit of the Compact is to drive innovation and progress in four core areas: information and knowledge sharing, basic science, drug and vaccine development and best laboratory and regulatory practices. As shown in Figure 1, these missions are interconnected; without a strong foundation of basic science, the drug and vaccine pipelines dry up. Similarly, in the absence of effective biosurveillance it becomes difficult to project which strain of an emerging disease represents the most significant threat, which in turn hampers our ability to create countermeasures. Information technology and knowledge sharing will drive new science, which in turn can modify and inform regulatory initiatives. Standardized regulatory regimes enable new drugs and vaccines that will change global epidemiological patterns and these patterns must be reintegrated into a central database, beginning the cycle again.

Addressing the problem as a whole creates powerful incentives for stakeholders to participate. For example, in order to access a central database containing information on current clinical trials, epidemiological data and new compounds and targets, participants would pledge to implement best laboratory and regulatory practices. By bringing together government, the private sector and academia the Compact allows each group to institutionalize their relations with the others. Pharmaceutical companies and public-private development

¹⁷ *A Potential Influenza Pandemic: Possible Macroeconomic Effects and Policy Issues*, Report Presented to the Congressional Budget Office December 8, 2005; revised July 27, 2006. <http://www.cbo.gov/ftpdocs/69xx/doc6946/12-08-BirdFlu.pdf>

¹⁸ *Bad Bugs, No Drugs*, the Infectious Diseases Society of America, July 2004.

¹⁹ G J Ikenberry and A Slaughter, *Forging a World of Liberty Under Law: US National Security in the 21st Century* <http://www.wvs.princeton.edu/ppns/report/FinalReport.pdf>

²⁰ We deliberately use the concept of “compact” in order to avoid the term “treaty” for many of the reasons discussed by Jean-Francois Rischard in *Global Issues Networks: Desperate Times Deserve Innovative Measures* THE WASHINGTON QUARTERLY – WINTER 2002-03, 26:1 pp. 17-33. We expect that the compact will have a structure resembling networked governance as described in Rischard’s paper. We also do not rule out on the alternatives, both legal and political.

²¹ See George W Downs, David M Rocke, Peter N Barsoom, *Is the Good News about Compliance Good News about Cooperation?* International Organization, Vol 50, No. 3 (Summer, 1996), pp. 379-406.

partnerships can find partners to help take promising leads through to development. With the inclusion of post marketing/post distribution clinical trial data in the database, philanthropic organizations and governments will be able to understand the effects their investments are having throughout the world. Academics will acquire additional funding streams for their research as well as input from their colleagues all over the world. Finally, all parties will work together to harmonize regulatory processes across the board, reducing barriers to market entry for much needed therapeutics and ensuring their wider distribution.

There already exist a large number of databases that address one or more of these issues, eg, the revised 2005 International Health Regulations (IHR). We propose developing an information technology architecture that will seamlessly integrate these databases, make them user friendly yet provide the necessary security and add new data as recommended by the wide user community. The challenges here are formidable, but hardly insurmountable. The greatest obstacle is the need for trust between signatory nations and a willingness to share data. There are technical challenges as well. Any attempt to create a common architecture for information systems would require common ontologies. New algorithms and models of disease spread need to be developed and validated. Lastly, the language of the Compact has to address the issue of non-compliance by establishing a robust platform for the public dissemination of compliance status.

Organization and Governance

In order to accommodate the various interested parties and work within the limits of international law, the Compact will embrace a two-pronged approach, working with states in the form of a treaty and with other interested parties (NGOs, academic institutions and the private sector) as a softer, pledge-based agreement. While these differences are structural rather than substantive, both approaches have their limitations. Treaties must be ratified through domestic processes that vary widely from state to state and take an extended amount of time to enter into force. Furthermore, states jealously guard their sovereign prerogatives and thus enforcement regimes must be devised in a manner that maximizes both effectiveness and feasibility.²² However, once in force a treaty creates a body of “hard law” around an issue, providing a legal basis for international enforcement. A compact structure, in contrast, allows NGOs, the private sector and academic institutions to submit a pledge of membership and voluntary compliance, making it quick to set up and allowing interested parties to coalesce around an issues.²³

By providing parallel frameworks for different parties, the overall project will, over time, achieve the benefits of each. Domestic groups that pledge their membership can apply pressure to their home states, hopefully speeding ratification of the treaty framework. By bringing together both state and non-state actors, the overall aims of the Compact will be debated from a variety of different viewpoints, thereby enhancing the legitimacy of the project and promoting a thorough understanding of its goals.

In addition to the enhanced situational awareness that will come from the establishment of a truly global database, the benefits to signatory nations from both the developed and developing worlds are significant. Once fully implemented, the Compact will provide access to relevant pharmaceuticals at a low cost, ensure better quality control, reduce barriers to entry in underserved markets, provide signatories with access and participation in high-level research endeavors and distribute the costs and risks of R&D across a number of countries.

The key to any progress against infectious diseases is a structure that brings together these diverse interests in a lasting fashion. Without such a structure, the commitment to reducing the impact of infectious diseases on our national, economic and personal security will be subject to the political vagaries of the moment, leaving us unprepared for the next global health crisis. Language and concepts embodied in the Compact have already found their way into international statements of the problem by diverse communities including those with a global human and economic development agenda—see for example the recent OECD sponsored Noordwijk Medicines Agenda,²⁴ and the biodefense/biosecurity community, see the Lake Como Consensus Statement of Priority Actions for the Promotion of Global Biosecurity.²⁵ In addition, the House and Senate are considering the bipartisan Strategies to Address Antimicrobial Resistance (STAAR) bills xi and the Commonwealth of Pennsylvania has declared the development and rational use of antibiotics a research priority for the state in 2008–09. Fully aware of the challenges inherent in a global initiative of this scale, we propose as a matter of urgency that efforts be accelerated to draft, debate, refine and implement the first *Global Compact for Infectious Diseases* as the common international instrument to achieve these goals.

²² See Rischard, Matthew, *Global Issues Networks: Desperate Times Deserve Innovative Measures*, *The Washington Quarterly* Vol 26, No 1 pp 17–33 and *High Noon: We Need New Approaches to Global Problem-Solving*, *Fast*, *J Int Economic Law* 4: 507–525.

²³ http://www.oecd.org/document/31/0,3343,en_2649_18532957_38202975_1_1_1,00.html and comments found in Callan B, Gillespie I, *The path to new medicines*. *Nature*. 2007 Sep 13;449(7159): 164–5.

²⁴ <http://www.ransac.org/Projects/Biological%20Threat%20Reduction%20Project/index.asp>

²⁵ <http://www.idsociety.org/Content.aspx?id=7000>

6. *What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?*

Our work is divided into three components—the first is quite local, I have a clinical practice specializing in infectious diseases in a major teaching hospital in the US (The University of Pennsylvania Health System), secondly my laboratory investigates the molecular mechanism of latency and dormancy in tuberculosis; it is funded by the US National Institutes of Health, the US National Science Foundation, and the Global Alliance for TB Drug Development. In general, the NIH funding has been flat for several years and additional resources must be found to expand their funding for basic research in infectious diseases. Public-private partnerships, such as the Global Alliance play an extremely important role in supporting new research and development in this domain; these organizations should be expanded and strengthened with additional resources contributed by governmental agencies. Third, we are involved in proposing far reaching policy recommendations, such as the Global Compact for Infectious Diseases discussed above. We have had excellent cooperation from organizations such as OECD but we need more complete cooperation and support from States parties. The UK government can play a central role in this global endeavour.

7. *What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient “joined-up” thinking in approaching the problem?*

These non-health causes are enumerated in response to question 1. There is no question that the health and non-health factors are intimately linked and intergovernmental actions in these so called non-health domains are essential for an integrated attack on the problem of communicable diseases. At the current time, joined-up or integrated thinking is not happening; there are too many stove-piped approaches. As discussed above, we propose to bring these components together under a common, enforceable Global Compact for Infectious Diseases. Eventually States parties must be involved but our efforts will start with NGOs, academic centres and industry.

8. *Cases of Tuberculosis fell progressively in the UK until the mid-1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of Tuberculosis infections in Britain? And how could intergovernmental action help to reverse the trend?*

This is now fairly well studied. A recent paper (Clin Infectious Diseases 2007 May 15;44(10): 1261–7.) shows that the increase is secondary to immigrant populations—Between 1999 and 2003, overall tuberculosis notification rates in the 25 EU countries decreased by 4% each year, down to 14 cases per 100,000 population in 2003, but Italy and the United Kingdom registered increases because of tuberculosis in immigrants. In 2003, EU countries reported 62,743 tuberculosis cases; of these, 76% were in persons who were previously untreated, 22% were in persons > 64 years old, and 30% were in foreigners (the percentage in individual countries ranged from 2% to 75%)”.

In addition, drug resistance is an increasingly global problem. Intensive screening, diagnostic evaluations, contact tracing and directly observed therapy are the hallmarks of essential governmental interventions.

9. *Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising, Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions eg HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?*

Improvements are needed on a number of fronts—there is a pressing need for more medical professionals and ancillary medical personnel in the developing world, diagnostic infrastructure must be built, these will contribute to better surveillance data, improved drug distribution. Drug monitoring systems need to be put in place and need to be constantly evaluated for efficiency and efficacy, co-infections, poverty, and many of the issues raised in response to question 1 are in play here as well.

10. *To what extent do you believe that the 2004 Stockholm Convention limiting the use of DDT against Malaria-carrying mosquitoes has been a factor of increases in the spread of the disease? Has any risk analysis been carried out comparing the relative dangers to human health posed by DDT and Malaria?*

I not have the data to make a judgment on the extent to which the 2004 Stockholm Convention on persistent organic pollutants contributes to the current incidence of malaria, however the World Health Organization is clear about their positive recommendation for the ongoing use of DDT for indoor residual spraying (IRS) in epidemic areas and in areas with constant and high malaria transmission, including throughout Africa (<http://www.who.int/mediacentre/news/releases/2006/pr50/en/print.html>)

11. *What intergovernmental action is planned or in hand for early detection of the transmission of Avian Flu from birds to humans and of human-to-human transmission in potential source countries? Is this proving sufficiently effective to prevent an Influenza pandemic? What more could be done?*

Extensive surveillance for H5N1 is extant (please see response to Question 3). However surveillance is only one aspect of preventing a pandemic—data sharing is critical, appropriate contingency plans and availability of countermeasures are also necessary. It may be that H5N1 will not be the origin of the next influenza pandemic, there has never been a recorded pandemic with the H5N1 strain and it is altogether reasonable to assume that an H/N strain will emerge as the pandemic strain.

12. *To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?*

The data is clear that drug resistance in *Mycobacterium tuberculosis* and *P. falciparum* and *P. vivax* is on the rise.

13. *In a number of countries, including the UK, there is a problem with hospital-acquired infections. What intergovernmental sharing of knowledge is taking place to help bring this problem under control?*

This is a major problem in the US as well and is generating high level attention. To attack this problem, congressional leaders Senators Sherrod Brown (D-OH) and Orrin Hatch (R-UT) introduced the Strategies to Address Antimicrobial Resistance (STAAR) Act (S. 2313) on 6 November 2007. Representatives Jim Matheson (D-UT) and Michael Ferguson (R-NJ) introduced the House-version of the bill (HR 3697) on 27 September 2007. <http://www.idsociety.org/STAARAct.htm>). The state of Pennsylvania just announced that attacking antibiotic resistance will be one of the state's research priorities for 2008–09.

I strongly support the STAAR bills and recommend that similar approaches be considered in the UK as well as other countries. The major components of the bill follow:

SECTION 3. ANTIMICROBIAL RESISTANCE TASK FORCE

Congress established the interagency Antimicrobial Resistance Task Force in 1999 but authorization for the Task Force (Sec 319E, PHSA) expired in 2006. Created to coordinate federal efforts to combat antimicrobial resistance, the Task Force quickly developed the Public Health Action Plan to Combat Antimicrobial Resistance. Implementation of the plan, however, was not optimal because the Task Force had little authority or funding. There were no personnel dedicated to executing the plan; Task Force members all had full-time responsibilities in the federal health agencies.

****New: Office of Antimicrobial Resistance and Advisory Board****

Section 3 builds on the work of the Antimicrobial Resistance Task Force by enhancing authority, funding, and personnel to execute a coordinated federal response to antimicrobial resistance. The Task Force is reauthorized to review all data and issues related to antimicrobial resistance, make recommendations on how to combat resistance in the United States and internationally, and integrate these efforts into the Public Health Action Plan to Combat Antimicrobial Resistance through periodic updates of the plan. An Office of Antimicrobial Resistance in the Department of Health and Human Services is created to supply the dedicated authority and personnel for this effort and to coordinate planning and implementation of efforts across federal agencies and departments. And because antimicrobial resistance is not simply a federal governmental issue, a Public Health Antimicrobial Advisory Board is created to allow outside experts from domestic and international health communities to contribute to the effort.

****New: Antimicrobial Resistance Research Strategic Plan****

This section also calls for the creation of a federal blueprint for antimicrobial resistance led by the National Institutes of Health and Centers for Disease Control and Prevention in collaboration with other federal agencies and the new Office of Antimicrobial Resistance.

Drafted in consultation with leading infectious diseases experts, including veterans of the Antimicrobial Resistance Task Force, Section 3 will take the hard work already done planning a comprehensive response to antimicrobial resistance, and furnish the tools necessary to execute that plan.

SECTION 4. COLLECTION OF ANTIMICROBIAL DRUG DATA

There is a significant shortcoming in the United States regarding the collection and dissemination of data on the amount of antimicrobial products used in humans and animals. In contrast, such data is collected in Europe and made available to government experts there. This provision directs drug sponsors and appropriate government agencies to collect these data and share them with the Office of Antimicrobial Resistance as the central repository for such data to facilitate interagency planning on antimicrobial resistance.

SECTION 5. ANTIMICROBIAL RESISTANCE CLINICAL RESEARCH AND PUBLIC HEALTH NETWORK

There is presently little capacity to rapidly and effectively monitor, assess and address the spread of new or particularly virulent resistant microbes. Section 5 addresses this problem by establishing a sentinel surveillance system through CDC encompassing at least 10 geographically-distributed sites to track and confirm in near real time the emergence of resistant pathogens. Further, with CDC's and the National Institutes of Health's (NIH) support, these 10 or more sites will conduct research (including epidemiological, interventional, basic, and clinical research) to study the development of antimicrobial resistance and enhance our capacity to prevent, control and treat resistant organisms. Finally, this provision establishes a national isolate collection capacity under which CDC would serve as a national repository for samples of emerging pathogens with a focus on pathogens that show new or atypical patterns of resistance.

SECTION 6. ANTIMICROBIAL RESISTANCE QUALITY MEASURES DEMO PROJECTS

This provision directs the Office of Antimicrobial Resistance to award grants to establish demonstration projects with the goals of better understanding the scope of the antimicrobial resistance problem, decreasing inappropriate antimicrobial drug use, and validating evidence necessary to establish quality measures related to antibiotic prescribing. The demonstration projects will have particular emphasis in important areas infectious disease experts have identified as requiring more information.

SECTION 7. GAO REPORT

This provision requires that the Government Accountability Office of the United States submit a report by 2012 measuring the successes and failures of this Title in improving the ability to monitor, prevent the spread of, and otherwise limit the impact of antimicrobial resistance on human health.

Funding Authorization

The STAAR Act authorizes new funding to support the federal response to antimicrobial resistance. This funding includes: \$45 million in 2006, \$65 million in 2009, \$120 million in 2010 and such sums as may be necessary for subsequent years.

14. *Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?*

Unfortunately intellectual property rights still stand at the centre of the discussion over discovery, development and distribution of antimicrobial agents and technologies. There is no question that intergovernmental action is needed to break down this barrier. A number of solutions have been presented and can be found in 1) Carl Nathan *Nature Medicine March 2007. Aligning Pharmaceutical Innovation with Medical Need*. 13(3): 304–8 and 2) *A Breakthrough in R&D for Neglected Diseases: New Ways to Get the Drugs We Need*, Mary Moran PLoS Medicine Vol 2, No, 9, e302 doi:10.1371/journal.pmed.0020302.

15. *What interchange exists between States in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?*

I will defer responding to this question because it is best answered by those who have more data than I.

16. *The International Health Regulations 2005 are intended to provide a global framework for the rapid identification and containment of public health emergencies. How effective do you consider this response system to be? Do improvements need to be made?*

The new IHRs are a step in the right direction. It is too soon to tell if it will make an important impact. The problem with IHRs reflect the problems associated with all surveillance systems as I discussed above.

17. *What intergovernmental planning has been undertaken to cope with the impact of an outbreak of infectious disease caused by deliberate release of micro-organisms into the environment? Is there adequate liaison between the various agencies involved, including intelligence, law enforcement and health care professionals? How could action by intergovernmental bodies help further?*

This is an emerging threat that needs a great deal of attention from the scientific community, governmental agencies, NGOs as well as the law enforcement and intelligence communities. There is a dearth of cooperation among these groups at this time which is a major flaw in national as well as international strategies. We recently addressed this problem in an international meeting held at Lake Como, Italy which were presented to the 2007 Biological Weapons Convention meeting of states parties. Here are our recommendations:

**Statement on Improving Global Biosecurity
Presented to the BWC 2007 Meeting of States Parties
By the Partnership for Global Security
10 December 2007**

The forces of technological and economic globalization have radically altered the nature of the biological challenges the world faces. There is general agreement on the need for improved global biosecurity, but there is currently no consensus on how to design or implement it. New approaches are needed to develop a stronger, more flexible biological security strategy that can adapt to the rapid pace of technological and economic changes and include all stakeholders. There are several key issues to be considered in building a consensus for this enhanced global biosecurity system. A successful approach to improved global biosecurity will have to balance the need for adequate controls with flexible mechanisms. The goals should be to mitigate risk, increase confidence in bioactivities, and limit intrusiveness to that research which is truly dangerous. Any improvements in this area must account for the fact that the majority of research, activities and applications are beneficial and therefore the emphasis must be on minimizing the dangers without hindering the wide-ranging benefits of bio research.

The majority of biological materials and most research are controlled by the private sector. Unfortunately, to date the participation of this sector in the dialogue on how to improve global biosecurity has not been commensurate with its dominance in the field. Eighty percent of the world's biotechnology companies are privately held. Revenues for the world's 710 publicly traded companies in 2006 totaled \$73.4 billion, or 14% growth over 2005. Therefore, because the private sector plays a dominant role in the advancement of the life sciences it must be better integrated into the discussion of global biosecurity.

Another major challenge is harmonizing global biosecurity regulations and oversight. Currently more than 40 nations are involved in biotechnology and life sciences research and development. However, there is a lack of consistency around the globe in biosecurity regulation, oversight, standards, and facility transparency. Creating a balanced approach is the key to success. In the near term much more could be done on a voluntary basis by the private sector and governments. A voluntary and balanced approach could allow for the creation of uniform security standards, practices, and procedures in the developed world. For example the biosecurity standards and practices in most OECD countries are not that different and their common characteristics could be informally codified. These could then be endorsed through industry or trade organizations or intergovernmental organizations. The biotech industries in the developing world then could be encouraged and assisted to work toward these levels.

Another significant challenge is the need to coordinate and facilitate communication and knowledge sharing among the broad range of stakeholder communities. In this regard, PGS proposes that the states parties to the Biological and Toxin Weapon Convention endorse the creation of a yearly global convention on

biosecurity that would involve all relevant stakeholders. Such a global conference would facilitate the goal of establishing harmonized global biosecurity norms and allow for the interdisciplinary coordination and information sharing that are now lacking.

PRIORITY ACTIONS

To help achieve this new level of biosecurity this statement endorses the five priorities for urgent action by the international community that were proposed in November 2007. Titled the *Consensus Statement of Priority Actions for the Promotion of Global Biosecurity*, it was endorsed by six biological security policy and technical experts: Kenneth N Luongo, Executive Director of the Partnership for Global Security; Maurizio Martellini, Secretary General of the Landau Network-Centro Volta; Gerald Epstein and David Heyman, Co-directors of the Biological Threat Reduction Forum at the Center for Strategic and International Studies; Harvey Rubin, Professor of Medicine, Microbiology, and Computer Science at the University of Pennsylvania; and Barry Kellman, Professor of Law at DePaul University.

Sharing Baseline Information

Development of a baseline of information on global biological holdings, research facilities, and infectious disease patterns. Specifically this could include identification and alignment of all existing global databases of pathogen stockpiles, research facility and collection storage locations, inventories of biological materials and equipment, and infectious disease monitoring and patterns. This network should be connected and integrated by an information technology architecture that will allow it to be utilized for the benefit of global public health and security while protecting sensitive and proprietary information.

Education and Awareness Raising Promotion

Greater education and heightened awareness promotion on the nature of the biological threat in the scientific, academic, and policy communities. The potential for the accidental or intentional misapplication of biological technology needs to be recognized while protecting the enormous benefits the life sciences, provide to humankind.

Interdisciplinary Coordination

Interdisciplinary coordination and information-sharing in support of the improvement of global biosecurity. The threat posed by the misapplication of the life sciences cuts across numerous sectors, including public health, science, technology, law enforcement, and private industry. Therefore greater cross-communication among the diverse stakeholder sectors is essential to improve information flow and promote awareness of the concerns and major issues in each sector. Yearly global conventions on global biosecurity featuring a broad cross section of life sciences stakeholders should be convened.

Engaging the Private Sector

Engaging in a dialogue with the private sector on the risks posed by the potential misapplication of biological materials and advanced scientific techniques while emphasizing the need to protect the scientific and economic value created in the biotechnology and life sciences fields. This dialogue must advance—not hinder—the vast benefits biotechnology can contribute to the promotion of public health and raise the quality of life globally.

Promoting Compliance with Harmonized Standards and Practices

Development and acceptance of globally harmonized biosecurity standards, improved gathering of intelligence, and better integration of law enforcement to enhance the quality, rapidity, and effectiveness of efforts to prevent and respond to biological dangers.

18. *Though our remit is focused specifically on known infectious diseases, we would be interested to know how you view the global threat from new or previously unrecognised ones and from the transmission of infections from animals to humans.*

There is an enormous database confirming that there is a significant global threat from new or previously unrecognised infectious diseases and from the transmission of infections from animals to humans. The issue should not be left unaddressed by the Committee.

19. *What resources (subscriptions, staff, training, medicines etc) does the UK Government commit to intergovernmental bodies to help in the fight against the four diseases listed?*

I do not have the information necessary to adequately respond to this important question.

20. *Do you wish to provide any other relevant information in addition to what you have said in answer to the above?*

I think I may have already exhausted the Committee with the above responses. I am happy to discuss these issues in person with the Committee if the Committee would find that helpful.

May 2008

Examination of Witness

Witness: PROFESSOR HARVEY RUBIN, Director of the Institute for Strategic Threat Analysis and Response (ISTAR) at the University of Pennsylvania, examined.

Q912 Chairman: First of all, can I welcome you to the Intergovernmental Organisations Select Committee on Communicable Diseases. The architecture of the intergovernmental organisations is the issue which we are fundamentally interested in rather than the diseases themselves, although they are underpinning the discussions. These events are being recorded this afternoon and a transcript will be sent to you and you can correct any factual matters that you feel need correcting. I also want to invite you to send in any further comments that maybe, when you have read it, you feel you have left out; or, if you want to add things, do not hesitate to do that through the Clerk here. Again, can I thank you very much for your very generous offer of coming over to see us at your own expense and in your own time; clearly you do have a very great interest in this area and in the the Global Compact which you are putting forward. You are the Director of the Institute for Strategic Threat Analysis and Response in the United States. So, picking up your wording from your written evidence—which, incidentally, I found very helpful and very detailed—you say there “the only way I see to overcome [the obstacles to achieving progress in the prevention and control of the four diseases] will be to completely develop a Global Compact for Infectious Diseases”. Could I invite you, first and foremost, to summarise the content of that Compact, particularly placing emphasis on whether you see it as being a treaty or an organisation. How would you see it being set up and how would you describe it?

Professor Rubin: Thank you, and thank you for inviting me. I greatly appreciate the opportunity to come and share some of our thoughts on this really important issue and I congratulate the Committee for

taking this on as a major enterprise. The Compact is comprised of four interlocked, interdependent, linked missions that will enable, produce and regulate the problem of communicable diseases. That is a mouthful, so what do I actually mean by that? And how will we do that? The key to that statement is that these four missions, these four enterprises, are linked; involvement in one implies involvement in the others. So what are the four issues? The four issues are to develop a knowledge base, a fully integrated, interdependent, interoperable knowledge base of infectious diseases. The second mission is to create major basic research centres that focus on specific areas of infectious diseases, in particular helminths, protozoa, viruses and bacteria—so a knowledge base plus basic science research centres. The third component is the development of best practices, both best regulatory practices and best laboratory practices. And, finally, the fourth component is to use all of that to increase the accessibility, the manufacturing and the distribution capacity and capabilities to distribute new agents and even current agents that are useful as vaccines or drugs. The key here is to start building the knowledge base, this is something that can get done relatively quickly; it does not require a lot of money, it requires a lot of knowledge and intelligence though. The surveillance that we are talking about is more than figuring out what disease is current now in Zimbabwe or what disease is current now in Philadelphia. The knowledge base is an entire integrated knowledge system. There was a wonderful paper published by a woman named Kate Jones (first author), who is right here at the Zoological Society in Regent’s Park, in which she and her colleagues described, 335 new

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Professor Harvey Rubin

infectious diseases that have emerged over the past several decades since 1940. Within the past decade there has been a significant increase in vector-borne diseases, within the past decade there has been a significant increase in antibiotic resistance in terms of bacterial diseases. These are new events, and she was able to map these events. In fact the authors says that we can now start correlating the emergence of these diseases with new environmental issues and new human demographic issues. We have not been able to do that before in such detail so linking the kinds of knowledge that one can gather by tracing disease and linking that to other data sets is really important. The data sets have to be interoperable, the data sets have to work in a multi-language environment, and the data sets themselves are vastly different: they could be lists of numbers, they could be images, they could be chemical structures. All these data sets now exist in different places and very few are actually linked together. Without having integrated data there are a couple of things that happen: we get behind the eight ball in terms of tracking new diseases for which there have been no descriptions, like SARS; we also get behind the eight ball in creating new drugs. Without that kind of integrated data set we do not know how to actually fill the pipeline. So surveillance in our definition is more than just tracking diseases, it is tracking and integrating enormous sets of data functions and data algorithms. We include surveillance of disease outbreaks, but it should also include clinical data from ongoing clinical trials, failed clinical trials; we can always learn from our mistakes—those are buried away for the most part but it would be very nice to have access to that kind of data. We need to generate access between the community of scientists and doctors working on these problems. Right now we can call our friends, we can look on Google and see who is working on things, but it would be great to have and build a community of scholars, a community of epidemiologists, a community of private sector, involvement a community of government officials and committees like this that actually are working on the problem. That does not exist either. Then there are suites of services that exist in the private sector for example what is the best way to design a clinical trial, where clinical trials could be focused these data sets exist out there in various ways that are not totally linked. The basic science part, the second component of the Global Compact for Infectious Diseases, is based on the old Rockefeller Foundation, Ford Foundation and eventually the World Bank endeavours in plant research; understanding that the world lives mostly on cereals and grains and rice, these agencies decided that we had better start figuring out what the basic science of these natural resources are and can we use basic science to increase the viability of grains and seeds, can we develop

grains and seeds that are resistant to blight, can we increase grains and seeds that would exist under very wet circumstances or very dry circumstances? That early infusion of money was the basis of the green revolution. We need to have similar kinds of basic research centres, overseen by an integrating organisation. We must study these diseases and these organisms and we will fill the drug development pipeline? The drug development pipeline is basically empty. The Global Compact for Infectious Diseases will link the basic research centres to the surveillance/knowledge centres; if you want to be part of the basic research centre, you must be part of the surveillance group. The third component of the Compact is to harmonise intergovernmental, inter-state regulations. Right now there is a vast array or a hotchpotch of regulatory issues, a hotchpotch of best laboratory practices that have to be standardised. This will not happen under the current kinds of agreements that exist between States. Finally, put all the components of the Compact together, populate the knowledge base fill the pipeline, have harmonised regulations, and understand how we will direct antimicrobial agents to the individuals who need them and build the capacity to make new vaccines and new drugs. Big pharmaceutical companies, in this country, in my country, in France, in Switzerland, and around the world are effectively out of the game of making new antibiotics, there is no business model that makes that an effective business enterprise for the largest companies. The goal of the Compact is to link all these missions together and, in linking them together, we will be able to begin to address the communicable diseases problem. There are lots of organisations that are doing one or the other and are doing them relatively well, but there is no overall incentive. The incentive is the linkage between the four missions of the Compact and the ultimate improvement of the quality of life and economic development.

Q913 Chairman: Before I go on to the next bit, you thought this would be an international treaty. What should be the formal structure for it? Or are you suggesting that it is an informal structure?

Professor Rubin: We have given great thought to that issue and we are not so confident that a treaty in this day and age is the right way to start. What we believe is to start with NGOs, academics, the private sector, to agree that this is an important enterprise to study and to solve, and then, as that grows, to start engaging governments, built very much on the Ottawa Landmine Convention. I was privileged to hear four questions discussed earlier in the day in the House of Lords and we heard about cluster bombs and the treaty that is going to be debated in Dublin, I understand. Like the cluster bomb issue, the issue of communicable diseases really revolves around that

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same fundamental process, of engaging the worldwide community. It will start with small groups, and the Noble Lord actually mentioned the Landmine Convention: this is the same idea. The difference between our Compact and the Landmine Convention—and we are deliberately calling it a Compact, not a Treaty—is that infectious diseases is a symmetric issue, it is not “over there”. There may not be an landmines out on Pall Mall, there are no landmines on Broad Street, we hope, there are no cluster bombs in Broadway in New York. But there sure as heck are infectious diseases there; 90,000 die of antibiotic-resistant bacterial infections in my own country; 30,000 will die of influenza in my own country; this is happening here, in your country as well. You pick up the newspaper—when I was here last August, MRSA was all over the newspapers, the same thing in my country. Unlike cluster bombs, unlike landmines, this is a totally symmetric issue. We should start with NGOs, start with academics—all of whom by the way who have been given this talk have agreed that there is a need for a new approach to communicable diseases—and then engage governments. I would be delighted if governments would be engaged even sooner, and that is why—you said thanks for coming over here—I would have not missed this opportunity.

Q914 Chairman: Thank you for being so clear about that. What you have described is bringing together these non-governmental organisations and so on. I suppose I would first of all like to know what the feedback from them to you has been like but I would also ask you to address the question of why is it that you would not just end up with another intergovernmental organisation, which to some considerable extent would squeeze out, if you like, some of the things the World Health Organisation does.

Professor Rubin: That is a great question and, I must tell you, one that I have been used to answering; this is not the first time I have heard that question. The answer is that yes, we are need to set up a new intergovernmental organisation, absolutely, to fill a vast gap and a yawning abyss, to fill a need which is the need for an integrator. My secondary appointment at Penn is in the Computer Science Department; this problem of communicable diseases is one that we call part of complex system, it involves everything from a sick and dying patient to synthetic biology, and everything in-between. It is a complex process and in any complex system you have to have an integrator. You build an Airbus and there are thousands of embedded computers in an Airbus; you must have a systems integrator. As good as the World Health Organization is, as good as the Bill and Melinda Gates Foundation is, there is no systems

integrator and without a systems integrator the plane will not land safely.

Q915 Chairman: Why should it not be the WHO?

Professor Rubin: The WHO has a limited scope, a limited vision. They have limited funding and they have a very narrow but nevertheless very important mission in this world; it does not extend to the kinds of things that we just laid out in the parts of the Compact.

Q916 Chairman: Following the logic of this, if the WHO had more funding, then people like you could work within that?

Professor Rubin: If the World Health Organization were able to expand in some sense its mission and its goals, then it might be a viable alternative; it has not been able to do that in the past, its constraints are legal, political, social, geographic; for example the World Health Organization has very little to say about MRSA in my hospital.

Q917 Chairman: Before I bring some of my colleagues in, is not the fundamental issue here that you, as the proposer of this organisation, can either create a new organisation, which you are suggesting would act as a body that drew people together, or you could say we should build on what has already been built, do things step by step almost, rather than the grand new venture. How do you respond to that?

Professor Rubin: We would certainly not exclude the existing organisations. Those existing organisations have to be included, but as I said it is just like building a very complex aeroplane. There has to be a systems integrator. The World Health Organization does one thing in a great way, the Bill and Melinda Gates Foundation does another thing in a great way, Merck and Pfizer and Sandoz do things in a great way; but nobody is integrating them, it just does not exist and it has not existed ever. The situation in the written testimony you asked me to write is actually getting worse and so the system is not working. The only way that I can see, and I could be wrong, is to create an integrated system.

Q918 Baroness Eccles of Moulton: Leading on, Professor Rubin, from what you have just been saying, but looking at it slightly from the other end of the telescope, under your four aims is there not in each category—maybe not so much in research but in the other three—already a fund of knowledge in the World Health Organization—I quite take the point about the systems integrator. Have you got any sort of policy yet? Or have you talked to them or whatever about actually drawing on this quite considerable knowledge base that already exists within the objectives that you are going to achieve?

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Professor Rubin: A great observation! We were part of the OECD's Noordwijk Medicines Agenda. I was talking to my friend Ian Gillespie at OECD—and I understand you will be speaking to Ian as well, and as far as I understand the World Health Organization is an intrinsic and important part of the solution but not the full solution. The reason for that is because there are no linkages; this goes back to the very fundamental idea that we need to have an organisation that will enforce linkages between these issues. Yes, one could be part of a research endeavour, but that as currently configured has nothing to do with the part of receiving antibiotics and vaccines. One could be required, as the World Health Organisation is now beginning to do with IHRs, to do reporting and surveillance. Part of the problem of this whole Indonesia H5N1 issue, I believe, never would have come to the table if we had linked the idea of receiving vaccines and drugs as part of contributing surveillance data. If we had understood that fundamental idea from the very beginning, the Indonesians' resistance to sharing sequence data, I believe, it never would have become a problem. Yes, WHO have a fantastic fund of knowledge and we need to use that knowledge and we need to use some of the normative ideas behind IHRs, but we need to go further than that and a lot of the problems then will be avoided if this linkage is recognised initially.

Q919 Baroness Eccles of Moulton: If you get off the ground and this happens, do you see it working more and more closely with the World Health Organization as time goes on. Or would you say that they could be an encumbrance on your progress?

Professor Rubin: I do not believe they will be an encumbrance. If you read the language of the Noordwijk Agenda, it sounds very much like part of our Compact, and that is because we deliberately put it in there. I see the World Health Organization welcoming this kind of structure, allowing them to do what they do very well but also involving countries and States well in advance and trying to get around some of the issues of this whole notion of how do you get a federal government to mandate to its localities and its regional enterprises. The WHO has not solved that problem and they also have not solved the technical problems; the World Health Organization is great at what it does but it does not have some of the actual technical abilities to solve this problem. We would see us working very closely with them.

Q920 Lord Avebury: You said a few minutes ago, Professor Rubin, that you wanted a mechanism for enforcing linkages; I wonder how you do that, particularly with the military organisations that are mentioned in your evidence such as ESSENCE (US Military Electronic Surveillance System), the US

Department of Defense Global Emerging Infections Surveillance and Response System. These are military operations and they are not going to take kindly to being told that they must adopt the linkages which are suggested by some supra-national organisation; and neither, I suppose, would the commercial companies, people like Merck and Pfizer, who have got to come into the picture. How are you going to tell commercial organisations that they must conform to these supra-national structures and exchange data with people who have an interest other than a commercial one in using the information which is their intellectual property?

Professor Rubin: Lord Avebury, you read very closely! ESSENCE is definitely in that list of surveillance organisations, and I put that in there for completeness. It is clear that the military may not be part of this; on the other hand, I was just appointed to the Biological Cooperative Threat Reduction Programme, which is funded by the United States Congress to the Department of Defense to go out and identify infrastructure resources to ensure biosecurity in various countries around the world—the most prominent in the last programme was the former Soviet Union. There are areas in which the military will co-operate, there are areas where they certainly will not. In terms of the private sector there is a whole new movement out there—I am sure you will know about this—the notion of public/private partnerships.

Q921 Lord Avebury: But they are voluntary, are they not?

Professor Rubin: They are voluntary, that is exactly right. But it is in their best business interest, so in some sense, although it is voluntary, in terms of developing drugs for the developing world many of them have already signed on. The Commonwealth of Pennsylvania has just made antibiotic development a State research priority and we have already had conversations with major pharmaceuticals, where they will be part of a public-private partnership. They have what are called non-progressing assets in their freezers; non-progressing assets are compounds that have gone through various stages of development as antibiotics and have literally just been frozen away following a corporate decision. It is not as business-wise as making other kinds of drugs, but they are very willing, as it turns out, to share that information and share those compounds. You are right, however, that there is only a certain amount that we can start doing. But the notion, just like the cluster bomb issue, is that once this thing starts moving it will be seen, I believe, in the best business interests and, perhaps, even by our respective militaries as providing force protection. But that remains to be seen.

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Q922 Chairman: Lord Avebury's point you have answered to some extent, but this question of these enforced linkages is a bit of a difficult one to envisage when it is hard to see what force would be applied. You are implying, I think, that eventually there would be an acceptance that might stand legal challenge. Am I right?

Professor Rubin: You are exactly right. It starts off in a sense voluntarily and then, as you get closer and closer to a Treaty notion, it becomes more legislative and more enforceable. I do not know that we will ever have to get there though, to be very honest if we do—then we do; if we do not, I still think that based on things like the Landmine Convention and other “soft law” issues—the apartheid issue for example—many of them started with “soft law” that may never require legal intervention.

Q923 Baroness Whitaker: Before I get down to the detail, could I just ask you very briefly to paint a picture of what the world would be like if your Compact was up and running? What would be the major changes?

Professor Rubin: If you allow me to be relatively grandiose, because I want to paint the best picture, if we had a fully developed compact, we may not have had SARS.

Q924 Baroness Whitaker: Do you mean that people would not have got the infection? Or that the animal infection would have been contained?

Professor Rubin: It would have stopped at a small local outbreak in China, it would not have been the worldwide outbreak.

Q925 Baroness Whitaker: So the polecats, or whatever it was, would still have transmitted the infection?

Professor Rubin: Right. In that case, with the full-blown Compact, we would have been tracking even the zoonotic infections, which is what Kate Jones's article suggests. Kate Jones in *Nature* said we had to have what she calls “smart surveillance”, which actually includes the zoonotic infections. This notion of smart surveillance can be based on embedded systems; embedded systems include tiny sensors distributed everywhere. The European Union had a study of embedded systems and there will be 2.7 billion Euros devoted to so-called embedded systems, distributed sensors with very fancy mathematical algorithms to encompass that.

Q926 Baroness Whitaker: You predict that?

Professor Rubin: We will even get to the zoonotic infections, but short of that, zoonoses going into humans would have been picked up much earlier. One could even imagine—this would have been remarkable—that we could have intercepted HIV/

AIDS at a much, much earlier stage. Imagine a world without HIV/AIDS. We would certainly have better control over extremely drug-resistant tuberculosis than we do today, because there would be infrastructure built, there would be understanding of rapid diagnosis that would come under the basic science research programmes that we are suggesting; and then, if you add in the whole notion of the profound economic impact of these diseases—and you would know this better than I—the economic impact would be much less an issue. Yes, sure, there are still going to be infections, nature will also provide infectious doctors like me with a livelihood. However, there would be much less potential for pandemics, epidemics and overwhelming infectious disease on a global scale.

Q927 Baroness Whitaker: Would it be fair to say that what would happen would be much, much better contained?

Professor Rubin: Absolutely!

Q928 Baroness Whitaker: But that would not necessarily affect the diseases which are very prevalent and not at all new, like Malaria, which require a developed infrastructure to get the bed nets to the people, to get to the rural areas, to have somebody trained enough to explain what is needed, and that would be done by a different organisation?

Professor Rubin: No, I think it would still be part of this. Why? Because being part of the surveillance programme means that you have to start building the infrastructure, so the big question is where is the money going to come from? There are strategies out there: for example, a 0.005 per cent tax on international currency exchanges would generate billions of dollars, so there are strategies out there that could fund this.

Q929 Baroness Whitaker: As I read your evidence, the original timetable which you have for the drafting and signatures has now been revised, so you are putting in further groundwork. Can you tell us if there are any NGOs or IGOs joining in this process and how it is going?

Professor Rubin: That is a good question, and I have thought about that because I was sure you might want to know who else believes in this crazy idea. There are a number of NGOs and IGOs that have at least heard about the story; it has not become their main mission of course, but it has become part of their mission. In no particular order—we have a local connection here in London with King's College the University of Pennsylvania, King's College, London, the Interdisciplinary Centre in Israel and the Jordanian Institute of Diplomacy, have a four-way formal arrangement that we have with MOU signed, agreed to by our universities. This group is

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investigating political violence and biosecurity is part of that programme. There is another programme funded by the Bill and Melinda Gates Foundation called the Centre for Global Development out of Washington DC, and they have asked me to be on their Working Group on antibiotic resistance. That is a very vigorous organisation and I emailed Rachel Nugent just before I came and asked could I mention their work and she said "Please, tell them about us." The Bill and Melinda Gates Foundation, therefore, is looking specifically at the drug resistance area, that is another NGO. The Global Alliance for TB Drug Development, also funded in part by the Bill and Melinda Gates Foundation, which actually funds part of the basic research in my own lab on tuberculosis resistance, is very engaged in this whole area. We are in varying follow-on discussions with the newly merged college at Oxford: Templeton College merged with Green College to become Green Templeton College. We have been talking to Colin Bundy, who is the new Principal of that new college, and Michael Earl, and we would like to address these issues as part of a collaborative effort between my organisation and Oxford. I mentioned earlier the OECD, with whom we were engaged in drafting the Noordwijk Medicines Agenda. The Partnership for Global Security and the Landau Network-Centro Volta run by Maurizio Martellini in Italy is another group of NGOs interested in this area. We presented the idea for the Global Compact at their meeting in Lake Como, and it became part of the statement they made to the Biological Weapons Convention recently. Then I mentioned the Commonwealth of Pennsylvania as devoting themselves to the antibiotic resistance issue. So there are the biosecurity people, there are the antibiotic resistance people, and policy people my point is that we need to integrate these efforts. They need to do their work because they need to focus but there has to be an integrator. There are a number of these organisations that are picking up one or other parts of the Compact.

Q930 Baroness Whitaker: How do you rate the chances of getting there?

Professor Rubin: Each individual organisation, I think, will get there but in the end it will still take somebody with representatives from all these groups sitting round a table much like this, saying are we getting it done? That is why we need a new organisation to hold people to that issue.

Q931 Chairman: Do these organisations say to you they like the concept?

Professor Rubin: Yes, absolutely. Please ask Ian Gillespie for example. While many love the concept, they have very similar questions—this is not the first time I have heard these questions, but you have to think large to answer a large problem.

Q932 Lord Avebury: What I cannot get my head around is your suggestion that a group of people sitting around a table would say "Are we getting this done?" and they would then have the power, as I understand it, to direct all these various organisations to do something different to what they are already doing, that this group of university professors will say to the Bill and Melinda Gates Foundation, say, you have been doing the wrong things, you must adjust your programme according to our diktat almost.

Professor Rubin: No, that is exactly not the intention, the intention is to have them say to the Bill and Melinda Gates Foundation "You are doing a spectacular job and here is how it fits—at no cost to you—into the really big picture." They know that they do one thing or two things or three things extraordinarily well—and I have to tell you, almost as an aside, that without the Bill and Melinda Gates Foundation the developing world and this whole endeavour would fall apart, they are doing a spectacular job. But it is not the whole job, so the goal would be for everybody to go back to their organisation and say we are doing such a great job that it is part of this big picture, that is the goal.

Q933 Baroness Hooper: I am just interested to know, if you have all these people around the table, who is actually funding the organisation? Obviously the Bill and Melinda Gates Foundation might be in the picture. But, if you are inviting people to join and people volunteer to join and to be involved, do they have to stump up something? How does the mechanism work?

Professor Rubin: That is exactly what my Dean asked me and that is a good question. Right now my organisation is funded by the University of Pennsylvania, by the Provost at the University; each project is funded on its own and for this particular project, because it is really at the conceptual stage, we have been talking to various donors but we do not have the big, big slug of money yet to really make this happen. That is why we have been going for these individual components and it looks a bit fragmented, because you have got to convince the individual components. You are absolutely right; right now it is being funded by the Provost.

Q934 Baroness Eccles of Moulton: Professor Rubin, in 2005 the IHR established a global surveillance system for public health events of international concern and, at first sight, there does appear to be a certain overlap between the Compact and IHR. Could you, please, explain to us what value the Compact will add and also, slightly differently, what you consider the main weaknesses of the current IHR to be?

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Professor Rubin: That question comes up again quite frequently. As you know, the IHRs originally were for the three diseases after the eradication of smallpox—cholera, plague and yellow fever—and then it became very clear to many people that that really was not sufficient, and now this new definition of communicable diseases of international consequence has been proposed. As of May 2007, it was finally put into effect in the United States. The IHRs have their own sets of really wonderful surveillance and infrastructure-building components to them, and this is not my own work but people have written extensively about the shortcomings of the IHRs, in particular a colleague David Fidler, a Law Professor. David has written extensively about some of the issues and, again, enforcement even of the IHRs is a major problem. Kumanan Wilson and Fidler had an article in the March issue of the *Bulletin of the World Health Organization*—I have a copy here if you would like to see it—addressing these enforcement issues and they break it down as legislative, a memorandum of understanding between governments, guidelines and so on. So the recognition of enforcement even of the IHRs is certainly a major issue. The second major issue with the IHRs is, again, their technical limitations in recognising new and as yet unreported diseases. There are also political issues with IHRs; it is a great start but there are still a number of shortcomings that need to be addressed. The World Health Organization did issue advisories when SARS was found to be spreading around the world much to the surprise of many people in sovereign States, who thought that the World Health Organization may not really have that mission. Yet they did it anyway, much to the consternation of Canada. There is not yet, therefore, a governance structure for IHRs and, quite frankly, there is still very little incentive other than to be a good guy, not to be named and blamed. That is exactly why we need to integrate this with enforceable linkages. The answer is that there certainly will be overlap with some surveillance but they are not interested in extending that mission, for example to cataloguing and having a queryable database on chemical structures or chemical libraries. When I give this talk at basic science conferences, the first thing people say to me is “Hey, will there be a catalogue of all the libraries of chemical compounds out there that we might be able to access because I am interested in this disease?” The IHRs database is small compared to the universe of data that we need.

Q935 Chairman: You used that word “enforceable” again, and I am still not quite sure why this is any more enforceable than the International Health Regulations.

Professor Rubin: Linkages, that is my answer. Without being linked to the benefits of the Compact the hard part, ie the surveillance and the harmonisation, will have a much tougher row to hoe. If you report your data, you will be high in the queue to get the vaccine; if you do this harmonisation, your scientists will be part of the governing board of the research centres. When I travel around the world and I talk to foreign governments and foreign scientists—and it may be just because of the environment and the venue—it is very important around the world for scientists to feel that they are part of the community working on this project. The developing world, the developed world, the former Soviet Union, the Russian Federation, you name it, it is important to be part of the scientific community addressing these problems, where you can get on the phone or go to a conference or get on an email and say “What is up?” is almost like ping-pong diplomacy; it is the players that are playing together that will really drive the governance.

Q936 Baroness Eccles of Moulton: If the Compact succeeds in its aims, would there no longer be any need for the IHR?

Professor Rubin: No, the IHR would be an integral part of the Compact, absolutely: it would be that part of the data set and we would help build that data set. The scientists and the engineers and the algorithm builders will help build that data set.

Q937 Baroness Eccles of Moulton: But it could still be a separate entity?

Professor Rubin: Absolutely, sure.

Q938 Baroness Eccles of Moulton: But it would be part of the Compact?

Professor Rubin: It is like a federation.

Q939 Lord Jay of Ewelme: If I could just pursue for a moment this question of influence, leverage and enforceability, in your paper you draw the analogy between the Compact and the Landmine Action Group, and we were talking about that earlier on. My understanding is that that really succeeded through a combination of powerful and effective advocacy and great moral authority in the end, convincing first of all the NGO and academic community and then successive governments that it was right. Is that the kind of process which you see here? Is that how you see the linkage between the two or why you use that as an example?

Professor Rubin: The answer to that first question that you asked is that this is absolutely a moral imperative and it should carry the same weight as landmines. We do not have those graphic images, although if you come to my hospital or go across the River to St. Thomas’ Hospital you will easily see people

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intubated with blue fingers and blue hands because they are dying of a bacterial infection, one could generate those kinds of very intense visual images. Again, as I said before, this is not an “over there” problem, this is an “over here” problem as well as an “over there” problem. So I think—it could be that I am believing my own public relations—that the moral imperative here is as great if not greater than landmines and cluster bombs.

Q940 Baroness Hooper: The notion of joined-up thinking is always very attractive, but I know from my own experience in government how very difficult it is, even here in Whitehall, to get joined-up thinking between government departments or even, dare I say it, within the same department. When you are looking at these other areas of global warming, poverty, changes in land use, international travel, lifestyle et cetera impinging, I see a danger in too many organisations wanting to become involved and maybe too many of the ones who you do not want and perhaps some of the ones that you really do want, like say China, not wanting to become involved. It is really a question of where do you draw the line. Would you, for example, in looking at academic institutions, look at the Finlay Institute in Havana, Cuba, which has done such incredible work in the area of vaccines? Who will decide who should participate and become involved? And does it again link up with the funding issue that I raised earlier?

Professor Rubin: I hope we get to that problem, that would be just a wonderful outcome. We would have to put together a governing board—and, you are right, it would not be just everybody. If you read Dr Jones’ paper in *Nature*, you will see that these issues of urbanisation—as of this year or last year, more than half the world now live in urban centres and, trust me, it is not downtown London, it is slums. This form of urbanization is going to have an enormous impact on infectious diseases, so we cannot ignore these non-medical impacts and influences and we have to be very smart on which ones we do include and which ones we do not include. There will have to be a board of governors, and we would have to have people with vast experience, lots of wisdom, lots of knowledge, saying that these are the issues that are part of the solution and part of the problem. Urbanisation, global change, transportation, even the carbon imprint, these all are part of the problem; and, if you do not have somebody thinking in an integrated way, you will not get the solution that I think is the most optimal one. That is, after all, the point of systems engineering, to get to the optimal solution.

Q941 Baroness Hooper: I can see this operating as a think-tank, but you want it as more than that?

Professor Rubin: I have spent too long in my career just thinking, it is time to do something.

Q942 Baroness Whitaker: Your point about urbanisation made me think that in fact, although it certainly makes transmission of infection much easier, it also makes access to healthcare much easier than, say, up-country in a rural area.

Professor Rubin: That is not necessarily true.

Q943 Baroness Whitaker: But that cannot happen so easily in a slum. There are people who say that, if we really want to reduce these serious infections, what we should do actually is to aim at getting rid of poverty, because once you have economic growth, even if 50 per cent of the population of the world lives in cities, they will have access to healthcare, they will have better nutrition, better hygiene and so on. How do your ideas fit in with that view?

Professor Rubin: Actually it is not true. If you look at the UN report on urbanisation, the comment there is made that it is probably more dangerous to your health to live in an urban slum than to live in a rural area. So the issue of easier and more ready access to healthcare probably will not emerge from this urbanisation issue. That has to be recognised very clearly. On the other hand, you are right in the sense that there is this notion that, if we solve the poverty issue, we will solve the infectious disease issue; that blatantly cannot be true. Sure, there is certainly a component of poverty that needs to be addressed, absolutely; but it is certainly not the only solution, not the only part of the problem. It is a great point that needs to be further debated.

Chairman: I want to return to this question which is troubling me, and I think my colleagues, about enforcement and compliance mechanisms. Lady Falkner.

Q944 Baroness Falkner of Margravine: Professor Rubin, you are extremely optimistic and the optimism is quite infectious; it is a terrific concept that you have got here. You take me back a little bit to when I was a student doing regime change; one of the problems of regime change is that on the one end of the spectrum, as with treaties—and you have ruled out going down the treaty route—you get a momentum building up in the States Parties, and then Business and other interested parties follow or do not; the other end is this people-driven thing. While I can see the Compact coming about perhaps more than some of my more sceptical colleagues, I have a bit of trouble—and I work for an international organisation, so maybe that is why I am slightly more sceptical—about the other end, the enforceability. You say in your own paper that we need to address the issue of non-compliance by establishing a robust platform for public dissemination and so on, but how

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do you actually get reluctant States Parties in States that are perhaps authoritarian or closed states, where information dissemination itself is a challenge and where the economic implications of something such as SARS would be quite significant? How do you get those flows of information and the co-operation that a Compact would be absolutely predicated on?

Professor Rubin: I have to tell you that this is one of the major issues of discussion around our own coffee shops with my colleagues, in particular Professor William Burke-White, who is a Professor of International Law at the University of Pennsylvania. He was the person who taught me about this notion of “soft law” because I originally called this a treaty, and he said “No, no, not a treaty, it will never fly, certainly not in certain administrations, even in the United States”. Then I said OK, we will have strict exclusionary criteria that, if you do not share information, even if you were able to get it, then you will not be part of the research mission. He said even that is too draconian, that will not work, because that would penalise the least well-developed countries. We are working through that, and I do not have all the answers to that specific question. Failed States will never be part of this, there is no question about it; States that are totally authoritarian may have a harder time. The way that SARS was picked up was somebody using the ProMed database, somebody was reporting that there is an outbreak of something here, so it did not really come from the Government of China. With the advance of technology, therefore, information will not be so dependent on the federal government, and that is actually what IHRs are also predicated upon as well, that there will be non-federal sources of information. One of the problems with the IHRs by the way is that everything has to get followed through a point of contact, so that even for the IHRs it has to go back up through one specific government organisation. One can gather—correct me if I am wrong—non-governmental information but formal reporting comes through the government organisation. I think the only way to get around your issue, which is a serious one, is the ever-increasing information technology that is going to become more and more available.

Q945 *Baroness Falkner of Margravine:* And the academic community, who do talk to each other irrespective of State boundaries?

Professor Rubin: Exactly. It is not going to be easy; I may be optimistic but I am not stupid and it is certainly not going to be easy. Countries will eventually come around when they see it is in their best public health interest, and in fact in their best economic development interest, because this clearly affects economic development. Those are the two real drivers that we are counting on.

Q946 *Chairman:* I can see the pressure, both economic and moral, that might lead a country, even an authoritarian country, to say “OK, we need to co-operate here.” But if you looked at a developed country—and I mean that phrase fairly loosely—which has got a good structure of law, for example, if their Health Officer tried to conceal an outbreak of something, they would be committing a criminal offence and so there is a very real meaning to the word “enforcement”. That does not apply to your structure.

Professor Rubin: Every country will still be under the same legislative and legal structures that already exist; this new organisation is certainly not going to usurp that and there will be no guys in blue helmets and rifles moving into any country. So that person concealing an outbreak in a developed country will certainly still be under the constraints of that legal structure. We would not usurp that role for sure.

Q947 *Chairman:* And you cannot envisage a situation emerging where a government, faced with the loss of significant trade if it admits to the outbreak of a particular disease, would not actually say “To hell with this Compact, we are more worried about the economy than we are about this disease?”

Professor Rubin: Sure, I would be foolish not to recognise that. It happened with biological weapons; the Soviet Union signed that agreement back in the Seventies much as the United States did and happily went along and developed 60,000 bio-weapons personnel and built huge facilities to develop biological weapons, even though they signed the convention. There are examples, the Nuclear Non-Proliferation Treaty, but then you get states like North Korea, Pakistan and Iran. And so, absolutely, there is always the problem of abrogating agreements and there have to be, again, deeply motivated moral, economic, social and scientific reasons to adhere, and I think again, unlike many other issues, this one of communicable diseases has that broad appeal.

Q948 *Baroness Falkner of Margravine:* Let me come back and help you a little bit. Would I be correct in saying that your argument in terms of enforcement is predicated on the fact that it would be in a country’s interest, should an outbreak happen, to go through you because you actually then provide the expertise to help them combat it in a coherent, across-the-board fashion, because you have got the drugs link-up, the surveillance and everything else, so you build up sufficient expertise in the area to be the fire-fighter who helps them fight the fire?

Professor Rubin: The trusted agent, that is exactly right. We are not going to have the infrastructure that the World Health Organization has, they have people on the ground that they can rush there. The infrastructure to put people together is exactly what

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you were referring to, so the trusted agent, the integrator, that is what we see is needed, you are exactly right.

Chairman: Your comments on deliberate release of pathogens bring us on neatly to that issue. Lord Jay.

Q949 Lord Jay of Ewelme: Thank you very much. This is an area which we shall want to cover adequately in our report, but we have not gone into it in great depth yet. I was interested in what you said in your report about the deliberate release of pathogenic organisms as an emerging threat needing a great deal of attention and your conclusion that there was a dearth of co-operation among the relevant groups and that that was a major flaw in national as well as international strategies. I would be interested if you could say a little more about that and also just be clear whether you are talking about what one might call upstream, in other words counter-proliferation—in a sense to stop these things getting out in the first place, or whether you are talking about it downstream, i.e. what we need to do better together when they have got out in order to control it. Then could you comment on a point which has been to is in evidence, that the kind of arrangements which are necessary to control an outbreak of deliberately-released organisms are in fact much the same as though it had got out by mistake, like SARS. Could you answer that set of questions?

Professor Rubin: That is a huge set of questions and I appreciate the opportunity to talk about it. It is a deep and very complicated issue, because deliberate release could be anything from an aborted release that really does not go anywhere, much like some of the anthrax attacks that were attempted, all the way to a potential new pathogen that is synthesised—a *de novo* release. Let me take your last point first, because I think that is the easiest one. In general, yes, it is basically the same set algorithms for the identification, response and reporting for a natural outbreak as well as for a deliberate outbreak. On the other hand, if it is a deliberate release, it becomes a completely different investigative set of parameters, in that you now have a criminal case that you have to worry about. There is this necessity to maintain the chain of evidence and a whole idea of attributing culpability, while carrying out an investigation (in some sense secretly) so that you can get the bad guy, so you do not tip your hand. That is a completely different kind of investigation—and the epidemiologists will bear me out—with a naturally occurring release, where it should be in the open, and you are not trying to catch somebody. How do you know if it is deliberate or not deliberate at first? There are various algorithms that one could think about, so how do we know that the original anthrax attack in 2001 was not naturally occurring anthrax? It became

clear very quickly that this was not just naturally occurring anthrax and it became a different kind of investigation, so I do not necessarily agree that the whole spectrum of response is the same, in fact it is quite different. There is a wonderful new book out by a colleague of mine named Barry Kellman, who wrote a book called *Bioterror and Biosecurity*, that addresses this very issue. You should definitely read Barry Kellman's book or talk to him and he will talk at length about this issue—the dearth of co-operation. The idea about deliberate release is a difficult one to think about in terms of enforcement, because you can think about deliberate release by a rogue scientist; you can think about deliberate release by a failed State that just in some sense facilitates the release—much like Afghanistan facilitated al-Qaeda by allowing training camps; and you can think about deliberate release actually as a State policy. All three are quite different from each other: the investigation, the capabilities, the dissemination parameters would be quite different. In one instance dissemination could be by a missile, by a State or a failed State, whereas the chances are that a rogue scientist will not have that kind of access to a missile delivery system. On the other hand, a rogue scientist in his basement could be doing a synthetic biology experiment and making up a compound, an agent that you have never seen before, one that does not exist in nature any more. So that kind of issue really has to be placed in the context of a criminal investigation on an international scale. It is a very complicated process and one that needs a lot of attention.

Q950 Lord Jay of Ewelme: If I may take you back a second to Lady Falkner's point, also in the spirit of help, I think one should not under-estimate the extent to which moral persuasion can actually be enforced on governments, and one has seen that over the last couple of days—it was not self-evident to me that Burma was going to open its borders to international aid but, if it had not done, so the pressure would have been huge. So in a sense that sort of thing can make it work.

Professor Rubin: That is a perfect example. Talk about a State that is authoritarian that you could not get into, the media plays a tremendous role in this world and the moral persuasion is absolutely overwhelming. That is a perfect example, thank you.

Q951 Lord Howarth of Newport: First of all my apologies, Professor Rubin, that I could not be here at the beginning of the session. You observe, in respect of the deliberate release of pathogenic micro-organisms and that range of problems, that there is a dearth of co-operation between the intelligence agencies and other organisations; that is hardly a surprise, is it, because their methodology is to work in secret and their whole disposition is to be

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minimalist in the sharing of information—they will work with other organisations but only on their own terms. Can you foresee that you would be able to engage the intelligence and security agencies in, as it were, the fullness of co-operation that you and the other participants would desire?

Professor Rubin: We can do some things but the impossible takes a little longer. The intelligence community—and we have very good relationships with them, at least in the United States—has come to us to ask us to put on workshops on biosecurity, and we ran some for the National Security Agency. They are very willing to admit that there are certain areas of expertise that they need to gather in. I do not believe we will ever be able to work in an open way with the intelligence community; I think they will come to us when they need us and they will not tell us things when they do not want to. That is a fact of life—you would throw me out of here if I gave you any other answer.

Chairman: That is very straightforward.

Q952 *Baroness Whitaker:* Just on that one issue, the academic witnesses we had right at the beginning of our session did talk to us about committees co-ordinated by the WHO which looked at this. This may not be quite as full as the co-operation you were asking for, and obviously they felt under certain constraints in being very open about what was going on. But we had no doubt that there was an organisation which integrated the WHO and the medical academics, our professional representatives on WHO committees, with the intelligence services. Does this not happen in other countries?

Professor Rubin: I have a certain level of clearance, but I certainly do not know the details of some of those relationships. In our case the intelligence community is an intimate part of the National Science Advisory Board for Biosecurity which is an NIH committee; the intelligence community sits on that board as a non-voting member, they hear what we have to say and they have given us briefings. I cannot say there is an enormous amount of information that is shared back and forth; it is generally one way, and the academic community has said to them, and I have said to them in the earlier sessions that we are more than willing to help if we know the questions you want us to help you answer. Very appropriately, they are not that willing to share that kind of information, at least in my experience; I cannot speak about what other folks have been able to do. The intelligence communities in the United States have clearly reached out to American academics, me included and colleagues of mine. Generally speaking it is a one-way conversation.

Chairman: Could we move on to market failure. Lord Avebury.

Q953 *Lord Avebury:* The ISTAR website says that the Global Compact will drive pharmaceutical innovation. Does that mean that this group of people that you have sitting in the room to integrate everybody together is going to decide what forms of pharmaceutical innovation are desirable and will take those to companies and ask them to perform?

Professor Rubin: I think the answer to that question is “yes”, and we have evidence that that works. I highly recommend that you speak to Mary Moran at the London School of Economics, who has written very extensively about public-private partnerships in developing compounds for the developing world, and I can tell you from our experience in the developed world—I will include Philadelphia in the developed world—there is great acceptance of the concept of public-private partnerships to develop antibiotics for major urban diseases as well. The Global Alliance for TB Drug Development has looked at my work over the past two years and, after a long process said “Hey, the targets that Rubin is working on are really potentially very important, let us fund him and see what we can develop out of that”, and then they will take that forward the public-private partnership way. I believe the answer to that question, and certainly with the OECD, part of the basis of the Noordwijk Agenda is to find ways to spur innovation. There is this notion—maybe this is what you will be getting to—of Trade-Related aspects of Intellectual Property, the TRIPS Agreement. I do not think that is a major issue any more. The TRIPS agreement is fairly flexible and, while I cannot speak for the pharmaceutical industry who say it is not quite appropriate, I would say that that is not really an issue any more as far as I am concerned. I believe we really will be able to spur innovation and there are real examples of that.

Q954 *Lord Avebury:* What you have just said is that somebody is going to provide the money for the development of these new pharmaceuticals. So, if it is the market mechanism, the market mechanism is that an agency, be it the Global Compact or the Global Alliance for TB, or GAV in the case of the Advance Market Commitment, is going to pay for the innovation. You are suggesting that the Global Compact will come in and take over from all these agencies, so you have to have one person to decide who is going to fund what and who is going to develop which particular pharmaceutical instead of having a certain amount of diversity and freedom of different organisations, who may be experts, as in the case of TB, or as in the case of Pneumococcal disease, which your Global Compact would not address?

Professor Rubin: With all due respect, that is not what I am saying, I am not saying that it will be one person. I am saying that we will include all these organisations as fully-fledged members and we will

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encourage these public-private partnerships with their own sets of experts and their own boards of directors. We may bring new faces to the table, we may bring new entities to the table, new ideas, new surveillance data; that is the idea, not to take over what is working well; maybe to close down things that are not working well is a real possibility, if we have that kind of moral capability and persuasion.

Q955 Lord Avebury: I am sorry to be a Devil's Advocate, as I seem to be, but are you not adding a layer onto what already exists?

Professor Rubin: We are absolutely adding a layer, at a most necessary level.

Q956 Lord Avebury: What is wrong with the mechanism of the Global Alliance?

Professor Rubin: Nothing—it works extremely well as far as it goes.

Q957 Lord Avebury: So why do you want to add something to it?

Professor Rubin: Because we need integration with the bigger picture, that is why. If the single system is working—well that is fine, let the single system work fine. However in any complex organisation, where there are multiple data types, multiple players, and multiple systems, there must be that layer of integration; if not, the system falls apart. The very fact that your Committee exists is a tacit agreement that the system is not working; if the system was working so well, let us go out and have a beer.

Q958 Chairman: That might be a good idea but, before we do that, could I suggest that another way of putting Lord Avebury's point might also be to say that actually what we need in the countries that have not got a developed healthcare system would be an effort to develop infrastructure that creates the healthcare system in those countries, and that without that any number of special institutions or new bodies will not actually be able to deliver a good healthcare system.

Professor Rubin: That is absolutely part of the Compact. There is no question that we lack the individual people power, we do not have enough individuals out there in the health system not only to develop the whole scientific side of it but to deliver once things start to work. At OECD and Noordwijk the Finance Minister from Liberia got up; she gave us the most horrendous set of data—I think she said

there were 40 doctors in her whole country and that the amount of money they are able to use to support the health mission of her secretariat was far below that recommended by the World Health Organization. You debated this notion of aid to Africa just a short while ago; there is no doubt that, even if we are vastly successful in developing new compounds, if they do not get into the villages, if they do not get into the hospital across the River, all of this is for nought.

Q959 Chairman: Finally, you talk in your paper of a need for someone to seize this idea and take it forward. Obviously, you would like that to happen. But who were you thinking of doing that? Would you like the government to do it?

Professor Rubin: You asked me for a list of NGOs and people who are interested in this; there are lots of people who are interested in this and the scientists gave me a voice. We could short-circuit that time from NGOs and academics to full implementation if we did have a highly respected government to take this as their own enterprise. I have my thoughts about which country should be that country, and I am delighted that you folks have shown this level of interest. I have to tell you that it would be wonderful if the Government of the United Kingdom and the English people would be able to step up to the plate and become the champions of this issue. You have the right global perspective, you have already invested an enormous amount of work and it would just be wonderful.

Q960 Chairman: You could not see the WHO being that organisation?

Professor Rubin: No. They are an important component, there is no question about it, they have done spectacular work over the years. But they just do not have the scope.

Q961 Chairman: Very well. Professor Rubin, you have certainly earned your beer and it is a very nice day, so I suggest you find yourself a pub to have your beer. But can I thank you very much for coming over and for all the information you have given us. As I indicated, if you feel there are any other comments that you have when you have thought further about this or if we have missed anything out, please let us know. But I would like to thank you very much and congratulate you on all your work.

Professor Rubin: Thank you very much, it is greatly appreciated.

MONDAY 12 MAY 2008

Present: Avebury, L
Eccles of Moulton, B
Falkner of Margravine, B
Howarth of Newport, L

Jay of Ewelme, L
Soley, L (Chairman)
Whitaker, B

Memorandum by Professor Fidler, Indiana University School of Law

This document contains responses to the Committee's Call for Evidence on "Acting through Intergovernmental Organisations to Control the Spread of Communicable Diseases." The Committee should be aware that I am an international lawyer and not a scientist, epidemiologist, or public health practitioner. My responses reflect my area of expertise as an international lawyer with experience working on global health issues, especially communicable disease threats, and working with intergovernmental organizations, particularly the World Health Organization. I have coded my responses to the questions set by the Committee (eg, responses 1.1 and 1.2 address Question #1), but, for space reasons, I have not included the questions. I have limited my responses to the questions relevant to my expertise and to the 6-page (A4) limit set by the Committee, but I would be willing to provide further responses in writing or travel to London to answer questions from the Committee.

1.1 The UK Department of Health was correct to identify the unfounded nature of the post-war sense that industrialized societies had conquered communicable diseases. The reasons for this complacency are complex, but all countries, including developing countries, are now paying a heavy price for it. Despite the progress made since the mid-1990s in global health, the international system has not yet achieved change that is sustainable. To paraphrase Churchill, we have only reached the end of the beginning of mounting adequate national and international responses to the threat posed by communicable diseases.

1.2 Opining on whether the "global situation" is deteriorating is difficult because we have multiple "global situations" that reflect different levels of progress, inertia, and deterioration. For example, HIV/AIDS is a different kind of threat from avian influenza, so any progress on HIV/AIDS does not necessarily translate into progress against containing avian influenza and preparing for its possible genetic shift into a killing microbial menace. The Committee needs to disaggregate the global situation, examine the various types of communicable disease threats, the capabilities of intergovernmental organizations (IGOs) across these threats, and then reassemble the pieces to get the composite picture. Talking in terms of a crisis is not an exaggeration, and the scale and intensity of efforts over the past decade underscore that a sense of crisis has, and continues, to exist.

2.1 As an international lawyer, I am not trained in epidemiology, so I cannot comment on the reliability of data generated by national governments and IGOs. I can share some thoughts on the political and legal aspects of data generation and use concerning communicable diseases. From a public health perspective, data collection and analysis (eg, as done in surveillance) forms the basis for formulating and implementing interventions (eg, vaccination, quarantine). Public health strives for evidence-based measures, so reliable data gathered as frequently and comprehensively as possible are critical. The acceleration of globalization has made the need to accomplish this task domestically and internationally ever more important. Achieving this objective politically and legally in an international system of nearly 200 sovereign States has proved, however, a very difficult task.

2.2 Globalization has helped revolutionize the environment affecting communicable disease emergence and spread by facilitating convergences of disease "vectors," such as trade and travel, migration, antimicrobial resistance, and social determinants of health (eg, poverty). Globalization has not, however, had an equivalent impact on the structure and dynamics of international politics and international law. We are chasing the whirlwind of 21st century globalization with an international system still tethered to 19th century patterns of State behavior and cooperation. Caught in the middle are IGOs, such as WHO, which appreciate the disease trends but remain accountable to sovereign States and their interests.

3.1 The intergovernmental surveillance with which I am most familiar is the WHO's Global Outbreak Alert and Response Network (GOARN). GOARN's capabilities have grown impressively since its establishment in the early 21st century, and the progress made connects to WHO's strategy of making GOARN a "network of networks," including information sources beyond governments. Despite GOARN's development, this

intergovernmental surveillance capability remains inadequate because (1) WHO member States do not fund it properly, and (2) underlying national and sub-national surveillance systems on which GOARN ultimately relies, especially in developing countries, still remain in poor condition.

3.2 Intergovernmental surveillance systems exist at regional levels as well, such as in the EU, ASEAN, APEC, and the Americas. Efforts to strengthen these regional systems themselves, and how they integrate into GOARN, should be pursued by individual governments, these regional organizations, and WHO.

4.1 Without more funding and sustained political commitment from governments and IGOs, the development of global surveillance and intervention capabilities could easily stagnate and regress in the next 10 years. I already detect a growing sense in non-health foreign policy circles that enough, for the moment, has been done for global cooperation on communicable diseases, and that other pressing issues (eg, global warming) deserve priority attention. So much progress has been made that people unfamiliar with global health's precarious evolution sometimes assume that the challenge has been adequately met, not realizing that the progress made does not get the international community where it needs to be with respect to the communicable disease threat.

4.2 One pattern already conspicuous is the growing gap between developed and developing countries in terms of public health capabilities to address communicable diseases. The likely continuation of this pattern will not only create epidemiological holes in global capacities but also stimulate tensions between rich and poor countries. We have seen these tensions arise in the controversy over Indonesia's stance on withholding avian influenza samples.

5.1 HIV/AIDS. Although some trends are positive (eg, increasing numbers of persons infected with HIV in developing countries receiving antiretrovirals), the scale of the pandemic still beggars the imagination. The decrease in the rate of new infections (if the data is reliable), still means the international community has a massive, long-term problem on its hands. Looking ahead, I see a number of potential problems: (1) funding levels that plateau and begin declining; (2) continued lack of a breakthrough on an HIV vaccine; (3) continued or accelerated "brain drain" of health care personnel from developing to developed countries; and (4) the emergence and rapid spread of resistant strains of HIV.

5.2 Tuberculosis. I am most worried by the prospects of the increased and accelerated spread of MDR-TB and XDR-TB (still linked to the HIV/AIDS crisis) without development of new TB antibiotics that are affordable and accessible in developing countries.

5.3 Malaria. Potential obstacles to better malaria control and prevention include (1) continued development and spread of resistant forms of malaria; (2) lack of development of affordable and accessible anti-malarial drugs; (3) lack of sustained commitment to current effective initiatives, such as the increases in distribution and use of bed nets in Africa; and (4) multiplying challenges from other vector-borne diseases, such as dengue fever, that may divert resources from anti-malarial campaigns.

5.4 Avian influenza. Future challenges include (1) resolving the standoff on sharing virus strains for surveillance and vaccine development purposes; (2) continued weaknesses in cooperation between animal and human health agencies nationally and internationally; (3) tapering off of political interest in pandemic influenza preparedness; and (4) signs of genetic drift or shift causing countries to revert to narrow approaches to their self-interests, which would undermine global cooperation.

5.5 Better intergovernmental cooperation. "Better," "smarter," or "improved" intergovernmental cooperation and action is often prescribed for the challenges these four and other communicable diseases present. Strengthened intergovernmental cooperation is not, however, a panacea for these challenges. I doubt whether better or smarter intergovernmental cooperation will remove the obstacles mentioned above. The scale of these problems overwhelms intergovernmental capabilities, the priorities of member States are too diverse, and the rise of non-state actors (eg, Gates Foundation) may exacerbate the on-going fragmentation of global health diplomacy.

7.1 I have been an advocate for giving global health higher priority in States' foreign policies because communicable and other disease problems require political commitment from more than the public health sector. Without heightened political priority, strategies against the four diseases will tend to drift back towards technical, ad hoc, and reactive responses that will not address underlying causes of the emergence and spread of communicable diseases.

7.2 Intergovernmental action in non-health areas is important, but, to the surprise of many in public health not familiar with the history of intergovernmental efforts on poverty reduction, population control, or climate change, the track record of efforts on non-health issues is not typically impressive. Framing non-health problems as health crises, as happens more frequently today, only goes so far in generating greater political interest in tackling the issues. In addition, to address some underlying problems in an effective and sustainable

fashion would require regime change for public health in many countries, a task that understandably makes foreign policy makers interested in global health select less ambitious objectives.

7.3 More trans-intergovernmental cooperation on communicable diseases occurs today than in the past, and this “joined-up” thinking and action has produced benefits. The elasticity of joined-up thinking within national governments and between IGOs is not, however, as high as anticipated. Breaking national ministries and IGOs out of their traditional policy “silos” remains fraught with difficulties that limit what “joined-up” governance can achieve. This low elasticity contributes to the proliferation of more initiatives rather than consolidation of activities into more centralized policy synergies within and between governments.

9.1 The growing global TB problem has multiple facets--the connection to the worldwide HIV/AIDS epidemic, the breakdown of public health and health care systems in many countries, the declining effectiveness of anti-TB drugs, and the failure of strategies pushed by WHO (eg, DOTS) to be sustainable in many countries. These facets, viewed collectively, should call into question the assertion that TB is, in fact, a treatable disease. This assertion assumes that conditions prevalent in industrialized countries (eg, available drugs, functioning public health and health care systems, social conditions that make sustained therapy regimens work) exist or can easily be created in countries struggling against TB.

9.2 Again, intergovernmental action is important, but intergovernmental approaches against TB should be more intense at the regional level, and not just at WHO. Diffusion of anti-TB activities across regional organizations will become even more important as regional spread of MDR-TB and XDR-TB occurs.

10.1 The impact of restrictions on the use of DDT on malaria’s spread started before 2004 because donor countries and governments in malarial regions decreased funding and use of DDT for anti-malarial control before adoption of the Stockholm Convention. In addition, care must be taken in assigning causal effect to the non-use of DDT in malaria’s spread because other factors have played significant roles as well (eg, misuse of anti-malarials, failure to make effective use of bed nets, lack of funding for anti-malarial programs, climatic changes encouraging spread of mosquitoes to new areas). I am not aware of a risk assessment that specifically compares the dangers to human health from DDT use versus exposure to malaria.

11.1 WHO, in collaboration with FAO and OIE, has worked to improve early detection of the transmission of avian influenza from birds to humans. WHO has also worked with WHO member States to improve surveillance on any potential human-to-human transmission cases. Although not perfect, the extent of the surveillance that does exist is, historically speaking, impressive, and these IGOs should continue to deepen and broaden their collaborative efforts on avian influenza surveillance.

11.2 This emerging early warning system for avian influenza is not sufficient to prevent an influenza pandemic. In fact, most public health experts would agree that the chances of identifying and containing a pandemic virus with the current system are very poor, which makes the developing global surveillance system a resource for alerting national capabilities for the potential spread of a dangerous flu virus. This dynamic is what irks many developing countries—they share data that only help developed countries use their superior resources to protect themselves. The controversy over Indonesia’s refusal to share samples of avian influenza strains reflects these underlying North-South tensions. More efforts need to address the lack of response capabilities in developing countries.

12.1 Antimicrobial resistance has been a major factor in the re-emergence of TB and malaria, but such resistance has not yet been as significant with respect to HIV/AIDS and avian influenza. Enough resistant strains of HIV and H5N1 have emerged, however, to make the antimicrobial resistance nightmare a real possibility with HIV/AIDS and avian influenza.

12.2 The problem of antimicrobial resistance has risen in importance on intergovernmental agendas in the past decade, and WHO supports a global effort against the threats posed by antimicrobial resistance. Data suggest, unfortunately, that intergovernmental efforts made to date have not had material impact on reducing the threat of antimicrobial resistance in these four diseases, and, worryingly, other diseases as well.

13.1 Intergovernmental efforts to address antimicrobial resistance globally include the problem of hospital-acquired infections. As illustrated by the problems with such infections in Britain and the United States, most attention generated on this issue has come from developed countries. Serious antimicrobial resistance problems in developing countries concerning HIV, TB, malaria, and avian influenza are not significantly related to the spread of resistant microbes through hospital treatment. IGOs have to set priorities on what antimicrobial resistance problems they should address.

13.2 Although WHO might need to prioritize antimicrobial resistance not related to hospital treatment, regional IGOs (eg, EU, APEC, ASEAN) can improve their cooperation and information flows about hospital-acquired resistant infections. One stumbling block to this suggestion is the reluctance of countries to share such data because countries are trying to attract “health tourists” by offering cheaper, faster health and medical services to a growing global market of health consumers.

14.1 I do a significant amount of work with WHO on the relationship between health and trade. In this work, many controversies in this relationship (eg, trade in health services, application of sanitary and phytosanitary measures) have settled down and given way to more constructive efforts at producing coherency between trade and health policies. The one area that remains contentious and unproductive involves intellectual property rights. Developments in international trade law, particularly the proliferation of regional and bilateral trade agreements containing TRIPS-plus provisions, ensure that the controversies over the impact of patents on access to medicines will continue unabated.

14.2 Despite the on-going controversies involving intellectual property rights, care should be taken in addressing just how much patents cause problems for global communicable disease threats. For example, of the four diseases of most interest to the Committee, patent concerns have arisen in HIV/AIDS (with respect to antiretrovirals) and avian influenza (with respect to patents and potential vaccine development), but not seriously with TB or malaria. Patent controversies have not, however, prevented massive increases in the availability of antiretrovirals in the developing world, nor have patents, to date, materially undermined treatment strategies for those infected with avian influenza. Development of the next generation of drugs for TB and malaria through public-private partnerships will probably not be hampered by the kinds of intellectual property controversies that arose with antiretrovirals.

14.3 Whether more intergovernmental action on the patent issues is necessary depends on whether such future action can break stalemated patterns in IGOs already established over many years, in particular within WHO and WTO. More of the same is, well, more of the same. As indicated above, the proliferation of TRIPS-plus provisions in regional and bilateral trade agreements has reduced the policy traction WHO and WTO previously had in this area.

15.1 IGOs, especially the WHO, and national public health agencies, such as the U.S. CDC, engage in programs designed to improve the ability of transition and developing countries to identify disease events, diagnose specific diseases, and undertake effective interventions. I understand that more of these kinds of programs are envisioned as part of the implementation of the International Health Regulations 2005, thus ensuring robust intergovernmental activity in this area for the foreseeable future.

15.2 The biggest problem is the mismatch between the scale of the need for such improvements and the paucity of resources made available to undertake these capacity-building programs. WHO does not have sufficient resources to engage in these activities on a sustainable basis, and many developed countries have to expend serious resources to improve their own surveillance and response systems after decades of neglect. For example, the United States has spent much more on strengthening its own surveillance and response systems than it has allocated to international assistance for strengthening communicable disease surveillance and response. Seeking more intergovernmental activity does not usually equate to more resources for such activity, and IGOs, especially WHO, typically are tasked to do more without increased access to resources.

15.3 Some big influxes of money into global health have come from non-governmental sources, such as private foundations, and the activities funded by these non-state actors have not typically focused on building sustainable public health infrastructure. In fact, many experts are concerned that the non-governmental programs are cannibalizing public health systems in developing countries (eg, through employing highly skilled medical and health personnel) and producing even weaker public health infrastructures in the very countries where stronger infrastructures are needed.

16.1 As my publications on the International Health Regulations 2005 (IHR 2005) indicate, I believe that the IHR 2005 are the most radical development in the history of the use of international law on global health problems. I refer the Committee to those writings for the details of why the IHR 2005 represent such a dramatic contribution to global health governance, and I can provide a list of these publications if needed. The global framework established by the IHR 2005 is impressive, but its effectiveness has yet to be tested or proven.

16.2 In fact, the first major communicable disease event implicating the IHR 2005—the Indonesian virus sharing controversy—revealed confusion about the IHR 2005's content and its relevance to this global health crisis. Attempts by WHO and others to argue that the IHR 2005 required Indonesia to share virus samples without conditions backfired because the IHR 2005 do not mandate such sharing, as properly interpreted under principles of treaty interpretation in international law.

16.3 In terms of future implementation of the IHR 2005, the radical new framework will not function effectively without significant improvements in national and sub-national surveillance and response capabilities. The IHR 2005 can easily end up as a piece of paper without more serious national and international efforts to build public health capacity to the point most countries can fulfill their obligations under the IHR 2005. Unfortunately, the IHR 2005 neither contains a strategy for achieving this capacity nor any mechanisms to fund capacity building. WHO does not have access to the kind of resources needed, and

non-governmental funding entities have tended to show little interest in the kind of capacity building implementation of the IHR 2005 require.

17.1 For my thoughts on the challenges related to biosecurity, including analysis on how States, IGOs, and non-state actors can improve global biosecurity, see David P. Fidler and Lawrence O. Gostin, *Biosecurity in the Global Age: Biological Weapons, Public Health, and the Rule of Law* (Stanford University Press, 2008).

17.2 In brief, existing intergovernmental and treaty approaches to biological weapons are in serious trouble and are rapidly trying to adjust to the new threats biological weapons and biological terrorism pose. The main treaty on biological weapons, the Biological Weapons Convention (BWC), has been overtaken by events, and its relevance for future strategies against biological weapons and biological terrorism is in serious doubt. Part of the doubt stems from the BWC's lack of provisions that address the national and international needs to integrate arms control, law enforcement, and public health capabilities into a coordinated biosecurity strategy. Constructing this new kind of biosecurity strategy will require, as we elaborate in *Biosecurity in the Global Age*, the construction of a "global biosecurity concert" that is not entirely dependent on the BWC or any one IGO.

18.1 The IHR 2005 are designed to prepare WHO member States to be able to identify and address threats from new or previously unrecognized communicable diseases, which is another reason why the IHR 2005 are so important to global health governance today. Attempting to deal with existing disease problems, such as the four diseases of most immediate interest to the Committee, and simultaneously remain prepared for unknown but anticipated threats constitutes a tall order for governments and IGOs, which causes strain in national and international public health systems that remain under-funded and under-staffed.

20.1 The Committee needs to examine more than IGOs because of the way in which global health governance is evolving. To provide perhaps the most dramatic example, many people now believe that the Gates Foundation is becoming the de facto center of gravity for global health policy and funding, eclipsing the traditional lead role of the WHO and even the historically influential U.S. CDC. This example constitutes just one feature of a rapidly changing context for addressing global health problems, a context that is increasingly posing more and more difficult challenges for IGOs.

20.2 Traditionally, States created IGOs to help manage their relations in a condition of anarchy, a condition in which States recognized no superior, common authority that regulated their sovereignty. States and cooperative mechanisms they created, such as IGOs, dominated this condition of anarchy. Global health now faces a new kind of anarchy, what I have called "open-source anarchy", in which State, intergovernmental, and non-governmental actors access and influence global politics on health in ways never before seen. The governance task now extends beyond getting IGOs to function more effectively because non-state actors play significant, and increasingly influential roles, in global health, and especially with communicable disease issues.

24 February 2008

Examination of Witnesses

Witnesses: PROFESSOR DAVID FIDLER, Professor of Law, Indiana University School of Law, and DR KELLEY LEE, Head of the Public and Environmental Health Research Unit, and Co-Director of the Centre on Global Change and Health, London School of Hygiene and Tropical Medicine, examined.

Q962 Chairman: Good afternoon. Thank you both very much for coming. The format, as you know, is that we will ask you questions along the lines of the reforms needed in the intergovernmental organisations to deal with infectious diseases. We are primarily interested in the changes needed in the intergovernmental organisations or the architecture by which we deal with infectious diseases and not the diseases themselves—although obviously we need to have some knowledge or information about the diseases when necessary. I would like to invite both of you to come in on a question whenever you feel you have something to say. Perhaps I could begin with the fairly clear question to you, Dr Fidler, but do remember what I said, Dr Lee: if you want to come in

on it, please feel free to do so. You are, in a way, Professor Fidler, recognising what I think some of us have been struggling with, that nation states are not always the best way of dealing with the problems in the modern world. The structure of health care is becoming very, very important in that, because of the changes that have taken place in the global economy generally and otherwise, the nation state bit is no longer sufficient, in a way. Do you have a solution to this? I read your paper with some care. There was a lot of very interesting constructive criticism in it. I am not quite sure what you would like to see as the alternative and I particularly want to know if you think it is a case of reforming the existing system or whether we need something absolutely new in some way.

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Professor Fidler: I would start by saying you need a bit of both. There are elements of the existing system that are simply going to have to be kept because that is the nature of the structure of the international system, but I do think that we need to move away from that State-centric model and think about different alternative strategies and approaches. We are seeing a lot of that taking place now, with different types of innovative governance strategies with regards to different threats that are faced from infectious diseases. I do not find the term “architecture” very useful for the purposes of thinking about this in the future; that is, looking forward as opposed to criticising what we have today. I think a more apt analogy is “networked governance”. We are going to have to build networks of State, intergovernmental, and non-state actors, in order to deal with these types of problems. You are already starting to see that happening. If you think about, for example, the International Health Regulations, the way they build non-State actors directly into a global surveillance system is a very different model of global governance from what we saw before. That is an innovative way of trying to integrate the new actors (non-State actors) and new technology (global information technology) with regards to global surveillance for these diseases. You see this in other examples as well; whether that is the International Finance Facility for Immunisation, or even the (PRODUCT)RED campaign, or the Global Fund, many of these are reaching out to non-State actors and building them into these global networks. That is really the way the future is going to be, rather an attempt to centralise, harmonise and rationalise, within a single governance architecture, the way we approach these problems.

Q963 Chairman: I understand that. You are not arguing for a single organisation? We have had indicated to us that that probably would not be a good idea—and certainly it would not be my ideal solution. You are saying build on what we have with new examples? The IHR—which we will come to a bit later in the session—is the type of approach that you would like to see. Is that correct?

Professor Fidler: Yes. This is being done in all the innovative governance areas. There is an attempt to try to integrate these networks across issue areas. It is not just the IHR; there are lots of examples of this. This is moving away from that State-centric approach. It is also, to some extent—although not in all cases—moving away from formal treaty-based mechanisms. The IHR is treaty-based but many of these other examples are not based on treaties, they are set up in more informal partnership contexts—which is also a different type of development going forward. I think these are going to have to develop with regards to specific issue areas, as opposed to

being one overarching structure. I can talk in more detail about some specific examples of that, or ideas that I have tried to develop in my writing. But, again, that is a combination of existing mechanisms/processes but building in some of these innovative features, particularly to harness and take advantage of what non-State actors could bring to the table.

Q964 Lord Howarth of Newport: Evidently it is extremely important to bring the non-State actors into the system as coherently as possible and take advantage of the resources that they can mobilise. On this networked model that you have been postulating, would we be better placed to achieve rational and decent priorities? Or would the effort tend to go where resources happen to be concentrated according to the predilections of the organisations that were the biggest players? If we resort increasingly to the informal relationships that you have been sketching, does that mean that the system would become even more ad hoc and that we have to say goodbye to any prospect of an evolution, for example, of international law which would fortify these international efforts and help over time to establish a better and more reliable capacity to address these problems?

Professor Fidler: Let me address the priority question first. I think you have to take into account that there are two different rationalities that are at work here. One rationality is when we talk about rational priority from a public health point of view. The other rationality is a foreign policy rationality, where you have to take into account the limits of what you are able to achieve. There has been no problem with regard to identifying what are major public health priorities, and where we need more money, and where we need more governance capacity. But, when you turn around and say “OK, US—or UK—please implement this”, the foreign policy people, who already have experience in a development context of trying to do these sort of horizontal, systemic, capacity-building reforms, push back, because from a rational point of view there are limits to what even a powerful country can do with regard to reforming the way in which another government operates. If you are serious about that, you are talking about regime change for public health or structural adjustment for public health. The foreign policy people say, “We have limits to what we can do here, so a more rational strategy is to pursue more limited, technical vertical programmes that we have more control over, so that we can see how our money is being spent.” That is a rational priority setting from a foreign policy point of view as opposed to a public health point of view. Even if you had a mechanism that you could set up—and to some extent we have

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that mechanism in the WHO—that rationality does not necessarily match up with the diplomatic and foreign policy rationale of the countries which have to provide specifically the resources for that. In terms of the informal partnerships versus more formal mechanisms, I think we are in early stages with regards to seeing how many of these informal partnerships operate. Again, it is not entirely the case that informal partnerships are all that is on offer at the moment. We have two big and very important examples of the development of international law, the IHR and the Framework Convention on Tobacco Control. But what is interesting about the informal mechanisms is the extent to which all of the players have avoided putting them in an international legal framework. They have avoided treaties. They have avoided even putting it inside the WHO. I think there is the sense, particularly in this initial innovative stage of finding some new alternative approaches, that a little bit more flexibility is better at the moment than trying to work this into international law. It is part of my scepticism about some of the proposals that have been made about having more treaties in connection with global health. I do not know if you have questions specific to some of those proposals. To some extent, the informal partnering mechanism does not detract from the development of international law. Many of the norms on which these informal partnerships are drawing, are already principles of international law; they just have not been effectively implemented in the treaty formats in which they were initially adopted. Here are efforts to try to influence some of the norms and ideas and processes that are in international law. That will feed back into the process of international law and create a dynamic context which we did not have in the past, where at least in public health, international law was stagnant.

Q965 Chairman: The problem of enforcement comes into that in a very big way.

Professor Fidler: Give me any topic in international relations and you have an enforcement problem in international law. People get hung up on enforcement with international law, and I think it is the wrong thing to get hung up on, particularly as a first step. The only place you find effective enforcement of rules of international law through independent third party adjudication is the World Trade Organisation. That is it. There is not anywhere else in international law that you find an effective enforcement mechanism. People ask me, for example, “How do you enforce International Health Regulations?” There is not an enforcement provision, but look at the way in which the incentives and the dynamics of the rules are set up and you start to see that the enforcement of this starts to drive off the creation of reciprocal self-interest that States

have to comply. That is what is more interesting about that development than an enforcement mechanism. I would encourage you not to get hung up on enforcement because that affects every single area of international law.

Q966 Chairman: I understand that argument but, to use a current example, if you had one of these infectious diseases coming out of a state like Burma, I am not quite sure what you would do about it, and I am not convinced that “Let’s persuade the State” would necessarily work. It would depend on which sections of the community were being hurt as to whether or not the State did anything.

Professor Fidler: You then have to start thinking of drawing on different types of rules of international law. For example: Would this require humanitarian intervention? Would that require the use of military force? There are rules of international law that deal with that. Here the question is not so much one of enforcement but one of relieving humanitarian suffering. So, even in that context, it is not an enforcement question.

Dr Lee: Before we get into more specific things around particular mechanisms, I’d like to return to the starting point of this discussion around State versus non-State actors. I think we are in a political and institutional transitional period. It is an incredibly difficult challenge—a lot of ideas get bounced about in the literature and the academic world. I conceptualise it as a need to shift the paradigm from looking at health at the border to beyond the border. At the moment, there is still an state-based emphasis on trying to create stronger borders, whether territorial or otherwise—perhaps through screening at ports of entry; looking at testing immigrants prior to coming into a country—trying to strengthen the fortress based on physical territoriality. All that you have described, these global forces at play, means that we have to recognise that such measures are irrelevant increasingly, because we cannot control many of these forces at the border. We have to think about, first of all, within our borders and how we can build institutions that address how effectively we can respond when a health risk comes into a country, and then beyond borders when we look at not just developing countries but all countries and how we strengthen institutions across countries—indeed, this may be a kind of networked approach. We can all recognise this when we say it, but doing it is really difficult. We still keep coming back to state borders. I think that the 19th century approach is still really well embedded in the way we see things. I will stop there. There are lots of other things to say but that is one of the key challenges. We have not all shifted our paradigms yet.

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Q967 Lord Avebury: If you start thinking that borders are irrelevant, does it mean that you have to treat communicable diseases in irregular migrants in your territory? Would that be part of the package?

Dr Lee: It would be. It may not be politically popular, but I think it would certainly be necessary. I will tell you why. It sounds incredibly idealistic and imagine the cost—people immediately say “Cost”. But the problem is that we know there are people coming in and out of many countries either documented or undocumented. That is happening. We cannot—and we may not want to—stem increased population mobility. That is part of globalisation. The problem is that, when people are here (and there are obviously practical challenges already to providing health care for all), certain parts of the population, whether they should be here or not, feeling they cannot access the healthcare system. From an immigration point of view, this is a complete nightmare, of course. Immigration policy would respond in a very different way. From a public health perspective, it is in the UK population’s interests to offer people access to basic health care, at whatever cost, because the implications are, if they are suffering from drug-resistant TB for example, as a worst-case scenario, and they do not feel they can access the health care system, that the population as a whole is at risk. We are creating incentives where these sorts of problems go underground. I am not saying it is going to be politically very easy to sell that, because at the moment it is about cost-savings, it is about keeping NHS costs down, and so on. But in other countries, Canada, for example, there are clinics where people can walk in, no questions asked, and it is seeing the bigger picture really around public health. It is a difficult one to sell, but from a public health perspective it is a cost-effective way to deal with global health issues.

Q968 Chairman: Professor Fidler, you said in your evidence—and it is obviously correct—that organisations like The Gates Foundation are playing an increasingly central role; indeed, to some extent taking over. I am not quite sure how we involve them in this process. Is this what you see as part of the general drawing up of new approaches?

Professor Fidler: Yes, it is. In terms of trying to conceptualise how things are operating today, this is part of how I see the very nature of the operation of international relations changing fundamentally. The Gates Foundation is the best example in the global health context of where you have a non-State actor now who is able to influence global health, partly and significantly because of the material influence—they just have a lot of money and money talks—but, second, because the material influence, the material power, if you will, that the Gates Foundation possesses also allows it to have impact on what

priorities get set in global health. This is part of what upsets people about the way in which non-State actors who are not accountable to anybody come in and affect the way in which global health is operating. First, that reaction assumes global health is operating in a rational functional manner to begin with—which I think is a problematic argument to make. Second—and I struggle with this: this is the normative question and it is probably what you are struggling with as well—as we look at States and non-State actors and intergovernmental organisations, all involved in this gigantic proliferation of initiatives, are we undermining the capability to do something sustainable for public health? That is a serious concern. As I think about that as a governance matter, it is very hard for me to see a single solution—which is why I think architecture is the wrong model, because I do not think you are going to be able to control the behaviour of either States or big powerful NGOs like the Gates Foundation. If you think it is hard to get the United States and George Bush to toe the line of the United Nations, try getting Bill Gates to toe the line of the WHO. He does not have to. Increasingly, the Gates Foundation is the first place people will pick up the phone to call; not the WHO. In fact, someone told me—and I do not know if this is true—that Bill Gates is now going to fly to Indonesia to help intervene in that controversy over virus sharing. Something has changed here. In an architectural model, I do not know how to control or contain it. With a network model you have a better chance. It is a serious problem.

Q969 Chairman: Before I move on to surveillance, Dr Lee, would you like to add any more on this?

Dr Lee: I agree with what Professor Fidler is saying. For me I see the problem as this lack of an overall Master Plan. There has been a market-based approach to health development in a way, as in other areas of development, for various reasons—and it is not just donors. There is a tendency to create another institution and another mechanism rather than fix what is already there. We have this proliferation, as we describe. It is a real problem. This is the first thing anybody who looks at this area sees. Global health, in particular, has a more crowded policy environment than any other sector. There is this lack of a Master Plan—and I do not have an answer. A lot of ideas are being put on the table as to how co-ordination could be improved. Where should authority lie and how should it be distributed? We may have disagreements about the institutional mechanisms we need—and we can go into some of the ideas that have been put forward—but without an agreed vision, I just cannot see how we can move forward. Various organisations are involved in special pleading, every disease has its advocates, these silos, these vertical programmes, as Professor

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Fidler has described. This is getting us nowhere, because we are not sitting back and looking at the overall priorities. Nobody is setting clear priorities overall; it is free-for-all. Until we move beyond that, I see this as the key problem.

Q970 Chairman: Having heard what you have said, I have to ask you another question on this. Professor Rubin, the Director of the Institute for Strategic Threat Analysis and Response, told us the other week that he favoured a Global Compact approach to this. Are you aware of this proposal?

Professor Fidler: Yes.

Q971 Chairman: We have found ourselves struggling with how it would deliver. Do you have a view about it one way or the other?

Professor Fidler: I think I would have to join your struggle. I have seen presentations on that Global Compact. Even for someone who is as steeped in the machinations of global politics as I am, it is a little hard to see exactly how the idea would work. You can see what they are trying to do: they are avoiding immediately the problems you get into by using formal or harder international law. They want to have more of this flexible partnering approach, issue linkage across four areas, to try to get people moving together on a coherent integrated approach to that. You can see they are picking up on these signals and these cues as well. It is another idea that has been thrown out there with regards to trying to move that agenda forward. I have some questions about why they have chosen what they have chosen and how they have put it together. I am not aware of how much traction that proposal has in the policy world. There are all kinds of ideas that people are throwing out here, and I have just tried to capture this transition phase. To some extent, it is a competition of ideas. The survival of the fittest is taking place right now. To some extent, that is a necessary part of this transition.

Chairman: It is not necessarily bad that we have that. I do think there is a bit of a struggle between: Do we start from somewhere where we are not, in the hope of starting again, so to speak? Or do we start from where we are?

Q972 Lord Howarth of Newport: In your excellent, powerfully drafted evidence to us, Professor Fidler, you said that you detect a growing sense in non-health foreign policy circles that enough for the moment has been done for global co-operation on communicable diseases, and that other pressing issues, for example, global warming, deserve priority attention. This is pretty pessimistic stuff. I do not know whether it is an instance of what you were suggesting in our earlier exchange that, from the point of view of practitioners of *realpolitik* in foreign

policy, it may be rational not to try very hard at all. Is it the case, do you think, that countries are not particularly interested in the diseases that are unlikely to communicate themselves in large-scale and dangerous ways into their own societies? If for the time being they are not particularly worried either about Avian Flu and SARS, then they do not bother. It may be that the conscience, in the sense of self-interest, of the world may be pricked a bit by current events in Burma and that people will start taking a livelier interest in these things again. But what is to be done about this tendency to withdraw when there is not an urgently perceived threat to our own insular interests?

Professor Fidler: It is true and can be empirically demonstrated that developed countries—and I would use the United States as an example—are much more concerned about direct disease threats than they are about indirect disease threats. My perception, from watching the United States and also from talking to people who are engaged with these issues and other global issues, is that, when they see the new International Health Regulations and they see PEPFAR. They see that there have been major responses to these issues. Their concern is, “We’ve put together mechanisms; now we are going to turn our attention to something else,” because they also have on their plate climate change, the energy crisis, the food crisis—and now we have the problem of this humanitarian disaster in Burma. In relation to what they have to do in terms of prioritising, most of those issues do not have anything. It is not that there is a retreat or a lack of attention to the health issue, but it tends to fall down the hierarchy of what they are paying attention to now, because for some of these other issues there is nothing in place. We have at least got things going in the global health context, so their assumption is: “That’s been handled, and we’ll let that operate.” Where that risks becoming complacency is that you now have to implement these things: you cannot just have a new treaty and then it is done. This is the problem with the IHR. How are these going to get implemented? If there is not sustained foreign policy attention to that, we are going to be back to Square One. I do notice that. I do not think it is anything malevolent on the part of foreign policy makers. Just look at everything else they have to handle—and the foreign policy process is one of ruthless prioritisation. Where is this going to fit in terms of political attention and political resourcing with regards to these issues? Burma is interesting because there has been, again as part of this transition, this re-thinking of health as a global issue, a lot of attention in the past 10 or 15 years on re-thinking humanitarian assistance for disaster response and relief. As part of this, there has been a lot of angst about not enough international law here to require Burma to let in humanitarian assistance

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when a disaster happens. What is interesting is over the past 10 or 15 years you have seen the international community, both the UN as well as non-State actors, develop the capacity to respond. If we look at what happened in Indonesia or the earthquake in Pakistan or other big natural disasters, we have not had these massive disease outbreaks. It is very interesting. Without any development of international law. The problem in Burma is unique to that regime. You cannot say that there is a systemic problem because of what is happening there. It does create the problem of how then do you respond with regard to this particular type of regime, not just with the diseases that are going to break out because of the cyclone, but, in Burma Malaria is a huge issue, Tuberculosis, HIV/AIDS. Burma is a global public health disaster. Again, how do you fix that problem? It is regime change. I do not know how else to describe how you would fix all those problems in a sustainable way. Are we willing to take that on as a foreign policy objective? That is where people start to hesitate.

Dr Lee: The starting point is that health is always seen as a low-politics issue on the domestic front. Then you move to the global level, global health has become a climber on the international agenda, but only where it intersects these key areas: security, trade, perhaps migration. When health intersects, with these issue-areas those at the top tables of foreign policy become interested. Of course, the problem then is that they interpret public health priorities from their own policy lenses, so certain diseases are given priority because they are seen, I suppose, as a particular security threat in certain countries, or there might be trade interests, where they intersect with health around drugs and so on. There is, I guess, this partial and potentially skewed view of what the global public health challenge really is. What do we do about it? This situation is probably familiar to anyone who has worked in policy. Our work at the London School is constantly about banging the drum that: "Public health is important because . . .", and then we try to break into these influential policy circles. For a while, you start to use this language of trying to scare people, saying, "If we don't do something, then this many people will die." You fall into this kind of language. It is a double-edged sword: you have to play that game, but at the same time you distort what really is your own agenda. I suppose I would say that we have tried to do "joined-up government"—that horrible phrase—trying to find ways to access those who have the policy influence and trying to convince them. An alternative approach would be that, given we do not know what the key threats will be we invest in basic health systems that will be much more effective than picking and choosing specific diseases. We do not know if a particular disease is going to become a risk and cross borders, but we can prepare for the types of

changes that eventually will happen because of globalisation and then shore up our institutional responses. If we just focus on what we think specifically today is going to be a threat, we do not know what is around the corner tomorrow. So we need put our focus on basic health systems here in this country as well as abroad.

Q973 Lord Howarth of Newport: Might you take that approach a stage further? I suspect that, historically, better sanitation and better education have done more to promote good public health and to reduce and eliminate diseases than the doctors have?

Dr Lee: Yes.

Q974 Lord Howarth of Newport: If we are really trying to get to the roots of these problems, then the whole thing becomes such a vast and amorphous policy agenda that it is even harder to get focused and targeted and prioritised in ways that might be useful. *Dr Lee:* I do not know. If you think of 19th century public health reforms in the UK, they were not just public health reforms, they were social reforms. We were moving from the Industrial Revolution, where we had cholera outbreaks, disease was rife, there was large scale urbanisation. These are also things that are happening today in the developing world, but at a much more rapid rate, I suppose. What did the Government do? They adopted broad social reforms: better housing and better sanitation. These were doable things. It did take a much longer period, and today we have a bigger scale to deal with. But focusing our resources, on developing the next vaccine or the next drug for whatever disease we happen to think is going to come to our shores, is really a short-sighted way of looking at it. Perhaps we need both but, given limited resources, I think the shift in attention within public health and health sector aid is really towards health systems and realising that it is the institutional base within which we can then mount effective responses that is important. It can be a bottomless pit. It can sound like we are trying to create new societies in developing countries. We are talking about huge resources here. At the moment we do have resources that we are just mis-spending, and not doing any of this. I keep coming back to sanitation, water, clean water, basic health care—things we have known for at least a century or a century and a half that work. Why can we not apply those lessons to other countries?

Q975 Chairman: When you say we do have resources that we are mis-spending, had you anything particular in mind?

Dr Lee: I suppose that, if we add up all the new resources for global health spending on the three Diseases (HIV/AIDS, Tuberculosis, Malaria) by the

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Global Fund, UNAIDS, Gates, on and on and on. A lot of this money is, first, totally uncoordinated, but it is also going to quick fixes. It is looking for that magic bullet. It would be fantastic if we found a vaccine for AIDS or Malaria, but in the meantime there will be new diseases, there will be emerging diseases. We know this is going to happen, so do we then pour resources into the next disease? It is a very short-term approach. Seeing the longer-term development of societies is not very sexy or popular in terms of politics, but that is ultimately where you get the most impact.

Professor Fidler: Foreign policy makers understand this. They understand the importance of the social determinants of health—education, gender issues, poverty. The problem is that, unlike Britain doing this to itself in the 19th century, you are asking another country to do this to another country. This is where the “social determinants” approach, at least from a foreign policy perspective, begins to look irrational: “How do I do that, unless I impose a way of doing this and spend resources, over which I have to maintain control—because, by the way, I have 50, 60, 70 years of experience in developing countries and I know many of these governments waste money.” We have tried education fixes, we have tried sanitation fixes. There is a whole lot of development that has gone on which has not been specifically connected to health, even though it deals with the social determinants of health, and our effectiveness has, quite frankly, not been very good. There are reasons for that and that has to do with this international context of the limitations of the ability of developed countries, donor countries, to leverage their superior power over developing countries. This is a rational calculation that cuts across all development areas, not just health. Nobody has figured out how to get out of that trap.

Q976 Lord Avebury: They have, to some extent, in the Millennium Development Goals. That is telling the developing countries that this is a standard at which you should aim, and if you do take these goals on, then the developed world will help you. A reduction in infant mortality, for example. You can get a lot of money if you are prepared to do things that will approach that particular goal.

Professor Fidler: There are conditionalities to the use of donor and development assistance with regard to what you do. To some extent, there is controversy about whether or not the Millennium Development Goals are anywhere close to being where they should be at halfway to 2015 at the present time.

Q977 Lord Avebury: Except in sub-Saharan Africa, they are getting there.

Professor Fidler: There are controversies around even other parts of the world with regard to some of the health-related indicators.

Q978 Lord Jay of Ewelme: There certainly are questions, but I myself feel fairly confident that there has been more progress made than would have been made otherwise because there are Millennium Development Goals. To that extent, I would see them, personally, as an advance and as a policy step. I want to go back just a moment to this governance question and this rather difficult area between the present rather anarchic state of institutions which we all agree is unsatisfactory and, at the other end of the scale, the centralised directed system, which I think we all agree would not work. To be honest, I like the concept of networked governance, informal partnerships, but I am not quite clear whether that just happens or whether it is the survival of the fittest and there is a jungle mentality or whether somebody tries to encourage us all to go in that sort of direction, and, if so, who. I would welcome your thoughts on that. Then there is a specific question. Professor Gostin has talked about a possible Framework Convention representing “a unique opportunity to build normative consensus around the most pressing problems in world health”. Do you think there might be something in that? Do you have the same scepticism about that as you would do about Professor Rubin’s ideas of a Global Compact? Who pushes us in the right direction here? That is what I am trying to get at.

Professor Fidler: Let me give you an analogy which is going to be different from architecture.

Q979 Lord Jay of Ewelme: I deliberately did not use the word “architecture!”

Professor Fidler: Right, but I want to contrast that with the way I think about these issues, in terms of what are we doing and why we are doing it. I make an analogy to the world of software. You have a source code that runs the software/runs the programmes for global health. That source code is now accessible and influenced by all range of actors. Via people in this networked context, they are following what is going on. The source code is open source, it gets iteratively defined by the participation of the various actors. Much of this is driven by the basic, fundamental principles of public health. What do you need to do? Surveillance. Then you need to have intervention with regard to disease problems in transitory populations. That has to be based on evidence and scientific principles, et cetera. That is part of what is driving the development of the source code and finding then effective policy and governance mechanisms and political mechanisms to put that into place. That is where we see a lot of competition now with regard to different ideas being floated. At

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the moment, I do not know how you could avoid that, given this transition. I think we are sort of in that framework at the moment. Some things will fall by the wayside; other things, we will find out, perhaps to our surprise, actually work. We can then build on that with a further iteration. You will then start to see the nodes of the network governance become a little bit smaller, so you begin to get more coherency and you begin to get more consensus of what you are doing and where you are going in connection with those ideas. I think that is part of what Professor Gostin has in mind with a Framework Convention on Global Health. Where I have a little bit of scepticism with regard to that proposal is that we already have a framework convention on global health: it is the WHO Constitution. I have not yet seen, even in Professor Gostin's writings, a convincing case that having another large treaty framework would get us any farther than the ones we already have in connection with this. Keep in mind the Framework-Protocol approach is a specific process and dynamic. The Framework Convention means you sign up to not do anything and then the substantive obligations come later—at least, that is the classic way of setting up a Framework-Protocol Strategy. Many of the things that would be needed, the obligations in international law and a Framework-Protocol approach that Professor Gostin has in mind, we already have in international law. There are already international legal obligations with regards to basic survival needs: a human right to health, other forms of human rights. How well have we been implementing those existing rules? Is adopting them in yet another treaty going to be effective with regard to that proposal versus something else which may not be in a treaty format but for which you might get some more traction with regard to the implementation of capacity building?

Q980 Lord Jay of Ewelme: How do you get that traction? Like you, I did not see very strong arguments against everything that was put forward, but I still come back to the question of how do we get the traction to encourage the kind of better co-operation that we are looking for, if we are going to deliver the goals that I think we all want. How do we do that?

Professor Fidler: I think you have to match up these innovative governance proposals with the self-interests of States. Kelley mentioned that the problem is a double-edged sword. You appeal to certain new types of ways of thinking about global health: security, economic power. Even in the context of development, this is new. If you think about what are the basic functions of a country's foreign policies, they are to protect security, economic prosperity, development in strategically important areas, and human dignity agendas. If you look at those four

functions of foreign policy, global health and public health can play a very powerful role, so you need to work across those functions to embed the importance of public health as much as possible. If you start to do that, you are then picking up public health in more of these nodes of network governance than you were before, so it is being talked about in the Security Council as well as in the UN human rights organisations; it is being talked about in the WTO as well as at the Gates Foundation. Iteratively, this is a source code. It develops over time and becomes the standard against which the next innovation has to achieve. You are building through this network a source code that can be used for any given initiative. It is still to a certain extent decentralised: it does not have this sort of command and control feature. I do not think we can get there, but I do think it is possible to make progress with regard to embedding public health across these different policy areas in different types of governance initiatives that are taken inside the health context as well as outside the health context.

Q981 Lord Jay of Ewelme: Could I ask you, Dr Lee, whether you would like to comment on this. I got the impression that you had a slightly more directive approach than Professor Fidler.

Dr Lee: Perhaps I need to think about this network idea and source codes, to understand it a bit better. I suppose it is no secret that I have always been a supporter of the WHO, for all its faults. Maybe that is because it is probably the most democratic organisation for health that we have, although it is not perfect by any means. Maybe it is a step forward—if not the step that we need, enough of a step—maybe going back to what the WHO could do and what we could do to support the WHO. The thing that really comes out when I have looked at the organisation is that it has not been enabled to do what it is supposed to do. From the very beginning, it has always had one hand tied behind its back, if not two. As certain countries have been unhappy with its performance, they have withdrawn resources and they have withdrawn programme areas, and that, in turn, weakens the organisation more, so you get into this kind of cycle. I am not trying to be an apologist for the organisation—there are some huge problems with it. But, if we got rid of the WHO, we would have to create another one anyway. So somehow we have to fix this thing we have. There was a suggestion in the *Lancet* a few weeks about creating a Committee C which is a practical suggestion of how the World Health Assembly could bring in these various non-State actors, these various other institutions that influence global health probably more so than the WHO. In such a committee, global health actors would reach some sort of an agreement, a consensus. This would be a mechanism to create some sort of

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agreement. It is more of an immediate step, I suppose, a small practical step. I do not think it is going to solve everything, but I thought that was quite an interesting idea, to have somewhere where people could meet. I also thought the UK particularly had an interesting role, because of being part of the EU and having to negotiate giving up some degree of sovereignty as a result of EU membership to this supranational authority. There must be some lessons there for other countries, not just from the UK but other EU Members, about how we got there. I know it has been a painful process, but it is notable that, as a Member State, the UK has been willing to give up some sovereignty in order to serve some collective good. EU policy on public health admittedly has been a bit slow to develop and in the kinds of policy areas that the EU has focused on, but it is starting to come onto the negotiating table. Maybe this is where somebody could look at how this could be extended beyond the EU and think about some practical steps forward. I have some general observations about the Framework Convention. I do not feel I am an expert on the legal side, but, having worked on Tobacco Control. It is an area of interest to me. I have observed how the whole negotiation process works and have attended some of the negotiations. It is a very interesting political process in itself, but it was a particular issue. If we could not get an agreement on Tobacco, I do not think we could get an agreement on anything. It was an obvious public health issue. When you get into other areas, when you get into a Global Health Framework Convention, what would go into that? How would you identify what you need to do, what are the policy measures? I guess that, when we tried to look at the global strategy for diet, nutrition, and physical activity, there was a lesson that perhaps Tobacco was just different and it just had legs that other health issues did not. I am happy to consider all sorts of ideas but it does not immediately strike me as a way forward.

Lord Jay of Ewelme: Thank you.

Q982 Lord Avebury: If I can summarise what you were saying earlier, Professor Fidler, it was that we cannot control the behaviour of “States or Gates”. In the circumstances, we have what you described in the final paragraph of your memorandum as “open-source anarchy”. I suppose you have used that in a pejorative sense. In some of the things that you have been saying in your previous answers, I am in some doubt about that, because, drawing the analogy from the world of software, open source has been tremendously successful, not only in the development of Linux but in something that people play with every day, Wikipedia. It might be a useful analogy because, even though Wikipedia started off as being totally unpoliced, I believe that there are mechanisms now

whereby things that are objectionable in one way or another can be removed. In the public health debate we do not have any sort of Darwinian mechanism for removing things that are not productive or useful, so we get this proliferation of actors which is virtually without limit, so far as I can see. I wonder if you think that one could analyse the tasks that need to be done and divide them up into sectors (such as surveillance, monitoring the spread of existing diseases, treating people already affected, and building health systems) and create particular mechanisms that work within each of those fields? So far there has been a concentration on particular diseases, and you have already criticised that and you have said it is at the expense of developing public health systems, particularly in the countries that are lacking in proper standards of governance. Should there be some international mechanism for doing those things?

Professor Fidler: I think there needs to be an international mechanism for working on all those areas. To a certain extent, there has been a division of labour, if you will, with regard to those tasks for a long time. The question is: how is the division of that labour changing? Is the new context, which I call open-source anarchy, making things worse? Or is it making things better? Or is it too early to tell? I use that concept not to be pejorative or to be negative. I am trying to capture in a more conceptual and theoretical way how the nature of international relations is changing. I can send you an article where the entire theory is laid out, if you want, in more detail.

Q983 Lord Avebury: I would be interested.

Professor Fidler: I develop this idea not just for public health. This is also happening in every other area as well. This is a big problem with terrorism and counter-terrorism. What I mean by open-source anarchy is the following. Just to make sure you understand how I am using the terms, anarchy does not mean chaos. It just means that there is lack of—

Q984 Baroness Falkner of Margravine: Absence of order?

Professor Fidler: Well, no, it does not mean that. In the way it is used in international relations, it just means that the actors in the system do not recognise a common superior body.

Q985 Baroness Falkner of Margravine: Hedley Bull’s absence of order?

Professor Fidler: There is order in anarchy. It is the anarchical society. That is what Hedley Bull meant by that. How is anarchy changed? How is that creating order and anarchical system change? It used to be State-centric. States treated it as their property: they decided what happened, they filtered all the ideas, they were the only actors that really had

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material power to emphasise what ideas we chosen. That is changing now. Non-State actors can now access anarchy and influence anarchy in a way that we have never seen before. Again, that is true of terrorist groups and that is true of Bill Gates. This is a phenomenon that is permeating international relations generally.

Q986 Lord Avebury: I am sure he would not enjoy the comparison!

Professor Fidler: No, he would not, but this is part of what is going on. So, when I talk about open-source anarchy, that is what I mean. Again, this is where the “source code” comes from. How is that going to operate differently from the anarchical society that operated in ways proprietary to States. There is potential for great progress here. We have started to see this in global health: new International Health Regulations; the International Finance Facility for Immunisation; Advance Market Purchase Commitments; the Global Fund. These are all happening, where non-State actors are working with intergovernmental organisations and States in accessing that anarchy and trying to change the way in which things operate. You can see that happening. You can see progressive steps being made. We are concerned about whether or not this is going to have a sustainable long-term impact, but there is no question but that really interesting, important stuff is happening in this new context. Another feature of open-source anarchy is that those conditions which exist today that have allowed all this to happen could disappear very quickly, and you could see the re-emergence of a State-dominated proprietary system that is back to the old balance of power problems—what Hedley Bull was thinking about in terms of those issues. If that happens, you will see Health disappear—and I use that word intentionally—from the global agenda. The political prominence we have in Health today is the result of the very specific political conditions that have developed in the post-Cold War period. Unless Health gets embedded in all these functional areas of foreign policy and gets deeply embedded, if we have big systemic changes, where we have great power rivalries coming back to the surface again, this will disappear. We will not be talking about health as a foreign policy issue in the way we do today.

Q987 Lord Avebury: The great thing about the AMC is it does not encroach on the political sovereignty of states. Mechanisms of that kind could be developed with everybody’s approval. It does not require some consent mechanism from the international community.

Professor Fidler: That is also interesting about the International Finance Facility for Immunisation organisation: you are accessing private debt markets

to fund childhood immunisations. Wow! This really is thinking outside the box. In the PRODUCT(RED) campaign, you buy a product that is coloured red and part of the profits go to the Global Fund to help AIDS, Malaria and Tuberculosis. These are all interesting initiatives which are having a positive impact. The big question is: are they sustainable in the long term? There is a public health concern about that and then there are larger political concerns, but the conditions have facilitated that at this particular moment in time.

Q988 Baroness Falkner of Margravine: From your rather Hobbesian, Leviathanesque State, let us go to developing countries, where perhaps life is pretty nasty, brutish and short. Many of the witnesses we have had here have identified some factors that are common to many developing countries that face public health issues, of far larger significance than in the developed world. They focus on governance, poverty, and some of the usual suspects in identifying where problems lie. If you were to leave Hobbes and move to Immanuel Kant, which is where I come from, where would you place external actors (whether they are intergovernmental organisations, other States, the donor community) and their ability to be able to help with some of these challenges? You were quite negative about regime change. I am a great believer in regime change. I think we have evidence of regime change all over the place. Incidentally, perhaps I could take you back to something you said earlier which I was dying to come in on, when you were talking about the power of Gates intervening in Indonesia. Chickens come home to roost. Back in the 1970s, it was the multinationals which had those powers; even more recently Monsanto. If Gates is a counter to Monsanto, some of us are not complaining about that.

Professor Fidler: Let us go with Immanuel Kant, if you will. In Kant’s recipe for perpetual peace, the first principle is that every constitution of every State shall be a republican democracy. The second thing you need to do is to develop economic interdependence between States. These are major macro political changes that have to be pursued with regard to improving governance. There is not a whiff of Health here at all, in terms of Health being a factor in creating the conditions necessary for good governance in the societies. Let us connect this immediately to the EU. Why can we not EU the rest of the world? How did the EU develop? Public health was not on the agenda for integration, right—

Q989 Baroness Falkner of Margravine: But Coal and Steel were!

Professor Fidler: Coal and steel were, but it was not Health. From a foreign policy point of view, if I want to fix the governance problems that exist in

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developing countries, I have these governance problems, and if I am versed in what the EU did and I understand or I believe in what Immanuel Kant did, I am not talking about health issues. Health issues are not on my agenda. I am talking about the bigger changes. I am talking about regime change with a big 'R': (1) we have got to change the nature of the government; (2) we have to hook that government into the global market-place, so that it becomes economically interdependent, so it is less likely to go to war.

Q990 Baroness Falkner of Margravine: Then the Compact comes back on the table, because the Compact is one way forward?

Professor Fidler: The Global Compact?

Q991 Baroness Falkner of Margravine: Yes.

Professor Fidler: No. That has nothing to do with spreading democracy and spreading free trade.

Baroness Falkner of Margravine: No, but it is a co-operative mechanism.

Chairman: We are heading off into a different area here. Essentially, you are after whether we should be focusing more on, if you like, the ability of governments to cope. We will not get into regime change now. It is a very interesting discussion and I would be very keen on such discussion, but not here and not now.

Q992 Baroness Falkner of Margravine: My Lord Chairman, that is right.

Professor Fidler: From a Kantian point of view, intergovernmental organisations are not the key.

Q993 Chairman: That is what I picked up from your paper. You are saying it is not the intergovernmental organisations.

Professor Fidler: If we are talking about the Kantian approach, we would not be talking about the role of intergovernmental organisations. If you get those underlying domestic conditions set properly (democracy, free trade), intergovernmental organisations are secondary. We can move from Kant to the real world, where intergovernmental organisations have to play a facilitating role; for example, on Free Trade, the WTO; or the European Union, to go from Coal and Steel to a Common Market. You need institutional mechanisms in order to do that. But what is interesting, if you are talking about the big reform issues—and the EU is the classic example of this—public health has not been on that integrating agenda until very recently. If other countries are going to take a lesson away from that, it would be: to fix these problems, you are not worrying about public health.

Lord Jay of Ewelme: I think myself there is a slightly tighter connection between the two. The real motivation behind the European Union was the avoidance of war. The equivalence here is the avoidance of disease. I think there is a slightly more interesting link than perhaps you have suggested. Anyway, that is another point.

Q994 Baroness Whitaker: There are those who argue that, far from fading from foreign policy, health is becoming more part of it. Not, unfortunately, in the way that I think Dr Lee advocates—that there is a point in investing in the health infrastructure of developing countries so that the disease will not be communicated to the developed world—but health as a security issue is part of national policy: all this stuff about screening migrants and so on. Health as a security issue—which is quite bad for the improvement of health—is surely a live matter in foreign policy?

Professor Fidler: It is at the moment. There is no question that health as a foreign policy issue is now more important today than it has ever been in history across all of these functions. That is true today. My point is that there are particular political conditions that have allowed that to happen. For example, many of us in the United States are quite worried about what happens if Iraq goes under. We pull out; things go bad; you are not going to see health talked about as a security issue. We are going to have much bigger problems on our hands with regard to these issues. Or if the rivalry with China intensifies. The competition with China in Africa, I know, is of huge concern to the United States as well as to African countries. I am here to tell you that public health is not on that agenda as a security issue. Things could change that alter the political conditions which have allowed health to become more important. That is why it is so critical right now, at this moment, to try to get that right and embed it as deeply as possible, so that it will remain higher on the agenda as these changes occur—which we know they are going to. That is just the nature of international politics. That is why, again, this network, this iterative approach, might be more effective from that point of view than trying to think about a command and control structure from one or any number of intergovernmental organisations. That is my concern. I do not think we are disagreeing in that context, but I think we have to be careful not to assume that the conditions that exist today, which have allowed health to be more important politically, are going to continue.

Q995 Baroness Eccles of Moulton: Professor Fidler, before I get into asking you your views about Health Impact Assessments, there is something I am quite curious about. Earlier on you have mentioned once or twice that we are in a state of transition with regard

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to global communicable diseases, and I just wondered if you could say what has caused this and why we are at this particular point.

Professor Fidler: The major reasons why we are in the transition that we are in at the moment are: first, there has been global realisation but, more importantly, realisation on the part of the rich developed countries, the great powers, that emerging and re-emerging infectious diseases are a threat to us and our interests directly and indirectly. That is part of the reason why it has arisen on all these various agendas. Second, what we have in place now is not working. We have had to move towards creating new types of mechanisms, new types of strategies in order to deal with it. As part of this proliferation, in all of these areas we see all these kinds of initiatives taking place. Underlying all of that in terms of this crisis of emerging and re-emerging infectious diseases are all of the things which are accelerating the processes of globalisation. The speed and the scale of change, economically and politically or epidemiologically, if you will, is speeding up events. This is part of the world in the 21st century, but globalisation still being tethered to the 19th century apparatus. We have got to shift that. That is part of the causation factors underneath why this transition is happening.

Q996 *Baroness Eccles of Moulton:* It is important to understand that in order to move forward progressively rather than regressively?

Professor Fidler: Yes. There is, to a certain extent, a widespread understanding that we are in transition. There are various levels of happiness and unhappiness about the transition and where it is going. That is part of this process that we are going to need to go through. Even in connection with the establishment of the World Health Organisation, that just did not happen. We had international health organisations prior to that, so that was also an iterative process leading to a mechanism which had its day in the sun, if you will. It is still very important, I agree with Kelley. We do not throw the WHO out of the window—far from it—because there are aspects of this transition where the WHO is going to become even more important than it has ever been in the history of its existence. That is also important to remember about this transition.

Q997 *Baroness Eccles of Moulton:* Perhaps against that background you can give us your views on Health Impact Assessments and whether they can be used in non-health areas as well in order to promote their function.

Professor Fidler: I think it is a possibility. I do not know whether the Committee has looked at the experience that the World Bank's International Finance Corporation has had with health, social, and environmental standards in connection with

financing foreign direct investment, but there is already a built-in process in that mechanism, where health, environmental, and other social impacts are assessed prior to decisions made on financing. Also in connection with the application of the Equator Principles, where a consortium of private banks that do development assistance have signed up to similar principles to what the World Bank uses. To some extent, there is already fairly extensive evidence of positive as well as negative impacts of using these sorts of impact assessment statements. Let me take you again to the health context specifically. I have not written specifically about this, but my sense in terms of looking at specific concrete disease areas is that Health Impact Assessments might play a role. I have some scepticism that, when you start broadening this out and you are back into the social determinants of health again, then, in order to have a Health Impact Assessment mean something, you really have to have two things in place. The first, whatever entity is doing the Health Impact Assessment, has to have the ability then to say, "You need to do x, y or z, because we find a problem." That entity also has to have enough resources to help that country do it according to the conditions laid out with regard to capacity building. That is exactly what the WHO does not have. It does not have the resources. It does not have the authority to do that. What organisation has that authority? The World Bank. This is what they do with their principles. Even the WTO does not have the mandate to engage in a Health Impact Assessment, or any type of assessment for that matter. That is something that is left to the State. When you start getting out these bigger capacity-building, horizontal systemic concerns that we are worried about, that is the point at which I start to wonder whether or not Health Impact Assessments are going to be effective, absent those conditions which make it effective in those contexts where we already see it.

Q998 *Chairman:* Perhaps I could ask you, Dr Lee, if you would like to come in on what has just been said about Health Impact Assessments.

Dr Lee: I have only done a little bit of work on Health Impact Assessments. I think there is a tendency to think it is a quantitative tool, I suppose. However, there is still a lot of qualitative skills and judgment used in the methodology around this. I think it really is not necessarily a bad approach but it always comes back to a battle of political vision a normative issue. I am not making myself very clear. I have been looking at trade issues. When trade agreements are agreed, public health people notoriously complain that they are not around the table to discuss trade issues and then some of these policy decisions are found to be quite adverse to health: The belief is that if we had a Health Impact Assessment perhaps we could get a bigger voice and prove that we should be

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around the table. However, I think it is a bigger political problem than that. There are limitations to how much we can use Health Impact Assessment. We may be able to use it more at the national level than the global level. There are examples where we have one initiative that is trying to promote health in a country, and then another initiative comes along and completely wipes out any benefit. It might be a trade issue. Or it might be a situation where we are trying to train up health workers in sub-Saharan Africa, and then another initiative seeks to recruit those health workers and bring them to another part of the world. There are these contradictions. If we had those sorts of concrete things, maybe we could apply HIA, but beyond that I am not sure. Maybe we could look at that more. Overall, at the global level, I think there are limitations.

Q999 Baroness Eccles of Moulton: We have been looking ahead very much for the wider, global policy aspects of this. I wonder, if we could travel through country governance, through regional to local, to the village, and look at the horizontal-versus-the-vertical effect on applying health work to the locality, where having the horizontal structures in place are obviously hugely important in order to be able to provide the vertical health care—although so often, as we understand it, the vertical comes in and has a project and dishes out the medicine and goes away again. What is your view on doing everything possible to encourage the powers that be to get better established the horizontal structures?

Professor Fidler: Part of that, again, as you embed the public health principles of what is needed, even if you are just talking about raw self-interest—or maybe this is enlightened self-interest or whatever phrase you want to use in connection with that—we need to understand that we are concerned about protecting ourselves. That is not only in terms of my understanding of the capabilities that we need, but I think it is also important that developing countries have to understand that as well. Again this goes to the governance issue: unless they are willing to understand that—again, they do not care about health in the US, right, but for their own purposes, their own security, their own economic power, their own sense of development, they need to pay attention to these issues. That would be an enormous step forward, because, despite all the talk and rhetoric about global health, it is often the case that governments do not care. They will take the vertical programme, take the money, but they then pull money out: “Bill will pay for it, and I will spend the money on something else, or put it in my Swiss bank account.” There is not a sense yet, even in terms of that raw sense of national self-interest in many of these countries around the world, that this is an important issue. It sometimes frustrates people in

global health that selling the issue as a human right to health or as a humanitarian concern has not worked. We have to have a different approach that cuts across all of these interests that a State would have with regard to these issues. Second, if you start to have a little bit of resonance there, then perhaps you can start with programmes.—and maybe they are a hybrid of vertical and horizontal—which go with the basics of what you need. Surveillance, for example, is a classic example of that. You need to build core surveillance capabilities. We have the International Health Regulations here which focuses exactly on that. Here is an opportunity to implement this understanding now that we have about surveillance’s importance. Implementing that then obviously gives more credence and credibility to the World Health Organisation in terms of it trying to systematically—from local to sub-regional, state, national, global—build these systems. It is going to be bit by bit, because you cannot just all of a sudden have a health system developed. The second aspect, also stressed by the IHR, is core response capabilities with regards to these issues. Again, that is a horizontal and vertical issue that you need to work on. Implement that particular set of obligations that you have, tie these interests together, make them more interdependent, in the way that we have seen interdependence in other areas. This is something where people in public health confuse two things. They confuse interdependence and inter-connectedness. We are inter-connected in virtually every health context; we are not inter-dependent in all health contexts. It is interdependence that gives you the stronger basis for collective action internationally.

Dr Lee: I would support the idea that vertical and horizontal are mutually exclusive. There are ways of building in, and taking advantage of the political support for specific diseases that we will always have for various reasons and combining this with capacity building and other elements of the horizontal approach—disease-focused initiatives as a kind of Trojan horse, for health systems development perhaps. I think donors can do that very effectively. That may not cost more money, but it is the way you may train local health workers and build institutions for the longer-term. I think there are ways of integrating them better given I do not think we are ever going to get away from vertical approaches unfortunately. That is all I would say.

Q1000 Lord Avebury: Maybe Dr Lee would be able to answer this. In the Crisp Report there is a recommendation that DFID, in particular, is to meet with representatives of HPA, HCC, NICE, HCS, CIC and the private sector, to see how practically they could collectively strengthen health systems in developing countries and agree on plans for doing that. Would this be a general approach? Crisp is

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making that recommendation for us as a donor country. Might it be applicable to other donors as well?

Dr Lee: I think there is a shift beyond the UK to other donors and agencies in this direction. The World Bank certainly has a Health Systems Development Initiative now. Not the Gates Foundation so far, although there are ongoing discussions that they need to emphasise less the kind of magic bullet approach, the biomedical focus. There has been a shift in the debate in the last five years, perhaps, which is encompassing the WHO as well. I think there is a recognition that things are not working. Hopefully, it is not going to be the latest thing and people will focus on health systems as long term strategy—which is not a new message, it is just that nobody seems to want to listen to it. There are opportunities for the UK at present to try to push that message.

Q1001 Lord Avebury: It might be a new thing to co-ordinate the health authorities and health private sector partners in developed countries, to co-ordinate what they are doing with regard to the development of health systems in the third world?

Dr Lee: I think you are right. There is this consensus emerging. There are individual voices but I have never seen—though I have only been in public health for 20 years—such a shift in the discussion as marked as this in terms of support for health systems development. So I think you are right, there is something new there to grab on to perhaps and push.
Chairman: In Switzerland, in the second tier of their structure on the Department of Health there, they have appointed someone with responsibility for global health. It is an interesting development.

Q1002 Baroness Whitaker: I think we also have a global health concept now within the Department of Health. Turning to the splendid International Health Regulations, I think you mentioned, Professor Fidler, the problems about implementation. It is readily understandable that developing countries do not have diagnostic or surveillance capacity, nor for that matter preventive and treatment capacity for other aspects of health care. We also know that new serious infections emerge quite rapidly perhaps once a year, so the International Health Regulations have never been more needed. Would you say that the developed countries ought best to use their funds to help the developing countries have the infrastructures which could implement the IHR? Would that be the correct enlightened self-interest approach to prevent the spread of communicable diseases?

Professor Fidler: I think the IHR 2005 provide a sort of gateway for donor countries to re-focus some of these resources, again in a sort hybrid way—vertical

but having the capability for horizontal impacts through the implementation of the IHR. Again what is worrying is that no one seems to be terribly interested in funding that implementation. Even in the context of things like Prime Minister Brown's launching of the International Health Partnership, they are not talking about the implementation of the IHR, and so it leaves me to wonder whether any strategy is going to emerge that is going to address those issues directly. Everybody talks about implementation, but there is no strategy and there are no funds and seemingly no interest in doing this. Particularly given how important the International Health Regulations, are an opportunity is being missed here. Again, it is a hybrid approach. I think Kelley is absolutely right. We need to get away from verticality. You begin to build those core, basic systems and that is going to create, within the countries, synergies with regard to building that outwards as well. I see this being a multiplier effect with regard to doing this. I have to be honest and say that I do not see right now interest from State actors, from the NGOs either for that matter, in IHR implementation. That is not resonating with the source code. That is a big concern with regard to how I perceive that potential missed opportunity.

Q1003 Baroness Whitaker: Organisations do not seem to see the funding of a new laboratory as quite as sexy as a primary health care clinic. But that might well be a recommendation we ought to make. Even if they were much better implemented, so that you could detect and identify a new communicable disease very rapidly, they do not have much place in reducing the spread, do they? What about restrictions on travel and trade? That is not their bit. Should we do something about that?

Professor Fidler: Let me run through where the IHR 2005 are useful with regards to controlling or preventing spread—and, again, some of this is in theory remember. It is not only in building the core capacities for surveillance, but you are also obligated to build core response capacities. Assuming everybody had those core response capacities, that may in fact give you a better chance of controlling and mitigating the spread of infectious diseases if everybody has reached a certain baseline level. The problem we have now is that that does not exist, so it escapes, it gets away.

Q1004 Baroness Whitaker: Do you mean that on the back of IHR implementation, a government would have, as it were, a mandate to restrict trade or travel? They might not want to do that.

Professor Fidler: In terms of trade or travel restrictions, what the new International Health Regulations do—and this is part of why they are so

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radical in their design—is to give the WHO Director-General the authority to issue temporary recommendations which could, depending on the disease, involve recommendations about trade and travel restrictions that other countries do not have to implement but have to take into consideration. The mere fact that the WHO Director-General might do that is going to give you the incentive to co-operate early and often with the WHO in the event of a breakout you do not understand. If you get WHO assistance in early, and you are transparent in your reporting, that early assistance may help control the spread of the disease. Other countries too are going to be more willing to give you assistance if you have been transparent with regards to the outbreak that has happened. That is exactly what we want from a public health point of view. We want to create the incentives for getting the WHO and public health focused on that and get the assistance targeted right where it needs to be—because you do not want to be in the position where the WHO has to contemplate issuing travel or trade restriction recommendations against you. To a certain extent, that is part of how it plays with the self-interest of governments to do exactly what we would want from a public health perspective. It is not enforcement then; it is the fear of those recommendations. Even though they are non-binding, you do not want that to happen. You saw what happened with SARS: countries got hammered politically and economically when the WHO issued those recommendations—without any legal authority to do so. Now they have legal authority to do it. Your incentive? Work with WHO early when this happens. Be transparent, so we can get the assistance we need. That, I think, could have positive implications for the control of some diseases. A lot of this is in theory: it depends on having some capabilities, in country but also more in the sense of capabilities that the WHO needs to be able to ride to the rescue when they are asked to do so. They have done an admirable job of that with the resources they have at the moment, but I do not think anybody there would pretend that those resources are adequate for their responsibilities under the IHR.

Q1005 Baroness Whitaker: It is your assessment that the WHO themselves cannot fully implement the IHR in their action unless they have more targeted resource there?

Professor Fidler: They would be more able to implement the obligations they have effectively if they had more resources. There is no question in my mind about that.

Q1006 Baroness Whitaker: Particularly related to that?

Professor Fidler: Yes. Again, this is what is worrying. Even in connection with empowering the WHO to use the authority that the States, in an unprecedented way, gave them authority to do this, they are starved of resources.

Q1007 Lord Jay of Ewelme: While we are still on the WHO, I would like to pick up on something you said earlier on. You said that we should not forget that there will be areas under the new dispensation when the WHO will become more important. Could you say very briefly what those would be?

Professor Fidler: Surveillance and responses to outbreaks. Remember, the new IHR builds in these non-State actors informations, so the WHO can get information from anywhere. Utilising the power of information technologies, somebody with credibility and legitimacy has to sift through all that to figure out what is noise and what is a problem. That credibility is not going to exist for a single State—certainly not the United States, but not even a country like Canada, which is held in high regard with regard to this. It is just not possible. You need the WHO. You would have to create it if you did not have it. You need the WHO that has the legitimacy and the credibility to sort through that, so that, when it picks up information from an NGO source about something going on inside a country, and the WHO calls the health ministry of that country, they can have a productive conversation about that. Here is a situation now where the WHO is even more important than it has ever been with regard to surveillance, because it has the ability to take in all these new sources of information, whereas before with the IHR all it could take action on was information it got from governments. That was part of the problem. Second, the States Parties to the IHR have given the WHO real power. Except for the Security Council's authority under Chapter VII of the UN Charter, I cannot think of any other international organisation the States Parties of which have granted to the Director-General material power in this way, to do countries severe economic and political damage, over their objection. This is remarkable. Here again is a situation where the WHO possesses an authority which makes it more important than it has ever been with regard to thinking through how countries should respond with trade or travel restrictions to an outbreak. Again, the only entity that is really able to do that credibly is the WHO.

Q1008 Baroness Eccles of Moulton: But they cannot do it because they do not have the resources?

Professor Fidler: You could see a situation where we know, given the disease—if it is virulent, highly pathogenic, and it is easily transmissible—you are

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going to be in a situation where the WHO can exercise its authority. You know we are not going to be able to control it in that particular developing country: it is going to hit everywhere else. Everywhere else needs to be ready for when that hits, but you have to be sure that you are not engaging in irrational behaviour. “Here is what you should do,” the WHO is telling Member States. Other Member States are going to continue to have the sovereign right to issue their own travel recommendations and trade restrictions if they want to. You cannot take that away: it is a matter of sovereignty. But, under the new IHR, they have to follow scientific and public health principles when they do that; and, if they are putting something more restrictive in place than what the WHO has recommended, they have to justify that. Even in the context of the dynamics of that, the WHO plays an absolutely critical role. This is part of why the IHR is so revolutionary in what they are trying to do.

Q1009 Chairman: You used the phrase a few moments ago “WHO rides to the rescue”. You are not saying ride to the rescue as it has this overarching authority to say, “You must do this.” They do not necessarily do it themselves but they may offer the services or suggest the services of other organisations, countries or whatever, or suggest that the country does it itself. I ask this because there has been a bit of a debate about whether the WHO ought to be doing the job or overseeing that the job is done. Do you see what I mean?

Professor Fidler: Yes, I see what you mean. I actually think that is a false debate. The WHO is never going to have the capacity to do these things.

Q1010 Chairman: It is not either/or.

Professor Fidler: There is the sort of immediate response—and the WHO is very skilled at this. This often happens. If there is an outbreak in Africa, they think it is Ebola, in goes the WHO team to help the local capacity figure out what is going on and bring the outbreak under control. They are very, very good at this, but, again, that is small-scale outbreaks where the WHO can respond. If this is on any larger scale, you cannot make WHO the world’s public health agency. This is a problem in the US too. The CDC does not have enough staff to deal with an outbreak in California. It has to work with the California authorities. But it is often in the role of leading how the response will occur, and the WHO has to play the same role. It is not that you have to have this massive capability where they can handle any outbreak. This is never going to happen. That is why I say I think that is false debate. But do they have enough even to do what they are required to do under the IHR? I hear that they really do not have enough resources. They could do a more effective job if they had, not

huge amounts of money, but a little bit more money than they have at the moment. Remember, they are tapping into a lot of these networks which are on autopilot. This is the other great thing about network governance: you do not have to sit down every year and come up with a budget for the network; it operates based on different incentives that people have. More resources for the WHO in that context would allow it to do a more effective job with regard to the authority and responsibilities it has been given under the IHR.

Q1011 Chairman: Before I move on to intellectual property rights, could I ask you, Dr Lee, if you would like to add anything there.

Dr Lee: I suppose I do not disagree with what has been discussed. Picking up on what Baroness Eccles was hinting at, there is a related issue maybe, and perhaps Professor Fidler took the discussion a different way. It is the capacity of the WHO, perhaps, to strengthen disease surveillance in countries. It does not have those resources. Where there have been new resources, disease surveillance has received quite a lot of resources but perhaps not enough. I have nothing against disease surveillance, and think there needs to be more resources. What I wanted to add is my concern that there is an emphasis on surveillance without looking at disease prevention and response. We need to have much more emphasis on these and not only using surveillance as an early-warning system for us—because it seems to be perceived that way in countries like Indonesia, that we are only interested in surveillance because we want to protect or own selves, and we want to have early warning so that we can, whatever we do, put up the fortress measure described earlier. It is really about enabling countries to also respond and supporting them to do that. These aspects gets even less resources. In fact, it probably is not even on the agenda. Whenever we think about response, we think about stockpiling antivirals in this country; it is not about enabling countries like Indonesia to prepare and respond to outbreaks. I do not want to disagree, but I think it is yet another example of a skewed priority list for donors and for the WHO as well.

Q1012 Lord Avebury: A thought has occurred to me. When we were discussing this a minute ago, you said that Burma was a global public health disaster and that the WHO does not have any entrée there, presumably, so that, if there were outbreaks of communicable diseases, they would not be calling the WHO to help, and the first we would know about it would be a large-scale appearance of that disease in the inhabited areas. Is that correct?

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Professor Fidler: Yes.

Dr Lee: I suppose so, yes.

Professor Fidler: There were huge problems in Burma before the cyclone, with HIV/AIDS, Malaria, TB. In the nature of this regime—

Chairman: One of the things that has struck me for a while is that the problem would be with States like that, North Korea as well and possibly Zimbabwe at the moment, where your opportunity to know when you have a major disease about to hit you is very little. It is one of the issues which, I think, does reshape the intergovernmental structure for the future. We just do not have a way of dealing with it.

Q1013 Lord Jay of Ewelme: I do not want to get into Burma conversations, but there have been some NGOs working quite effectively in Burma and are continuing to do so. It is not a completely hermetically-sealed state; something could get out, but not via the governmental or intergovernmental agencies. It is the non-State actors again.

Professor Fidler: That is how we know about the problems, not through the sort of traditional mechanisms. That is why it is critical that you build that into the global surveillance system that we have. You avoid the problem, at least initially, of these recalcitrant governments, but at the end of the day you still have to deal with them and, if they refuse to have the WHO come in

Chairman: I want to move on to Lord Howarth on the Indonesian issue which we have already touched on.

Q1014 Lord Howarth of Newport: Could we pursue for a moment the line of thought that Dr Lee was just now developing when she was talking about Indonesia and the attitude of Indonesia? Unwillingness to fulfil the letter and the spirit of the International Health Regulations is not confined to developed countries and the refusal to provide the resources needed to enable the WHO and the IHR to be properly implemented. The perception of Indonesia, as we understand, when they refused to provide the Avian Flu virus samples, was that these obligations were not designed with their interests in mind; they were designed to enable the vaccine to be produced, the benefits of which would be experienced in other parts of the world, wealthier parts of the world, but not for their own people. Is there an extensive perception in the developing world that international regulations, whether it is International Health Regulations or Intellectual Property Rights, are engineered, if you like, in the interests of others than themselves?

Professor Fidler: First, I think we have to be very careful about the Indonesian virus controversy and the new IHR. The new International Health Regulations do not require the sharing of virus

samples, so Indonesia was not violating the IHR. This is where the WHO came out early and said that they were, and ended up backing off from that. This is the first real test case of the IHR.

Q1015 Lord Howarth of Newport: Is that because the IHR were badly drafted. Was it the intention they should have had to or not?

Professor Fidler: This is interesting in terms of the debates that have come up with regard to this question because, as I presented the international legal analysis that Indonesia or any country that is party to that treaty is not required under the regulations to share live virus samples or any biological materials for that matter. The response was, "But that's absolutely critical to doing global surveillance." If that is the case, why did you not write it in the IHR? You knew at the time that the IHR were being drafted that controversies about virus sharing with SARS were already on the agenda, so it was not as if this issue surprised anybody. This is not a mistake, this is not bad drafting, it is what the parties intended. Indonesia is it is not under an obligation under the International Health Regulations to share these virus samples, but it is not willing just to rest on sovereignty. Indonesia has said that the rules that ought to apply with regard to this issue is the Convention on Biological Diversity, a treaty which is more sensitive to the interests of developing countries with regard to protecting their biological diversity. The problem with that argument is that it does not really work for Avian Influenza. The States Parties to the Convention on Biological Diversity before the Avian Flu controversy with Indonesia said that Avian Influenza was a threat to biological diversity and that everything ought to be done to eliminate the threat. What do you need to do to eliminate the threat? You have to share the virus, so you can have surveillance. They had a very weak argument on the flipside of that. Underneath all of this is an agenda directly connected to the controversy about Intellectual Property Rights. This I where I think the negotiations that are going on now are not being productive, because it has become a fight about IP interests and not about surveillance and the global health crisis that the lack of the sharing of those virus samples has become. There are issue linkages here which have made the negotiations very, very difficult. There may be this underneath agenda that is trying to shake up the way in which Intellectual Property Rights are protected in international law, because there is the perception from the developing world, as we have indicated, that TRIPS and that high-level of protection of Intellectual Property Rights is not in the interests of developing countries. That is where there is the divergence of national interests on that issue, and that is why, in Indonesia or in any other context, we

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have very little progress on that issue. There is no consensus. There is no meeting of minds on IP issues in global health. That is bogging things down across the board.

Q1016 *Chairman:* You did draw attention in your paper to the serious trouble we are in on threats of biological weapons. You have referred us to certain reading, which I have to confess I have not done as yet. Most of the evidence we have had on this suggests that the response to a deliberate outbreak is not essentially different from a natural outbreak. Do you share that view?

Professor Fidler: Partly. This is what the book goes into in great detail. It is what we call the synergy thesis: anything you do to prepare for a biological weapons attack will stand you in good stead if it is an outbreak of naturally occurring infectious diseases and vice versa. You have probably heard this over and over again. To start breaking that down into specific public health actions that need to be taken, the record looks is a lot different from what the synergy thesis would lead you to believe. In some areas you can develop deep synergies. The two greatest areas are in surveillance and response functions. But, even there, the synergy thesis is really in theory only, because with regard to the way countries are operating internally as well as externally, there are what we call in the book fault lines in this context. One fault line is between an emphasis on biological weapons versus an emphasis on infectious diseases. At some point the synergy breaks down and allocation choices are made. Public health people think they are made the wrong way, and security people think they are made the right way. The second fault line is between your own national needs and what the international community needs, and the tendency is to spend more money at home than on international needs. We have, as we have been talking about, this huge surveillance gap. Yes, theoretically you could develop these synergies, but you are not, so there is a gap that exists. It is the same with response. There is this huge response gap. In between, there are other interventions in which public health engages: prevention interventions and protection interventions, in which you are going to find virtually no synergies at all. When you have a choice you have to make: how are you going to allocate the resources; for example, you take actions to eradicate a disease from a naturally occurring infectious disease point of view. If you eradicate smallpox, what does that do on the biological weapons side? Oh, my gosh, you just created a biological weapon! This is clear also if we eradicate polio. We are then going to have to worry about polio being used potentially as a biological weapon because nobody will be vaccinated. You do not have any synergies there. With protection

interventions you harden the target. You know the population is going to come into contact with microbes, so what do you need to do to address that? Public health says vaccination, wash your hands, safer sex—there are lots of protection interventions in which you can engage. None of those help you protect against a biological weapon. Similarly, if you inoculate or vaccinate your troops for a potential anthrax attack, that does not give you any benefit on the public health side. Those interventions create no synergies whatsoever. The synergy thesis itself needs to be broken down and looked at very carefully with regard to specific interventions to public health when undertaken in either context. When you look at it as we do in the book, we analyse this in detail, you start to see the synergy thesis has some real problems.

Q1017 *Chairman:* As a lawyer, do you see there is a part solution in increasing the authority to inspect factories or units that might produce such material?

Professor Fidler: The possibilities for verification or compliance protocols through the BWC are dead and buried and will not be resurrected.

Q1018 *Chairman:* You are making that judgment why?

Professor Fidler: Because the whole process of the BWC, the traditional arms control process, is going through the same transition that we have been talking about with regard to global health. There is no longer confidence in the traditional approach. That traditional arms control approach, State-centric focused, based in a treaty, worried about the use of one State's biological weapons against another State, is not the problem today. We are much more worried about bio-terrorism. The BWC does not really have anything in it that helps us with that. Second, we are now concerned, mainly because of bio-terrorism, that we are going to have to respond to attack. There is nothing in the BWC to help. They did not even think about that issue, frankly. It has never been a serious part of that arms control approach. You see the BWC process more interested in issues which have no foundation in the BWC—and, again, we talk about this in the book. You see the BWC trying to catch up to governance trends which have happened outside the BWC context. How interesting! The WHO is trying to catch up to governance trends that are happening outside the WHO. You see these parallel things developing in both of these worlds. In the book we try to bring these together in a networked governance approach, building both on the BWC norms and the IHR to try to integrate these in a way that produces better and fully combined biosecurity, so there is detailed explanation of the way forward with regard to those issues. That way forward, however, does not catch everything. It is specific to certain types of infectious disease threats—

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not even all infectious disease threats but certain types of infectious disease threats. People who want to take a broader view would accuse us of being part of the problem too, adding another idea to the mix of ideas that has already been thrown out in connect with that. We, however, see a way we can bring the concern about biological weapons and infectious diseases closer together with a different type of network governance structure that we think would make more progress.

Chairman: Dr Lee and Professor Fidler, thank you very much indeed. We have kept you longer than I had anticipated but we are very grateful for a very full and detailed exchange there. If anything occurs to you after this hearing that you feel you ought to have drawn to our attention, either as something you wanted to say or some new suggestion or thought, please do not hesitate to write to us. We would welcome that. Thank you very much indeed for your time.

TUESDAY 20 MAY 2008

Present	Avebury, L	Hooper, B
	Desai, L	Howarth of Newport, L
	Falkner of Margravine, B	Soley, L (Chairman)

Memorandum by the Organisation for Economic Cooperation and Development (OECD)

GENERAL REMARKS

1. The Organisation for Economic Cooperation and Development brings together 30 countries committed to democracy and the market economy to support sustainable economic growth, boost employment, raise living standards, maintain financial stability, assist other countries' economic development and contribute to growth in world trade. The reach of the Organisation is increasingly global. In May 2007, OECD countries agreed to invite Chile, Estonia, Israel, Russia and Slovenia to open discussions for membership of the Organisation and offered enhanced engagement, with a view to possible membership, to Brazil, China, India, Indonesia and South Africa. The OECD also shares expertise and exchanges views with more than 100 other countries and economies.

2. The Organisation is a global source of statistics, and economic and social data. The OECD monitors trends, conducts analyses and develops forecasts of economic and social changes in numerous fields including in health and science and technology. The Organisation provides a setting where governments compare policy experiences, seek answers to common problems, identify good practice and coordinate domestic and international policies.

3. With regards to the Committee's inquiry, the current OECD focus is mainly on identifying steps that can be taken to improve the availability of medical innovations for neglected and emerging infectious diseases, especially those that principally affect developing countries.¹ However, the Organisation has a broad range of other related interests and activities under, for example, its Health Committee, Development Assistance Committee, and Africa Partnership Forum as well as elsewhere, that encompass from time to time issues related to accessibility and affordability.

4. Together with the Government of the Netherlands, the OECD recently held a High Level Forum on Medicines for Neglected and Emerging Infectious Diseases (Noordwijk, the Netherlands, June 2007). The Forum brought together over 200 high-level participants from OECD and developing countries, industry, researchers, funders, academics, philanthropic foundations, international and non-governmental organisations. Forum participants agreed the Noordwijk Medicines Agenda (www.oecd.org/sti/biotechnology/nma) which identifies a number of actions necessary to stimulate innovation and radically accelerate the development and delivery of new medicines, vaccines and diagnostics for neglected and emerging infectious diseases that disproportionately affect developing countries. The "Noordwijk Medicines Agenda" identified some of the best opportunities for creating a coherent policy environment for innovation.

5. OECD member countries are currently considering how to take forward action related to the Noordwijk Medicines Agenda within the Organisation's work programme and the Committee's inquiry is particularly timely in this respect.

¹ These diseases generally are designated by the WHO as Type III diseases which are overwhelmingly or exclusively incident in developing countries and include: leishmaniasis, schistosomiasis, onchocerciasis, lymphatic filariasis, Chagas disease, malaria, leprosy, African trypanosomiasis and dengue. Some experts also include HIV/AIDS and tuberculosis, which are Type II diseases incident in both the advanced and developing countries, but with a substantial proportion of the cases occurring in developing countries where drug specifications may need to be different. The OECD work is pertinent to both groups of diseases.

RESPONSES TO SPECIFIC QUESTIONS

Q5. *What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?*

6. There are without doubt blockages remaining at many levels to achieving progress, but the principal focus of recent OECD work has been on overcoming the failure of health innovation systems to deliver appropriate and affordable novel vaccines and therapies. The approaches advocated under the Noordwijk Medicines Agenda would not simply improve health through innovation but may also serve to improve the health of the very system of innovation itself.

7. In short, there is a dearth of new treatments and preventive technologies for the major infectious diseases which primarily affect the developing world. While more than a billion people are affected, the drug “pipeline” is weak and in many cases running dry due to the lack of research and, thus, discovery of new treatments. It is thus becoming clear that a major blocking factor is becoming upstream research and discovery as well as downstream delivery. The improvement of upstream research efficiency and effectiveness is thus of increasing importance for a continued pipeline of drug and vaccine leads (this “productivity problem” is of course a more general problem than for infectious diseases specifically).

8. The OECD has focussed on the question of whether and how health innovation systems can be improved, and new incentives schemes created, so as to encourage more investment in research for the public good. It has also asked how to improve policy coherence so that research, health, development and finance policies in member countries can be complementary and work toward achieving the goal of needed new medicines for neglected infectious disease.

9. More focused intergovernmental action could help improve innovation and availability by:

- (i) Making the health innovation system for infectious diseases more open by encouraging the use of more open business models (as exemplified by the new product development partnerships) and facilitating global partnering;
- (ii) Increasing R&D capacity and take measures that broadens the involvement of researchers, academic institutions, laboratories and companies globally;
- (iii) Developing innovative mechanisms and sources of financing based on both for- and not-for profit models;
- (iv) Improving access to information, know-how, technologies and encourage (or create mechanisms) that facilitate more sharing of knowledge and more collaborative approaches to research; and
- (v) Encouraging dialogue between the health, research, development, and financial policy communities.

10. Each of these issues is addressed specifically in the Noordwijk Medicines Agenda. The OECD is well placed to play a role in taking action forward, not least since it is able to draw together the key players (governmental, non-governmental, industry, researchers and civil society) in developing innovation systems and in delivering innovation.

Q6. *What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?*

11. The OECD has expertise in several substantive areas, including:

- (i) Mapping, measuring and analysing innovation systems and economic analysis of policy options to spur innovation to meet public needs, primarily through its Committee on Scientific and Technological Policy;
- (ii) Aligning and making more effective overseas development assistance, through the Development Assistance Committee;
- (iii) The measurement and improved effectiveness of health system through its Committee on Health;
- (iv) Its analysis of development needs and policy effectiveness, through the Development Centre and Africa Partnership Forum.

12. It is widely recognised that no single specific policy community—nor international committee that serves it—is likely on its own satisfactorily to address the full range of issues required to improve upstream innovation for neglected and emerging infectious diseases. This is as true for the OECD as for any other

intergovernmental organisation. However, the OECD has the capacity to convene constructive multi-stakeholder expert discussions of policy options, including with industry and non-governmental organisations drawing on its diverse committee structure which ensures representation from most member Country policymaking communities.

13. The OECD has a very broad base of collaborations with other organisations within this subject area. Perhaps most significantly, the OECD collaborates closely with the WHO (through the Intergovernmental Working Group on Public Health, Innovation and IPR (WHO/IGWG) and through WHO/TDR). This collaboration between WHO and OECD has been fruitful and the Noordwijk Medicines Agenda calls for action by OECD and other players in conjunction with the WHO/IGWG. Discussions on innovation and intellectual property issues (IP) related to global health are ongoing within the WHO, as the IGWG develops its Strategy and Plan of Action to be presented to the 2008 World Health Assembly. This notwithstanding, there are strong arguments to support deeper partnership for the future between the two organisations on health innovation for infectious diseases. Clear recognition of such, and a substantive mechanism for achieving it, is likely to be in the interests of both organisations and their members and constituents.

14. A full accounting of the breadth of OECD ties with other organisations active in the field is beyond the scope of this paper but is available if necessary. Some key illustrative partnerships include those with the International AIDS Vaccine Initiative (IAVI), The Institute for Strategic Threat Analysis and Response (ISTAR) at the University of Pennsylvania, United States and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA).

Q12. To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?

15. While the OECD has no current work on microbial resistance to antibiotics, the issue of resistance has been raised repeatedly by countries as one that needs greater international attention, and a driver for the reappearance and spread of diseases including in the OECD countries. The problems of developing new antimicrobials are said to be similar to the incentive problems that hamper investment into new vaccines and therapies for neglected infectious diseases. There is thus an opportunity for work on improving the policy environment necessary to spur development of new antimicrobials.

Q13. In a number of countries, including the UK, there is a problem with hospital-acquired infections. What intergovernmental sharing of knowledge is taking place to help bring this problem under control?

16. Patient safety is a main focus of current developmental work on Health Care Quality Indicators in OECD countries. OECD developmental work on this issue is currently focused on moving towards allowing consistent coding of hospital discharge records across OECD countries. This should lead to better and more reliable measures of the relative impact of hospital acquired infections.

Q14. Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?

17. The protection and use of intellectual property rights (IPRs) are important in encouraging investments in research and development of medicines, vaccines, and diagnostics. Those involved in developing new health care technologies for infectious diseases seem generally to agree that patents have not been a brake in the development process. Broad licensing agreements (such as set out in the OECD Guidelines on Licensing of Genetic Inventions, www.oecd.org/sti/biotechnology/licensing) play an important role in ensuring access to and dissemination of inventions.

18. However, patents have also not proven *sufficient* to stimulate innovation for neglected and emerging infectious diseases. Complementary reward systems have an important role in incentivising R&D for these diseases, though further robust analysis is perhaps necessary for how alternative financing mechanisms can contribute to the development of medicines, their strengths and limitations, and an understanding of what mix of alternative mechanisms could feasibly be put in place.

19. The Noordwijk Forum highlighted the need for a sustainable architecture that promotes the sharing and exchange of knowledge, data and research tools necessary for the discovery of medicines, vaccines and diagnostics for neglected and emerging infectious diseases. Increased collaboration and more open innovation

could help accelerate and reduce costs of research in this field. The OECD is exploring the potential value of collaborative mechanisms for IPRs (such as patent pools or other IP and data management entities) in the life sciences generally, and will consider its application to infectious diseases.

Q17. What intergovernmental planning has been undertaken to cope with the impact of an outbreak of infectious disease caused by deliberate release of micro-organisms into the environment? Is there adequate liaison between the various agencies involved, including intelligence, law enforcement and health care professionals? How could action by intergovernmental bodies help further?

—and—

Q18. Though our remit is focused specifically on known infectious diseases, we would be interested to know how you view the global threat from new or previously unrecognised ones and from the transmission of infections from animals to humans

20. In 2001 the OECD introduced the concept of networking repositories and providers of high quality biological materials and information, Biological Resource Centres (BRCs). BRCs are considered a key element of the international scientific infrastructure, whether within the health sector, the industrial sector or other sectors. In 2007 an OECD Task Force issued “*OECD Best Practice Guidelines for BRCs*” (www.oecd.org/biotechnology/brc) which cover, inter alia, specific guidelines for BRCs holding and supplying micro-organisms, specific guidelines for supplying human-derived materials and biosecurity-related issues.

21. The threat of bioterrorism gives rise to the need for security measures in legitimate bioscience facilities that work with, store or transfer dangerous biological material to protect them from being lost or stolen and subsequently misused for malevolent ends. In March 2007, the OECD Committee on Scientific and Technological Policy (CSTP) agreed “*Best Practice Guidelines on Biosecurity for BRCs*”. The Guidelines on Biosecurity contain a framework on Risk Assessment to guide BRCs in classifying pathogens, for example, according to one of four biosecurity risk levels, and robust Risk Management measures that may be applied as a function of a particular pathogen’s biosecurity risk level.

Q19. What resources (subscriptions, staff, training, medicines etc) does the UK Government commit to intergovernmental bodies to help in the fight against the four diseases listed?

22. The UK has been a leader in the field of thinking about how to improve the availability and accessibility of medicines for infectious diseases. The UK role in establishing an Advanced Market Commitment for pneumococcal disease and the International Financing Facility for immunisation are impressive examples of its forward thinking.

23. However, much remains to be done to both to (1) increase the incentives for research and development investment into neglected infectious diseases and (2) improve the efficiency of the international research so that it can deliver needed new technologies to combat these diseases.

24. The UK could focus more attention on the “upstream” part of the innovation cycle and it could encourage the development of open, international research infrastructures that to help both increase global capacity in neglected disease drug and vaccine development, and network that capacity so to break down silos, increase the flow of knowledge and know-how, and accelerate the discovery of promising new leads.

Q20. Do you wish to provide any other relevant information in addition to what you have said in answer to the above?

25. There are several ongoing OECD initiatives which have elements relevant to the policy discussion around how innovation systems can better respond to global health needs. These include the OECD Innovation Strategy which is considering “global challenges” including health, and the G8–O5 Dialogue on Innovation and Intellectual Property Rights which is part of the Heiligendamm process.

26. At the **OECD Ministerial Council Meeting** in May 2007, Ministers requested that the OECD develop an OECD Innovation Strategy. Ministers noted “that tools and networks that promote open access to knowledge and innovative products and processes are needed to ensure that IP policies continue to encourage innovation and foster the diffusion of knowledge”. Other aspects of the OECD Innovation Strategy also tie directly into the NMA (for example, meeting global challenges, including health).

27. The 2007 **G8 Summit in Heiligendamm** mandated the OECD be used as a platform for the Heiligendamm Dialogue Process between the G8 and Brazil, China, India, Mexico and South Africa, which includes dialogue on innovation and intellectual property protection. Moreover it invited countries to identify priorities that could be enhanced by collaborative research efforts, joint initiatives, and programmes on areas of common interest. Actions in the NMA are directly related to these two outcomes of the **2007 G8 summit**.

1 February 2008

Examination of Witnesses

Witnesses: DR IAIN GILLESPIE, Head of Biotechnology Division, and DR BENEDICTE CALLAN, Directorate for Science Technology and Industry, OECD, examined.

Q1019 Chairman: Good morning, Dr Gillespie and Dr Callan. Can I first of all thank you very much for your time today. As you know, we are a Select Committee of the House of Lords looking at the question of intergovernmental organisations and contagious diseases. The main issue is the way the intergovernmental organisations work together and, of course, the non-governmental organisations that link in with them. Although to do that we obviously need to have some sort of knowledge about those diseases, the main purpose is the interaction between the non-governmental organisations, intergovernmental organisations and the value that the British Government gets out of the taxpayers' money that we put into it. Today's proceedings are being recorded, but you will have an opportunity to see that before it is published and to do any corrections of factual matters. If anything occurs to you after this session that you feel was missed out or needs to be elaborated, please feel free to contact us and tell us. Please feel free for either of you to chip in on the questions as we go along. We want to get as much information as possible, that is the purpose of this hearing, so do not feel inhibited in that respect. Perhaps it would be helpful if you could start by just telling us a little about your two respective roles.

Dr Gillespie: Certainly. I will begin. Good morning. Thank you very much indeed for making the time to take oral evidence from us. It is a pleasure to do this in English as well. From my side it is a strange accent in English and from Benedicte's side even a more different accent in English. As you know, the OECD is an economics organisation focused on economic development and driving globalisation and free trade. Perhaps I could say something very briefly about how the organisation approaches its work on health and infectious diseases. In general there are three areas that we focus on across the OECD. There is our own area, which is innovation. We come from the Directorate for Science Technology and Industry. We both sit in a division called the Biotechnology Division, which is perhaps something of a misnomer because essentially what this division does is try to look at how the life sciences can drive growth and transition structural change through innovation. Other parts of the organisation with a role are particularly our Development Assistance Committee which, as you know, is very focused on aid

architecture, our Development Centre which looks at issues such as sustainable financing for development and, not least, our Health Committee which focuses on health system performance and health systems efficiency. We also host a couple of important processes which are not formally part of the OECD but they address issues around global health. One is the Africa Partnership Forum, which exists to help OECD countries engage in the NEPAD Agenda, and the second is the Heiligendamm process support unit which is a dialogue between the G8 countries and the so-called O5 countries, which are Brazil, India, China, South Africa and—

Q1020 Chairman: Mexico.

Dr Gillespie: Mexico, thank you. The Heiligendamm process is looking at IP and innovation as one of its lines. That is where we sit in the organisation. As I say, we come from the innovation side.

Q1021 Chairman: Thank you very much indeed. Can I, then, perhaps start by asking you about this question which has come up a number of times about the co-ordination between the vertical and the horizontal as it has been referred to, which I am sure you are familiar with. The general view, which I know you take from the evidence I have seen of yours, is that a functioning health system in a country is absolutely vital. There is a lot of emphasis put on the vertical treatment of disease, particularly by some of the NGOs. We have had various arguments put to us saying that these two are not as contradictory as they seem and, in fact, they are more angles than horizontal or vertical. I would like your view on that, and I would like your view particularly on where Noordwijk, if I have pronounced that correctly, fits in on this. Could you start with that, both the horizontal and vertical—is that right, is it a sensible distinction, and how does it fit into the Noordwijk Agenda?

Dr Gillespie: Let me begin and I will probably pass for specific comments on Noordwijk to Benedicte. Thinking about horizontal and vertical approaches, that is a perfectly reasonable holistic device to look at the various initiatives that are going on but, for us, there is no right way. The right way is not horizontal, the right way is not vertical, it has to be a mixture of both. Where we saw intervention in global health

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starting was very much on the so-called vertical axis, although, in fact, it was only partly a vertical axis; what we saw was a focus on getting products for AIDS, TB and Malaria to patients. The focus was, if you like, at the far end of the vertical part of looking at individual diseases. There was very little work done on the upstream R&D for any of these diseases. That seems to us a very reasonable place to have begun but where we are now, of course, is that we are looking for horizontality across the entirety of the system, first in functioning healthcare systems in recipient countries where we have some limited progress still, secondly in horizontality and systems efficiency, systems complementarity, across the various vertical initiatives, and, thirdly, around the innovation system itself, where focus has tended in the last few years to be on elements of the system, in particular on developing molecules for particular diseases. We see a more systems-based approach across the entirety of the innovation cycle in R&D to be a long-term, much more efficient way. In short, vertical and horizontal are both required but, in our view, what is really required is a much more holistic and effective systems approach to the development of innovation and the delivery of these innovations in recipient countries. As to Noordwijk, I think that was very much the starting point for our thinking, but perhaps I can ask Benedicte to say a little bit more about the specifics.

Dr Callan: Just to add to what Iain was saying, in Noordwijk, although it was a joint collaboration between those parts of the OECD that focus on innovation and health issues and those parts of the OECD that focus on aid and development assistance, there was a strong focus on what can be done to change the innovation system as a whole in order to meet the needs of the developing world. There was a focus on two complementary sets of issues. One, what can we do to increase the innovation system efficiency as a whole, and really there was a tension with some groups saying, "We have got to focus in on a few diseases", and others saying that rather we need to look at the set of incentive mechanisms and infrastructure needs that can lead to a more efficient innovation system. The second issue that was dealt with in Noordwijk was how do you build capacity, both in OECD countries for R&D in this field and capacity in the developing world for R&D. You are right to say that the OECD focus has been very much more on this horizontal aspect, and I think that our colleagues in DCD would agree that their present focus is more on health system capacity. That said, as you put it earlier, we do not want to give the impression that the vertical programmes have no value, they are of great value, and in R&D it is going to be almost impossible to construct an innovations system where there is not a disease-by-disease based approach to the improvement of research and

research capacity in those areas. Our focus really was on the more general innovation system dysfunctions.

Q1022 Chairman: Thank you. Dr Gillespie, you mentioned that you have looked at requiring holistic outcome, and one can understand that is an ideal thing to aim at, but, given the disparities between various countries on their basic health systems, I suppose the brute question is: where do you start?

Dr Gillespie: I think the pragmatic answer to that is that you start from where you are now. We have a whole range of interventions in place, a whole range of initiatives. The majority of them, as you said, are vertical, but that does not mean that efforts cannot be made to make these vertical initiatives actually stack up together to reduce some of the transaction costs in delivering the outputs of these systems and try to make the systems support one another. As you are very well aware, this is part of the real goal of the Paris Declaration on Aid Effectiveness on the delivery side. Equally, one wants to provide interventions, whether it be drugs, vaccines or whatever, into a system which have some absorptive capacity for these materials. That requires a more horizontal approach on actually developing healthcare systems. One size, of course, will not fit all. What Country A requires will not be what Country B requires. Equally, within the innovation systems, as Benedicte has said, we see disease-specific innovation, but at least in the upstream parts of R&D we feel that there are some structural issues that can be developed which can improve the efficiency of innovation. You are right, there is no one-size-fits-all for each of the different countries which have very different health requirements, but thinking about uniting, if you like, bringing together, reinforcing, the synergies across these vertical systems, for us at least is a key element in this notion of horizontality.

Dr Callan: Can I just add to that. Our DAC colleagues would say one of the most important elements of any programme that is going to help build health systems and strengthen health system efficiency is going to be a line-up of country plans. They would push very strongly for ownership and alignment by recipient countries of any programme that is designed to help improve their health systems. That is one of the areas where their position would be that you really have to start with the recipient countries and see what they feel their own health system needs are.

Chairman: Thank you. This leads us on quite neatly to co-ordination, which Lord Howarth will ask about.

Q1023 Lord Howarth of Newport: Could I ask you about governance, who does what in this already very complex scene, and what the value is that OECD in particular adds in a scene where there are already a

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great many intergovernmental organisations and groupings of one sort or another, a very crowded architecture? In your submission you said: “the OECD is well-placed to play a role in taking action forward . . .” with reference to improving innovation and access to medicines, “not least since it is able to draw together the key players (governmental, non-governmental, industry, researchers and civil society) in developing innovation systems and in delivering innovation”. Two questions arise from that. Do you have the executive power at OECD to drive this process internationally? And would it not be the responsibility of the World Health Organisation? Is that because perhaps it simply has not been very good at it or because it is not an appropriate role for it?

Dr Gillespie: Let me start off by saying there can be no doubt as far as any of the OECD countries are concerned that the intergovernmental organisation, that leads in these areas, is the World Health Organisation. The issue of innovation in public health is under discussion now, as we sit here, in the World Health Assembly in Geneva. We certainly hope, and I think I can speak not just for the two of us but for all of our colleagues in the OECD, indeed for all of our member countries, that there will be an effective resolution coming out of the World Health Assembly to strengthen WHO’s mandate and capacity in looking at innovation for global health. Let me say that upfront. Secondly, you asked the question: does the OECD have executive power. The work programme and the priorities of the OECD are set by our Council, the 30 member countries, through their executive committee. At the moment they are paused and they have paused following our Noordwijk meeting waiting for the World Health Assembly to take a decision on where WHO should be going on the innovation and public health agenda. It is not for me to say what they will do next, it is for them to decide what the OECD may do next, but it is very clear that whatever the OECD does next on the innovation and global health agenda that will be aimed to complement and support what WHO take forward coming out of the strategy that we are hoping is adopted at the World Health Assembly. This is a role that we see the organisation of the OECD increasingly looking to play, if you like, providing some of the analytical capability to supplement and support work that is going on across other parts of the IGO architecture. As far as the point about the OECD’s convening powers, there are some aspects around innovation that the OECD currently has a longer track record on and more substantive capacity at present than the WHO has, and that would be something I would expect our interlocutors in the WHO to advocate as much as we do. What we see ourselves doing next, if the OECD Council decides that this is appropriate, would be to work with the WHO, partly to help them build their

capacity but, frankly, more simply to bring some of the analysis that we have been doing around innovation efficiency in the delivery of health technology into their debate. This is something that we have formulated in a Memorandum of Understanding, a formal document between WHO and the OECD. We hope that we will continue to operate that partnership, we will strengthen it in the field of innovation and health over the coming years.

Q1024 Chairman: Dr Callan?

Dr Callan: I would just jump in and echo some of the points, but perhaps give a little bit more detail in the areas where the OECD has capacity that the WHO may not have worked quite so much in. First of all, as you mentioned, we have a whole division that does mapping, measuring and analysis of innovation systems, how they function, what are the policy tools to spur innovation, what is the substitutability of these different policy levers, whether they are complementary. There is a whole range of work that the OECD has done that is of relevance to this field of infectious diseases and has not been applied to infectious diseases but could easily be done if that was something that our member countries felt was necessary. In the DAC, the issue of how you align and make more effective overseas development systems is a big issue. They are taking the issue of global health as one of their primary areas of concern. The measurement and approved effectiveness of health systems is something that the community on health works on in collaboration with the WHO and they share both their methodologies and the data that they generate. For some countries this is a very important area; for others, it is more controversial. On this issue of policy effectiveness and policy coherence, the OECD has worked very strongly on how you create coherence between different policy fields in finance, health, development, science and technology, and how you create a larger vision of what your overarching policy goals are. Those are specific areas where the OECD has experience and a secretariat that could apply its expertise to the issue of global health should countries feel that was something that was absolutely necessary. More specifically, and this gets back to the Noordwijk Medicines Agenda, what was suggested in very politically nuanced terms, because it was a text that was negotiated amongst a large group of different individuals and organisations, was the OECD has work on open innovation models, collaborative mechanisms for IP. Those are things we have been working on for our own countries and looking at their applicability: when they are useful and why they are useful. This is something that has been taken up by the WHO as something that is important and should be pushed forward. We have experience in why these models work, why they often

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are hard to put in place, and that is something the two organisations need to work together to push forward. Innovative financing mechanisms for R&D, as I mentioned earlier, is something that the WHO is interested in and I think that is what they are going to be pushing forward as the first elements of work following this WHO resolution if my understanding is correct. Again, there is an awful lot of work on policy levers for achieving certain scientific goals or industrial goals. The OECD has certain capacity where we could collaborate more closely. I would perhaps mention as a corollary to that these alternative mechanisms to improve innovations that we have been working on. There are very specific things where there is possibility for more collaborative work but there are also some very overarching large general areas where the OECD perhaps has a history of work that might be useful.

Q1025 Lord Howarth of Newport: So the answer to the question as to what value OECD is adding in this field of international health is that you are analysing and reporting on such issues as the failure to innovate and on coherence and collaboration. Is anybody else doing that kind of work?

Dr Gillespie: On the work looking at collaboration and development of research networks involving individuals from the bottom up, at the international level I think it is fair to say that the OECD maintains, if you like, a substantial lead. This is an area which WHO, through their Intergovernmental Working Group on Public Health, Innovation and IPs, has said is important, but so far they are only beginning to dip their toes in the water. This focus on how you drive innovation efficiency, whether it be in health or other areas, is something which the OECD has a substantial lead in. In fact, this is the core of our new OECD Innovation Strategy launched by our ministers last year that we report back to ministers in 2010 on.

Q1026 Lord Howarth of Newport: So what is the bridge from analysis to action? You report?

Dr Gillespie: Yes.

Q1027 Lord Howarth of Newport: How are the implications of your reports taken forward? Is there some mechanism that exists or that you would desire should exist?

Dr Gillespie: It depends very much on the specific output that we are looking for. Like any other organisation we have a panoply of tools at our disposal. Sometimes what we will do is analysis and policy reporting where essentially what we are looking for are the actors who are involved in the analysis and reporting. I should just say in parenthesis here that the actors involved are from member countries, member country governments,

plus from the NGOs, from a number of non-member country governments and also from the innovative industry. The process of analysis and development of reports which are agreed by the actors has an impact on diffusion. What we are essentially trying to do is move some novel means of thinking. There is an adage in the OECD that says you can get anything done in the OECD as long as someone else takes the credit for it!

Q1028 Lord Howarth of Newport: Should that be the WHO? Is the WHO the lead organisation internationally for carrying forward the implications of the research that you carry out?

Dr Gillespie: It is one of the lead organisations. First of all, I should say there is analysis, but we also have a number of soft law mechanisms in place, governance frameworks, that allow or encourage our governments and the private sector to act in certain ways. Is the WHO the principal customer of analysis in this area? I would say it is one. The WHO has some executive power. Some of the recommendations are aimed very much at member country governments themselves. Some are aimed at the practitioner at the ground level and that practitioner may be a researcher in a university, it may be a pharmaceutical company, a biotech company or a product development partnership. The strength of the analysis is the fact that we try to internalise in that analysis all of the different actors and their perspectives, and it is the bottom-up approach to development of policy directions that we think is a critical strength of the approach that we bring to bear.

Q1029 Baroness Hooper: I suppose that the WHO has the lead in the sense that it is a truly global organisation in membership terms. I was just wondering whether the fact that the OECD is an expanding organisation has any impact on your work. I know Brazil is a recent new member with a very important and large economy and, of course, you have a new boss.

Dr Gillespie: Secretary General.

Q1030 Baroness Hooper: From Mexico. Does that help you with your work in terms of the follow-up that Lord Howarth has been talking about? I imagine it does. The second thing, if I may, is that I am a member of the Parliamentary Assembly of the Council of Europe and we do an annual report on the OECD which is coming up at the next session in June and we always try to focus on some health issues and educational issues as well as the general economic background. Is that helpful to you? Maybe we could concentrate more in terms of follow-up on asking questions about what is happening once the analysis has been done and the follow-up is due to take place.

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Dr Gillespie: I think they are both very helpful questions, if I may say so. We do, indeed, have a relatively new Secretary-General, Mr Angel Gurría, from Mexico. One of the core missions that he was elected upon was to make the OECD a more relevant organisation as a hub of globalisation looking much more outwards than perhaps we have hitherto. We have entered into discussions with five member countries to join the organisation and a further five so-called “enhanced engagement” countries, looking to build them into the work of the organisation without becoming full members. These include countries such as Brazil, China, India, Russia, Indonesia and a number of other key countries. That outward-looking face of the OECD must be helpful in the interaction with the follow-up to these kinds of global initiatives. Having said that, for some time we have had quite a lot of activity with non-member countries. If we look at the OECD in this area, our members still account for about 65 per cent of GDP but 90 per cent of global R&D. One of the real motivating factors for trying to play a role in this issue around innovation for global health is that most of the innovation, most of the R&D and most of the spend is in the OECD countries; so, if you like, we have a special responsibility for driving innovation to meet the needs of the majority of the world. That was very much the basis for our debate in Noordwijk. If you have a chance to look at the agenda, you will see there was quite a range of very senior players from non-member countries there as well. As far as the Council of Europe is concerned, by happenstance tomorrow we have a discussion with the Education and Science Committee in preparation for the Parliamentary Assembly’s debate. One of the things that we will be raising in that discussion will be our work on infectious diseases. It will also cover issues like genetics and genomics, GMOs, human data banks, et cetera. As far as how useful that debate has been, I think we wait to see. There is a real opportunity there for us to have more co-ordinated effort between the two organisations. I am sure that my Secretary-General will be extremely positive indeed in his engagement with the Parliamentary Assembly.

Q1031 Lord Desai: You have already mentioned the Paris Declaration and the five criteria that you are using. How do you assess donor countries, whether they are adhering to these five criteria? Secondly, does this initiative contribute to get donors, people like PEPFAR and so on, more into line with the way you think things ought to be?

Dr Gillespie: Perhaps I will begin and pass to Benedicte for more detail. How do we assess? We run surveys every couple of years—the last survey was in 2006—of the impact of the Paris Declaration. The report, which is in two volumes and quite lengthy,

was published last year. In very short terms, there is some progress but much less than we would hope to see.

Q1032 Lord Desai: Do you construct an index of effectiveness from the five indicators? You have got five indicators and you construct an overall index, do you?

Dr Gillespie: There are five factors and a number of indicators. Although the factors and the indicators are cross-sectoral, we also look at the number of sectors, so-called tracer sectors, and one of the tracer sectors that we are now looking at is the health sector. That will be one that is focused on particularly at the third High Level Forum in Accra in September. We have data from over 100 donors and around 60 recipient countries. Essentially we do many country reviews of each of the recipient countries, looking at the five factors and the 12 indicators, and publish data which looks across and between both donor countries and organisations and the recipient countries. As I say, in terms of the message from the last survey, a lot more needs to be done. Benedicte can perhaps pick up on some of the key messages and I can turn to the right page in my brief while she speaks. One of the focuses of the Accra High Level Forum will be about implementation of the Paris Declaration. In principle, it provides a basis for much closer integration and alignment of activities, but so far we would say on progress in some areas in all the 60 recipient countries there is progress across the donor community but a lot more needs to be done.

Dr Callan: One of the things that is different about the Paris Declaration is that it is endorsed by a much larger group of countries, there was broad consultation on agreeing what its goals ought to be and it set targets for 2010. There are three rounds of surveys, one that was done in 2006, one that is being done right now, 2008, for which they are beginning to get preliminary data, and there is one that will be done in 2011 to see whether or not the targets were met. As Iain said, unfortunately the results so far for 2008 show very limited progress towards some of the indicators about alignment of aid. One thing to note is that the survey does not track progress in any one particular sector, so there is not data that is particular to the health sector, which is something that I am sure this group in particular would be interested in seeing. What is important to add to this is that the DAC participates in discussions with the multilateral donors, which is the World Bank but also the philanthropists, in discussing how one is going to monitor progress towards its various goals, including its health outcome goals. There is an ongoing discussion. I know last year they met two or three times to discuss using health as a tracer sector and what indicators they would be looking towards developing and how they would align their own

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policies. There is an attempt to try to bring in other groups.

Q1033 Lord Desai: They have accepted your indicator methodology, have they? Are they happy with the methodology?

Dr Callan: I am sorry, I would not be able to speak to that level of detail. I understand that they are looking towards developing a common methodology, but I could not say whether they have accepted or have not when there are still discussions.

Q1034 Chairman: Before I move on to intellectual property rights and innovation, can I just ask you this in relation to the answers you have given so far—and it touches on other views we have heard over the preceding months? A picture is coming out, of a network of organisations, NGOs and intergovernmental organisations and so on, and initially we were perhaps thinking it is very crowded and there are too many organisations. But the picture that is emerging is a need to get a clearer view of how they inter-relate with each other, how the networks evolve and where the WHO sits in relation to all of that. There is an element of is the WHO the conductor of an orchestra trying to pull out which bits should be playing with each other and which bits should not. Does that sound sensible to you? I have been influenced in my thinking to some extent by Professor Fidler's evidence to us the other week, which emphasised the networks analogy.

Dr Gillespie: It is an excellent analogy, it is one that we have used ourselves and tried to follow-up on after Noordwijk. The challenge is the network exists but, if you like, the route through the maze of interactions in the network is poorly articulated and poorly understood, not least by those actors who actually form the network. As to whether there is one conductor or whether there are a number of bandleaders trying to follow a particular score, that is a question that remains open. Certainly the functionality of that network and the efficiency of that network, for us, is the focus of the kind of thinking we in the OECD have been trying to do, not just in this area but in others too.

Q1035 Chairman: It is very hard to decide whether or not the networks are working to best effect and maximising the use of the finances that are given to them, whether by the UK Government or others, unless you have someone or some organisation taking a bit of an overall view. I suppose one tends to jump to the conclusion that that ought to be the WHO. Is that right or not?

Dr Gillespie: There are a couple of issues here if we can just slightly unbundle them. The first is the way that the networks align with themselves, so the bottom-up networking, the bottom-up system. There

is a lot more that could be done there and there is a great demand from the individual actors, whether they be PDPs or whatever, to develop a better system. That need not necessarily be a top-down issue imposed on them. What we need is space for them to come together to develop these kinds of networks. The second point is one of assessments of what works and what does not work. It is certainly very clear to us in all of those that we have interacted with that we need to be looking at a mix of different interventions to deliver products for Disease X in Country Y. What that mix best is in each circumstance is something which has received scant, if any, attention so far. Which of the interventions actually make and give best value for money also, I am sorry to say, has received scant, if any, attention so far. In mitigation, this is partly because so much of this is so very new. As to whether WHO should be the orchestrator of this, if there were to be one orchestrator it would have to be WHO, but I am not sure whether the one conductor, one orchestrator model is the right one or not. I am not saying it is not, I simply do not know.

Q1036 Chairman: Do you want to add to that?

Dr Callan: I like that analogy very much and it is a hugely complex and very difficult field. We are struggling with the question of where the gaps are in the network, where do they fail and what do they fail to do. There are these multiple communities of practice. There is an incredible—and in large part this is thanks to the Bill and Melinda Gates Foundation—renaissance of ideas and groups that are trying to fill in various different gaps. Some of it is gaps in funding, some of it is gaps in information flows. The issue that we are struggling with is that, from a top-down policy level, we can identify certain things, but what really needs to happen is for the researchers, the participants in public-private partnerships, the doctors, to identify for themselves where it is that the network is failing to make an easy flow from the laboratory to the patient's bedside of the types of products that are necessary to reach some of the health outcomes that everybody is hoping to achieve. It is that identification of the gaps that is necessary. On top of which, in certain cases we are jumping quickly to conclusions about what is needed, what are some of the solutions, and for the most part I do not think we know what the solutions are.

Dr Gillespie: May I just add one thing. We have a group of new tools coming out now, policy tools if you like, that we think from what we can see so far could ease some of these networking problems. The kinds of tools I am speaking about are means to share intellectual property rights around patent pools or patent clearing houses, means to ease access to ideas, to molecules that are partly developed through what we are beginning to see termed as knowledge markets and, also, much more open innovation systems where

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innovators, even some of the very, very large companies still following a blockbuster model, are looking much more at going out and exchanging ideas and seeing that there is value in knowledge transfer across networks which is above and beyond the proprietary value of the knowledge that they hold. An application of these kinds of systems into the global network that we see here in the global health field could help reduce some of these transaction costs and improve their knowledge flows. We think this because this is what the actors who are trying to achieve knowledge say they are looking to have developed.

Chairman: Thank you very much. That moves on quite neatly to intellectual property rights and innovation with Lord Avebury.

Q1037 Lord Avebury: It certainly does lead in to what I was going to ask, which is about the protection and use of intellectual property rights, which you say is necessary but not sufficient for stimulating innovation for neglected and emerging infectious diseases. In your paper you discuss the complementary reward systems which have an important role in incentivising R&D for these diseases, but then you go on to say that further robust analyses are necessary to decide how these mechanisms can best contribute. You have just been talking about one or two of them. Is this a matter on which you are waiting for advice from the World Health Assembly? You said in answer to a question a few minutes ago that the issue of innovation was under discussion there. Have they got these complementary reward systems on the agenda? Do you expect to receive further advice on the subject after that meeting has been concluded?

Dr Gillespie: Perhaps I could begin by addressing your specific point about WHO and the World Health Assembly and then ask Benedicte to say something more about the specifics of some of the measures we are talking about. What we have seen so far, as an interested party in the process leading up to the World Health Assembly, is a draft strategy which is up for debate now. That draft strategy, if it is adopted, will give us, if you like, the architecture of what the WHO sees as being their priorities for the foreseeable period, at least until the next World Health Assembly a year hence. What we are waiting for is to see which areas of focus WHO will advance on, which areas of focus WHO will look to other organisations to work upon, ourselves included perhaps, and what they will not regard as a priority for them but might be a priority for us in our own work. Essentially, we are looking for complementarity with what comes out of the World Health Assembly. So far, in terms of what we have seen the proposed strategy—and it will doubtless change over the course of this week—has some focus

on some of the alternative systems, particularly on so-called prizes for delivery of new molecules. So far it has had a small amount of attention paid to looking at these collaborative systems for interchange of intellectual property rights. That latter area of work, the so-called collaborative mechanisms, pools, clearing houses, et cetera, is an area of work where the OECD already has a substantial head of steam looking at these mechanisms in innovation generally, and global health could be one of them. As to the variety of specific “push” and “pull” mechanisms, the complementary systems, perhaps Benedicte could say a little bit about that.

Dr Callan: Your question is an interesting one in that it asks, firstly, what are these different mechanisms and whether we are waiting for a signal from the WHO as to whether we are going to do work on them. I would first say that the number of mechanisms that have been proposed to try to accelerate the development and delivery of new vaccines or therapies for diseases of the developing world are not dissimilar from mechanisms being used to develop drugs more generally or that are used to try to reach other public policy goals in other technology areas. The way that these are usually distinguished is there is a category of mechanisms that are “push” mechanisms, which are essentially feeding the innovation pipeline providing subsidies to R&D early on, or pull mechanisms that guarantee a market, guarantee that there is an endpoint.

Q1038 Lord Avebury: Like the Advance Market Commitment?

Dr Callan: Exactly, like the Advance Market Commitment, like the prizes, but also things like patent extensions or patent buy-outs which essentially guarantee that there will be a larger financial prize at the end if the innovator decides to invest a certain amount of its R&D into developing new products. These “push” mechanisms, whether it is funding for PDPs, whether it is increased funding for infectious diseases, as the US announced in February of this year, or whether it is pharmaceutical companies that are saying, “We are going to invest more in these particular areas”, they are things that the OECD has studied. We have looked at tax credits and what their impact is on firm behaviour. We have looked at subsidies and what their impact is on firm behaviour, whether they are substitutes or complements. These are not things that we are not going to work on, we are working on them in a number of different areas. The question is, do we look particularly at what their impact is going to be on the behaviour of firms who would be willing to invest in infectious diseases. I think that we should be. There is an awful lot of interest in what incentivises firms’ behaviour and the OECD is in a good position because it has a good rapport with the industrial

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sector as a whole and is in constant dialogue with them about how policies actually impact their behaviour. We did some background work on “pull” mechanisms, such as the Advance Market Commitments and IFF. We have looked at what these mechanisms are, what their strengths and weaknesses are, but we have not got to the point that goes beyond what Lord Howarth was saying, which is analysis. We have not got to the point where we have had a discussion amongst countries or communities of users about what kind of policy recommendations or guidelines the OECD might want to put forward. That is the thing that the OECD may be waiting for. We are going to continue working on policy incentives for R&D and what works and what does not work in a variety of different fields. We will certainly continue working on the issues that Iain has talked about, which is all the issues about how you create a smoother knowledge flow of intellectual property, but the question of whether we particularly look at how this is going to change behaviour in one very particular field is something our countries have not come to any decision on.

Q1039 Lord Avebury: Can I ask, do you think of any particular lessons to be learned from the one really successful initiative, which is Pneumo-ADIP, in the case of the Advance Market Commitment? Is that capable of generalisation or is it a one-off that applies simply to pneumococcal disease? What similar models can you point to that are developed at a theoretical stage which remain to be launched in the case of specific products?

Dr Gillespie: It is a good question and I wish I had a good answer to it. Unfortunately, we do not, we simply do not know.

Q1040 Lord Avebury: This is where the robust analysis comes in?

Dr Gillespie: This is where the robust analysis comes in, exactly.

Q1041 Lord Avebury: Who is going to undertake that then?

Dr Gillespie: I do not know who will undertake the analysis, but certainly in our view if one comes back to the point raised by the Chairman of asking what works and what does not, where does the value for money lie, at the moment, as far as we can see, we do not have in place globally, internationally, a system for developing robust analysis of the different interventions and asking what works where. Who should do such analysis is for our governments to decide. I am not suggesting it should be us.

Q1042 Lord Avebury: But in your paper you say this is necessary, so why should the OECD not undertake it?

Dr Callan: I think there is some analysis of these different mechanisms. It is done for the most part by academic think-tanks and researchers, so there are people who are pro-AMCs, there are people who are against AMCs, people who will say that they are all very well and good when you have a bunch of leads already well-advanced and some will say it is going to be completely useless when you do not know what kind of vaccine you want to develop—it will be completely useless for AIDS, for example. What we do not have, and I think this is where the more robust analysis comes in, is any sense of, if governments are going to be funding these, what are the pros and cons of different options that they have before them. They have Advance Market Commitments before them, they have ideas of patent extensions, they have ideas of patent buy-outs, they have these ideas of the Global Fund, which is a “push” mechanism really, just to increase the amount of funding that goes into R&D more generally. There are pros and cons to these. They do address problems at different points in the innovation cycle. They are more or less systemic, and what I mean by “systemic” is that one of the major problems with AMCs is that one would have to create a series of AMCs for a series of different diseases and they would have to be done over time.

Q1043 Lord Avebury: Yes.

Dr Callan: There is an analysis of what the pros and cons of these different mechanisms are, but there is not really a good analysis of what choices governments themselves have and what some of the pros and cons of investing in these different mechanisms are going to be and where the gaps are going to be if we do go down the route of AMCs. Does that mean that we are foregoing research into riskier research ventures whose outcome is less well-known. That is the place where there is definitely a need for a better sense of what options are available to governments. There is a certain amount of academic literature that exists on these different mechanisms, they all come out of academia as ideas, but now the question is who is going to fund them and what is the best way for governments to spend their limited resources in this area.

Q1044 Lord Desai: I am going to slightly reverse the order of my question because what we are discussing about the knowledge base for deciding what is and what is not effective is very important. One of the things you said is that the Noordwijk Agenda identifies the need for further action on “facilitating the development . . . of a sustainable architecture for the sharing and exchange of knowledge, data and research tools necessary for the discovery of

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medicines..” What are the problems here? Are the problems technical data sharing or practical, technical, legal, political? We know in the Indonesian case they refused to do any virus sharing. Is that the sort of problem you face in constructing a proper knowledge base?

Dr Gillespie: You ask what are the problems and I would say that all of the issues you have listed are problems. I would probably add one to them, which is financial. If one steps back from this and thinks in general terms of what is going wrong here, I think our experience from Indonesia and from a number of other countries, often the subject of looking at the sharing of information is who are the winners and who are the losers in sharing of such information. It seems to us it is the practitioners, those who are generating and using information, who are the ones who are best placed to reach a judgment on what they win and what they lose, what do they gain by networking. A top-down approach of saying, “You will network, you will share”, is all well and good provided there is also the bottom-up approach of, “and here is what you will benefit from it. Here are some of the checks and balances in place. Here is the financing for delivery”. At the moment we see a desire to network, a desire to look at knowledge and information exchange. We see a number of models in other fields that seem to be interesting, seem to be being developed by practitioners and maybe working, but understanding the transaction and costing them is complex. Essentially, in many cases we are not seeing these two initiatives, the bottom-up and the top-down, come together. If I was to say there was one fundamental issue over the Indonesian case, I would say it was perhaps the lack of mutual understanding of the bottom-up and the top-down.

Q1045 Lord Desai: Is that because the people do not want to share information because there are economic consequences of revealing, so it is sort of a financial problem, not lack of finance but fear of loss of business?

Dr Gillespie: I think that is one of the issues. One of the issues is the notion of the inherent value of intellectual assets, whether it be a genome sequence or know-how. If you share that information and share that information openly, will you get a return on that investment? I was saying what are the checks and balances that allow you some recourse to having a return on the intellectual asset that you have put in. Here, the patent pool model is a rather interesting one, where the sharing of intellectual assets, in this case patents, allows anyone essentially to negotiate access to that body of information and there is a return, whether it is a monetary return or non-monetary return, and it is a clear and understood return to each individual who has put an asset into

the pool. That notion, that understanding and buy-in—that there is a return on that investment to the individual putting into the pool in that model—is the key critical factor here.

Q1046 Lord Desai: The Agenda calls for “the use of existing flexibilities of multilateral agreements to foster innovation and access”. There the question arises whether the flexibility afforded by TRIPS is being undermined by bilateral FTAs. Is there a lot of co-operation between you and WHO, WTO, WIPO and organisations like that?

Dr Gillespie: As an organisation, the approach that the OECD has taken on multilateral trade agreements is that it is for WTO and WIPO to negotiate them to make them work. Our focus is, firstly, on what are the economic impacts of these regimes and, secondly, as far as patents are concerned, it is around downstream licensing behaviour to try and encourage access and shift knowledge around. So it is to look at the patent system as a sustainable regime which has two purposes: one is rewarding investment; the other is the dissemination of knowledge. Our focus is more on the dissemination of knowledge in this field. As far as whether the individual trade agreements have stymied flexibilities or not, that is not something we have focused on or done any analysis of, so I could not really shed any light on that. Instead, what we have focused on is, as I say, the downstream behaviour; you have a patent or you have a trademark, how do you try and encourage access to that so you get a social benefit from that system.

Q1047 Lord Desai: Is there not some evidence that some of the bilateral FTAs signed by the US are designed to avoid the consequences of multilateral TRIPS Agreements? Have you come across that or is that just a suspicion but not a reality?

Dr Gillespie: We have certainly heard the points put forward and seen some academic analysis of this, but as an organisation we have not focused on that ourselves.

Q1048 Baroness Hooper: A switch of subject to the “brain drain”. I was shocked to learn that the number of foreign-trained doctors has tripled in some OECD countries over the last few decades, and I suspect there are even more nurses and other health workers involved in this. I was even more shocked that this represented something like 30 per cent of some African countries’ workforce. This is particularly so where there has been active recruitment by OECD countries, and indeed the UK is one of the culprits and now seems to have the bizarre situation that, having actively recruited, we do not have enough jobs for our own home grown doctors. I wonder if there is, in fact, a reverse “brain drain” and whether the

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OECD is monitoring these trends. My main question is about the Global Code of Practice for health worker migration which is being developed. I wonder how effective you think this might be and also, again, back to the question of who should take the lead.

Dr Gillespie: Well, I think in our view the efforts to develop a Global Code of Practice are novel. It seems to us to be a sensible way to develop in this area, but the problem, of course, is that a Code of Practice is exactly that, it is a Code of Practice; so the trick, if you like, is to convince entities to abide by that Code of Practice, particularly those who are going out and recruiting from Africa and other countries. That is something that I think will make or break the effectiveness of this Code of Practice. In itself, it is a palliative, if you like, for the problem, and the problem, as we see this, is predominantly one that comes back to this horizontal question that, if we invest as a global community in the development of the health systems and create job opportunities for home-grown doctors in all of the countries of the world, not just the country that you and I know best, then we think that is the only sustainable long-term solution to overcome this “brain drain”, which is probably going mainly in one direction at the moment. As far as the circulation of medical professionals around the OECD countries is concerned, we have a couple of metrics that look at that movement in the OECD countries, between them and outside the OECD countries. At this point, unless Benedicte contradicts me, I do not think we are in a position where we can say there is a negative “brain drain”, for example, of UK-trained medical professionals out of the OECD region. The long-term solution for us is about the capacity of local health systems to employ health professionals. In the short-term, a Code of Practice, if it is adhered to, perhaps particularly by private sector recruiters, seems to us to be a reasonable stopgap approach to addressing that.

Q1049 Chairman: I was told a short while ago, and I do not know how correct this is, that the Philippines has a deliberate policy of training excess nurses on the grounds that many of them will go overseas, but they benefit from them coming back with greater experience and training, and it also benefits them in terms of money sent home, which I understand in the case of the Philippines is very large indeed. Have you heard of this being true in other situations or is it something unique to the Philippines?

Dr Gillespie: We have no information on that on nurses, my Lord Chairman.

Lord Desai: Can I add to this, being an example of “brain drain”, or “drain” because I left my brain outside!

Chairman: Or a split brain, you go back and forth!

Q1050 Lord Desai: Is it not likely that, if people knew they could not go abroad, they would not enter the medical profession or train to be nurses? If I was a Nigerian woman and knew I could not go abroad, what is the incentive to go into nursing? There are pluses and minuses with this.

Dr Gillespie: I hope that is a very stark view.

Q1051 Lord Desai: I am a professional economist, I take the “brain drain” seriously.

Dr Gillespie: I think that, when we have to try and internalise the motivation for individuals going into the health profession, then I am sure they are not just monetary and about going abroad.

Baroness Hooper: It is a vocation.

Q1052 Lord Desai: You could kill the golden goose.

Dr Gillespie: If I may respond, because an economist asking an economics question of the OECD we must respond. I think I would go back to the long-term solution still being on a viable job market for professionals locally. If such a viable job market exists, then there is no need to go abroad, but that need not necessarily mean there is no choice to go abroad. What we are seeing is a driver for professionals to go abroad and can one address that from the delivery of healthcare, perverse incentives to move.

Dr Callan: I would add two comments, my Lord Chairman, if I may. One is that our DELSA colleagues did say that one of the issues one would have to think about if we were to develop a code would be that denial of employment due to country of origin would be illegal in most of the OECD countries, so it would be difficult to imagine how to put that into place; it would not be a Code of Conduct very much targeted at practice of the health sector. The second issue, although we do not have the brief to hand, is that we certainly do track remittances and, while we do not have any information on nurses in the Philippines, there is data in the OECD on remittances and the importance of remittances to developing countries, and we are following this issue very closely. It is of great importance because of the contribution to the finances of certain countries, the Philippines being perhaps one of the most important examples of remittances being a large proportion of their national budget.

Q1053 Lord Avebury: I just wondered whether in the development of the Code of Practice regard is being had to the progressive tightening up of regulations regarding highly skilled migrants in OECD countries as, for example, in our Highly Skilled Migrants Programme in the UK which I believe is being paralleled in other OECD countries. Would the Code of Practice automatically allow the existing

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methodologies of picking highly skilled migrants, including health workers of course? Or would the Code of Practice be tighter so that our own existing regulations would have to be changed?

Dr Gillespie: I do not think we are sufficiently well-briefed on what the Code of Practice is to answer that, Lord Avebury, but we can certainly write to you in response with a view on that after this session.

Baroness Hooper: Whilst I appreciate that Cuba is not a member of the OECD, or of many other things, Cuba is a very interesting example in terms of medicine, because they produce a number of doctors who do actively work in the region, in Africa and other places, and they are not doing it for financial reward or export in any way, and yet the recruitment of doctors in Cuba seems to be as high as ever. Do you look at this example from time to time?

Chairman: We are probably going slightly outside your remit now, but it is quite interesting.

Lord Desai: Even that of the Committee!

Q1054 Chairman: Yes.

Dr Gillespie: I think that, from the perspective of trained science professionals, one can look at a range of different motivations for movement, a range of different policies in place to encourage the kind of behaviour that you have articulated from the Philippines to actually see “brain circulation” rather than “brain drain” one way or another as really adding to the value of knowledge. We do not have any specific experience of Cuba, that is a slightly problematic country for OECD generally.

Q1055 Baroness Hooper: I was thinking more in terms of the Code of Practice.

Dr Gillespie: I am afraid, my Lord Chairman, this is something that we would not be briefed on.

Chairman: It is not a critical issue actually and I probably should not have led you astray with the Philippines example, although it interested me as to why they suddenly seem to have embarked on this. Can we move on to the issue of bioterrorism.

Q1056 Baroness Falkner of Margravine: It is nice to see an alumnus from the same Masters programme. I always wondered where people would end up. We were together in that London centre, were we not? It is very nice to see you again. Talking about Codes of Practice, I notice that you have quite impressive initiatives, particularly of late, in terms of dealing with BRCs and bioterrorism in particular, and last year the Best Practice Guidelines on Biosecurity for BRCs and so on. Several people we have spoken to among our witnesses have told us that deliberately initiated disease and naturally occurring disease are similar both in the way that they impact on populations as well as the public health response that

we need to cope with them. What is your view on that?

Dr Gillespie: I think that, in terms of impact on populations and response, we concur. The differences, which is where we have focused, have been around access to dangerous pathogens in the first place and mode of introduction, particularly the fact that introduction might be at multiple sites, it may be co-ordinated. So the response to a very deliberate introduction at multiple sites at a relatively high dose of an infectious agent that could impact a number of populations simultaneously could become overwhelming compared to an emerging infectious disease from the out-of-Africa or out-of-China model. On the specifics of the progress of disease, the specifics of how public health authorities would have to respond to the outbreak, we see clear similarities.

Q1057 Baroness Falkner of Margravine: In terms of your guidelines, particularly the part that focuses on robust risk management measures, the guidelines are effectively only guidelines. What is your assessment of the extent to which facilities, resource centres, are going out and adopting that best practice and being vigilant in terms of doing their risk assessment and sticking to it? I say that particularly because in the UK we have these spontaneous outbreaks.

Dr Gillespie: The UK, of course, was one of the key players in articulating guidelines in the first place. We have done some work so far looking at implementation and impact, and we are in the process of doing more. What we have done so far is that we have a number of countries that at the policy level, at least, are putting these in place. The Russians are moving to do this. The Chinese have published the guidelines in Chinese and seem to be adopting them. The French and the Germans have adopted them. The French have adopted them in law and the Italians in law. The Canadians are moving forward slowly. The Brazilians have adopted them. I have mentioned a lot of non-OECD countries, but what we have done so far is picked up on those countries that have worked with us and have reported to us, “This is what we are doing”. We have not yet gone out and systematically collected data but that is something we will be doing over the next few months because we are going into this process of enlargement of the OECD. I am not very good at listing countries, I apologise. We have Russia, Slovenia, Estonia, Chile and Israel at the moment where we have entered negotiations on enlargement. One of the things that we must do is make an assessment of the extent to which these countries have enacted these particular guidelines prior to the Council taking a view on whether these countries should join the OECD. First, to be able to do that we must also do the same analysis of the extent to which OECD countries have adopted these guidelines. By around the end of this

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year we should have a much better picture of the impact of the guidelines at least at the policy level.

Q1058 Baroness Falkner of Margravine: Coming back to those member countries, the existing ones that have adopted them, in terms of what you said in answer to the earlier question that the speed of infection would be much faster than it would be with naturally occurring, so the time to act in terms of a civil contingency plan would be rather shorter. Would most of your members have in place civil contingency plans to deal with that?

Dr Gillespie: The first thing to say is that the guidelines are very focused on access. They are about trying to control access by criminals to materials. They do not focus on response, on triggers of response. Having said that, I would say that the extent to which our member countries have engaged in looking at programmes to respond extremely quickly and effectively to a terrorist introduction of a dangerous pathogen are very variable indeed. We have some countries which have taken this extremely seriously and have strong capacities in place from civil defence, interaction with the police force and health authorities, in the stockpiling of vaccines, antivirals, antimicrobials. We have other countries which have done much less. It is very, very difficult to say.

Q1059 Lord Howarth of Newport: My question is on another aspect of OECD's work, if I may. I would think that the OECD is particularly well-placed to assess the relative contributions of policies, on the one hand, which are policies of specific medical intervention, the provision of vaccines, medicines and qualified medical personnel, that contribution to improving health across the globe, and, on the other hand, policies that are addressed at the conditions in which ill-health incubates, sanitation, poverty, education. Do you work to study the relative contributions of medical or social interventions? Do you have views on that?

Dr Gillespie: I think we come at this from two angles. First, Benedicte was speaking about coherence earlier. We look at coherence within policies, between policies internationally in the donor countries and in the provider countries. There is a policy coherence perspective to different interventions, whether they be at the technical level or the capacity level, being integrated well. At the moment there is not a huge focus in the organisation on any one sector of this coherence although, as we said, health is being looked at as a tracer sector for aid effectiveness. In principle, the OECD could do more looking at coherence amongst these kinds of policies, but at the moment we are probably not. The second point is

about what is effective. Here the focus of our countries so far in terms of cost and clinical effectiveness has tended to be very much on the OECD country concerns which have mainly been around pharmaceutical supply, pharmaceutical pricing, impacts on innovation, the cost-effectiveness of different pharmaceutical and other interventions. We have not done that kind of relative effectiveness assessment with a focus on particularly developing countries. That is not to say that we could not, but so far we have not.

Q1060 Lord Howarth of Newport: It would be helpful for your member countries and everyone to know which is better value if you are trying to address the problems of ill-health across the world and the dangers of communicable diseases. Do we do better to spend money on specific health objectives or do we do better to try to improve the general context of conditions in which people live?

Dr Gillespie: Again, the focus of the OECD is around the economics of prevention versus the economics of therapy. There we do have some work beginning. It will begin in general and it is too early to say how focused it will become. Of course, we are not the only organisation that is well-placed to look at good value for money on expenditure on health and other interventions; we have the World Bank which is at least as well-placed as us, probably better, to look into countries, for example, in sub-Saharan Africa, and this is an area where WHO do have rather strong economic capacities in looking at the relative cost-effectiveness of interventions.

Q1061 Lord Avebury: My question is about policy coherence in OECD countries. Do you think that irregular migrants should be treated for the main infectious diseases, HIV/AIDS, TB and Malaria, in OECD countries? And what advice have you offered on the subject?

Dr Gillespie: We have not offered any advice on that particular issue. I think that is one we would have to deflect to our member countries to answer. There is no organisational view on that specific issue.

Q1062 Lord Avebury: But, if we are trying to prevent the spread of these diseases, then surely it would be perverse and illogical for member states to refuse to treat it amongst their irregular migrant populations.

Dr Gillespie: You could well describe it as that.

Q1063 Chairman: This might be a question you want to respond to in more detail in writing if necessary because we have not got time for a long answer now. One of my interests is the World Bank and whether you think they are doing as much as they could or

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should in terms of investment in the infrastructure in the area which you are dealing with. If you want to give me a one word answer to that and then write to us about it, that would be helpful.

Dr Gillespie: The very short answer is that I am sure they could do more and would like to.

Chairman: If there are particular areas that you think it would be important for us to know about, then I would be very grateful if you would write to us and identify those areas.

Q1064 Lord Avebury: Could we have a copy of the Memorandum of Understanding between OECD and WHO?

Dr Gillespie: By all means.

Q1065 Chairman: I particularly want to know about the World Bank investment bit, because one of the factors coming out is whether the World Bank does do sufficient investment in the infrastructure. Having said that, can I thank you very much indeed for your evidence. It has been very helpful, very focused, and I am grateful to you.

Dr Gillespie: Thank you very much, my Lord Chairman, I hope you enjoy the remainder of your stay in Paris.

Chairman: Thank you.

TUESDAY 20 MAY 2008

Present	Avebury, L Desai, L Falkner of Margravine, B	Hooper, B Howarth of Newport, L Soley, L (Chairman)
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Examination of Witness

Witness: DR NILS BILLO, Executive Director of the International Union against Tuberculosis and Lung Disease, examined.

Q1066 *Chairman:* Dr Billo, thank you very much for coming here today and for your time. We are the Intergovernmental Organisations Select Committee of the House of Lords. Our interest, as you know, is in the intergovernmental organisations but also the non-governmental organisations and the way they co-ordinate and co-operate to deal with contagious diseases. We are primarily interested in the structure of the intergovernmental organisations and the machinery rather than the diseases themselves, although obviously we have to have some knowledge of that. The events today are being recorded. You will see a record of that in draft form for you to make any corrections of a factual nature that you wish to make. After this event, if anything occurs to you that you feel you left out or would like to add or elaborate on, please feel free to write. Our purpose is essentially to get as much information as possible for our report, so please feel free to elaborate as and when you wish. First of all, I think I should compliment your organisation. You have been around for a very long time, founded in Paris and with an impressive record. Perhaps, as we have some understanding of that, I can go directly to the first question, which concerns the Directly Observed Treatment Short Course—a fascinating title, if I may say so, and one which has received a lot of praise. We have also heard from Target TB that “the implementation of what is called DOTS in TB control . . . is sometimes seen to be too prescriptive from the top. What is prescribed by international organisations is not always easy to implement at a local level, so perhaps there is not a sensitivity to local conditions”. What would your view of that be?

Dr Billo: This strategy was developed by our organisation and was called DOTS by the WHO. The term DOTS is a little bit confusing because it means Directly Observed Treatment. Obviously this is an important issue because very often, if patients do not take this medication, then the risk of developing drug-resistance is imminent. That is why we believe it is really important that this is implemented properly. If a programme is not implemented, we face those risks, and we have seen problems especially in sub-Saharan Africa and former Soviet Union countries where this strategy has not been well-implemented. The strategy, by and large, if we compare it with

other strategies on Malaria or AIDS, has done a lot of good and many millions of patients have benefited. The criticism of being a programme which is top-down rather than implemented in the healthcare structure is not correct, because I believe there needs to be a mixture between a vertical and horizontal component. If you do not have a central co-ordination point—and that is true not only for TB but AIDS or any other disease of public health importance—then you have a chaotic situation at the periphery. This co-ordination is critical at national level but also at regional and local level, the peripheral level, where this needs to be integrated into the health system. Obviously this is a challenge in many countries where the issue is a deficient healthcare system, where there is a lack of infrastructure, a lack of medication, a lack of well-trained personnel, a lack of very basic management skills, and sometimes that impedes the proper implementation of such a programme. Tuberculosis can take the credit for having achieved quite a lot over the last 20 years. Before that, tuberculosis was not given proper attention and many, many people died unnecessarily. One other issue is that people ask why is the number of cases still going up. First of all, we did not find the cases in the past because the programmes were not efficient enough and, secondly, we have the AIDS epidemic, which diminishes the immunity of TB patients, or patients who are infected with TB, and because their immunity is down they will develop the disease. That is one of the complications of the two epidemics, they are so closely linked that they influence each other. To get back to your question about is it too much top-down that it does not reach the periphery, that may be true in some cases but, by and large, I would say the programme is well-implemented and the DOTS programme is now implemented in almost all the countries that have a big problem with TB.

Q1067 *Chairman:* Let me ask you, what happens in a country where the basic health service is very deficient? Would you not introduce DOTS there because, presumably, if you could not do the directly observable bit, it would not be appropriate? Is that right or not?

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Dr Billo: It is true in a certain way. I would need to specify and this becomes a little more technical. There are two phases in TB. The first phase is where you get four drugs, and in the next phase you only have two drugs. If possible, those drugs should be associated because that reduces the risk of the development of drug-resistance. Especially in the first month, one really needs to make sure that Directly Observed Treatment is being applied: otherwise, as I said before, there is a risk that patients only take the red tablet and not the other one, and this may cause them problems. One of the big problems we have seen, especially in countries where the health system was not sufficient and the drugs were not available,—one example was former Soviet Union countries like the Baltics—was they did not have the drugs, so they took what they had and that created a big mess and the situations we now have in those countries. Unfortunately, the two areas where we have most of the problems are in former Soviet Union countries with all these immigrants that may come over and cause problems in our countries, where we thought TB had been eliminated. I would like to say something about that because we forgot to invest in TB in many, many countries and that was a big fault. The Directly Observed Treatment is important to make sure that patients do not take a wrong or deficient treatment.

Q1068 Chairman: I understand that and understand the very great importance, not just for the sake of the patient but the danger of creating greater resistance, if the drug regime is not adhered to, but what I am struggling with a bit is, is the success of DOTS as it has been described because you only introduce it where you think the regime can be made to work? Or do you make a clear choice that you cannot deliver the Directly Observed Treatment system and, therefore, you will not introduce it there?

Dr Billo: Obviously if you do not have any health structure at all, then nothing is possible.

Q1069 Chairman: So you do not do it then?

Dr Billo: It is not feasible. You pilot a DOTS programme, or any public health programme, if possible in a difficult area, to see that it works. If it is too complex, then it is not going to work anyway. The DOTS strategy is not complicated. It demands organisation. It does not demand a lot of technology, but it demands some basic services. It demands a basic management unit in a district hospital or health centre, where patients can come and get their treatment and get supervised, and that is critical. The strategy will work less well in a situation where you have hardly any health system or health centre available, where it has to be done in the community somewhere. It can work but it is more complicated to monitor. To briefly summarise the strategy, it needs

political commitment, the drugs, the microscopy network, the treatment observation and, very importantly, the monitoring and evaluation part. If patients travel around, it is much more difficult to get that information. As you said, it is critical that to have a good programme you need the infrastructure and that is a problem in many, many countries, there is no question about that.

Q1070 Chairman: In summary, what you are saying is that you do need an element of top-down here unless you have got a very good system on the ground, because the only way you can be sure of not making the problem worse, by having the drugs not used appropriately, is having some way in which you can be confident that the proper use of the drugs is adhered to. Is that right?

Dr Billo: I absolutely agree with you, and that is what I always say: “If you are not able to guarantee a good programme, do not start, because you may create harm”. Unfortunately, this has happened in some countries where drugs are being distributed without any proper programme available, and then some drug resistance has occurred. The health system is critical.

Q1071 Lord Avebury: Can we apply this reasoning to sub-Saharan Africa, where you said there were problems. We did hear from the International HIV/AIDS Alliance that our Department for International Development does acknowledge the needs of marginalised populations but continues to invest a large proportion of its AIDS resources in intergovernmental organisations and governments that are unable or unwilling to respond to the HIV epidemics amongst marginalised populations. We wonder whether the same is true of TB and whether you could illustrate that by looking at the problems in southern Africa where there are marginalised populations. I am thinking particularly of the Zimbabweans and South Africa, who are much in the news at the minute. If those people are not being treated for HIV/AIDS, then presumably they are not getting any treatment for TB either, and this is not apparently a matter of much concern to DFID, which channels all its aid through governmental agencies that are discriminating against these marginalised populations.

Dr Billo: I really think that, in order for any AIDS, TB or public health programme to work, you need to support governmental organisations, governmental institutions, but also the communities and NGOs. In my opinion, it is a mixture. I can illustrate that. Our organisation works very closely with the WHO and we have many working groups where we are together, so we really co-ordinate our work well. Obviously, if you channel money to a government, it will depend how the government is organised. You mentioned

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South Africa, which is a very unfortunate situation. South Africa is probably the richest country in the sub-Saharan area but, unfortunately, I am sorry to say, they have a very deficient TB programme. AIDS, as you all know, is difficult for some peculiar reasons at the top level, where there is a lack of commitment. In addition, it depends on the political system available. In South Africa you have a federal system, so the federal government probably has difficulties co-ordinating among the different states and provinces of South Africa to really get things done. Unfortunately, especially for TB, they were not able to create an efficient programme and it is correct that, because of that, a lot of the marginalised populations have not been able to benefit from infrastructure which is there but is not well-organised. I always say that we make a big mistake by saying we do not have the technology, we do not have the science; we have the science and we have the technology but what is lacking is the management. In many countries basic management is deficient: how to organise a trip from A to B takes a huge administrative burden and that hampers the proper functioning of many things, including health systems. Again, I think it is critical to support governments, to support the WHO, but it is also very critical to support efficient community-based organisations and NGOs on the spot. It is the synergy between the two that will make for a good programme. There are many examples where, for instance, the government structures are weak and NGOs are very strong and it works then. An instance would be in Bangladesh, where we have a very weak government system but a very strong NGO system and the TB programme works extremely well. Then we have India, where you have a very strong government system, a little bit top-down, very controlled, and they struggle a little bit with getting more NGOs involved, but they are doing it as well. It is a mixture of both and to bet on one side only would be a mistake.

Q1072 Lord Avebury: Since you mentioned Bangladesh as an example of good practice, can you say anything about the minority populations there? They do have a substantial but reducing population of Hindus in Bangladesh and they also have a large population in the Chittagong Hill Tracts, which is separate from the majority ethnically in terms of religion. Are you sure that Bangladesh is applying the same treatment to minorities as it does to the majority?

Dr Billo: First of all, I do not know Bangladesh in detail, so I cannot answer your question accurately, but what I know is that Bangladesh has a very weak government system and BRAC, the NGO that works there, has been able to do a good job. I am not saying they are able to catch all the people with little access. I can probably come in here with an experience we

had in the Union. We got a grant from the Canadian International Development Agency to look at poor populations and improve access to innovative new ways, for instance with wall paintings, to really tell the poor people, if they cannot read, that if they have a cough they need to go and get examined. This project, which we implemented in China, India, Indonesia, Bangladesh, Pakistan and other countries, showed that through innovative ways you can improve access for the poor. Unfortunately, TB is a disease of the poor and marginalised. It is very difficult to get these people to the treatment centres. Their first worry is not the disease, it is getting food for their families, so the last thing they do when they are almost dead is they go to get treated and very often the prognosis is not so good. There needs to be an holistic approach if you want to give better access to marginalised and poor people. You need to offer them some incentives to come to the treatment centres, and that is true not only for TB but for HIV and any other diseases. Their worry is not the disease, it is daily survival. The whole system needs to be looked at and that is why we think non-governmental organisations that can give food, give incentives, are important in that sense to complement the services of governmental organisations.

Q1073 Lord Desai: We have had a number of people telling us about the problem of co-ordinating HIV/TB infections. How are the HIV and TB programmes operated? Are they co-ordinated nicely or are there problems?

Dr Billo: This is a very good question and I would say that for many years, unfortunately, this has been a challenge. It is improving, but it is improving slowly. If I can criticise WHO, the fact is that for many years they have had trouble talking to each other, the HIV department and the TB department.

Q1074 Chairman: Within the WHO?

Dr Billo: Within the WHO and also WHO with UNAIDS. WHO is part of UNAIDS but this has been a problem and translated into some co-ordination issues in countries as well. Obviously it is very easy to say that TB and HIV are very common, they need to look at things together; but it is not so obvious because very often there are different funding streams that go to the programmes and everybody is basically guarding their turf and that can hamper the collaboration. Many organisations are realising that this has been deficient. Also PEPFAR, the initiative of President Bush, which paid very little to TB and HIV, is now putting much more money into this and facilitating this co-ordination in many countries. Our organisation has taken up this challenge and we have several projects, for instance in Myanmar, DR Congo, Zimbabwe, where we have tried to get over this barrier. For

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instance, we have the TB programme as an entry point for HIV as well; so, when a TB patient comes, we also facilitate the HIV test to make sure we do not miss a person with TB who may have HIV as well. As you may have heard, TB is very often the first infectious disease that pops up for a patient infected with HIV who otherwise has no symptoms. It is very important that this is addressed strongly. For instance, in Myanmar we have had very good success, where with very little money we were able to get those two programmes together, but it is a constant dialogue that needs to be had from the TB programme to the AIDS programme and vice versa. Because historically the AIDS programme has been very strong, they always have a lot of money, and even before the era of anti-retroviral treatment they had a lot more money compared with the TB programme; they feel they have more muscle and do not feel the need to collaborate, but this is happening more and more. Also, very importantly, the AIDS activists play a crucial role. For many years the struggle was to get more money for prevention, for drugs; but now they realise that TB is a big issue they are pushing very hard. We had our World Conference in Cape Town last year and we had about 5,000 activists who asked for better TB treatment for HIV-infected individuals. We need to push that movement much more. We need to sensitise the HIV community about tuberculosis in order to improve that collaboration that you rightly mention.

Q1075 Lord Desai: Just to go further with that, even the UK has not got a proper, good co-infection strategy. As you say, AIDS is much more politically glamorous than TB.

Dr Billo: Yes.

Q1076 Lord Desai: Are you and your partners doing something to raise awareness of TB as being equally important?

Dr Billo: We are trying to do that, but it is very difficult. Just as an example, when the WHO Secretary-General, Margaret Chan, talks about big challenges, she talks about HIV, Malaria and many other things, and TB gets forgotten, and we have a problem with that. It is something that we need to improve on. We have made a lot of progress, but still AIDS is much more glamorous, it affects populations which are very strong in terms of advocacy, whereas TB affects mostly poor people and they do not have a lobby. That is one of the big issues. They do not go out onto the streets in South Africa, or very seldom, it is the HIV people who go on the streets and shout that they want something. TB people are poor, marginalised, and very often it is more difficult to raise their point.

Q1077 Lord Howarth of Newport: Can I just press you for a moment to elaborate a little bit on what you have been saying about the WHO and Margaret Chan? Do these problems of different departments that need to talk to each other and collaborate still persist? Or are they being addressed?

Dr Billo: They are being addressed. It is much better than it used to be. It is very much on the right track now. The activists have played an important role. They are pushing for this collaboration at all levels, including within the WHO, and this is much better. We have a TB/HIV Working Group and a liaison person who was delegated from the WHO TB Department to UNAIDS, so these links are much better. We had a press conference, for instance, here in Paris, where we looked at the major challenges and invited somebody from UNAIDS to give a talk. These things are much better co-ordinated now but, as we know, it is not enough to have this recognised at the top level. We always make the mistake or the assumption that, if WHO does it, it will happen everywhere, but this has to be translated through a policy transfer mechanism to the governments of countries, and that is often not enough, because it stays there, is discussed in a committee and it is not sub-national. It needs to go to all levels and that takes a long time. We have seen that with the DOTS strategy. For many years the strategy has been known by WHO, by the major NGOs; but still, if you ask somebody at the lower level "What is the DOTS strategy?", they would have trouble saying what it is.

Q1078 Lord Howarth of Newport: The budgetary processes are crucial, are they not, because if people are funded to do one thing and not another they will do the one thing?

Dr Billo: Yes. This is an important point. When you fund programmes in an isolated way, you may run the danger that they only look at their area of interest and not look in a lateral way. DFID has quite a good reputation in addressing that issue and not just funding programmes, they like to have a more holistic approach.

Q1079 Lord Avebury: Since you have mentioned DFID, I have in front of me this report from Results UK which is entitled *An Inadequate Response*, where they say: "of the 18 high burden countries in which DFID has a bilateral presence, only two country officers reported that they were providing any direct support for TB/HIV collaboration activities". Can you verify that? Why do you think it is that DFID has such a creditable record in the face of this criticism?

Dr Billo: To be honest, I do not have a detailed overview of what DFID is funding. I know that DFID has given a lot of support to many countries. I am not 100 per cent familiar with the way in which they give support, but I know they claim, at least, that

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they try to support holistic approaches where they say they will fund TB, HIV and Malaria and, if you make a proposal, you have to send a package which includes all important areas. The reality probably is still not as it should be, but I would say DFID has supported TB in a very substantial way, especially in India and other countries in Asia, and it is one of the development agencies that has done a lot for TB and supported the Global Fund in a meaningful way. Among all those agencies, I would think DFID has done quite a good job compared with others. There is always room for improvement, of course.

Q1080 Lord Desai: I want to come to my question, but, before I do that, you spoke about the difficulty of spreading it down to the bottom. Have you thought of a Global Ambassador for TB and HIV together, somebody who is so famous that their face is known everywhere?

Dr Billo: We have the former President of Portugal, Jorge Sampaio, who is the Ambassador for TB.

Q1081 Lord Desai: I am sure he is lovely, but his face is not known.

Dr Billo: No, it is not known.

Lord Desai: It is not like Pele or someone like that.

Q1082 Baroness Hooper: Elizabeth Taylor?

Dr Billo: That certainly is an idea and we have tried that.

Q1083 Lord Desai: I offer it to you.

Dr Billo: There are always some pitfalls with that. We got the footballer Figo, but he ran a cat over with his car and he now has a very bad reputation!

Q1084 Lord Desai: One of the problems, as you said, is that HIV/AIDS is glamorous and TB is not, but TB has been around for ages, TB is not a young disease. The Global Fund told us that TB people are using drugs which are 40 years old and diagnostics which are 100 years old. Why is there a shortage of new drugs and diagnostics for TB? Is it an intellectual property rights problem?

Dr Billo: It is a business. Why would you invest in the development of a drug that you cannot sell at a high price? There is no incentive. There is no incentive for companies to produce a drug which is going to be used obviously by a lot of people but who are not going to be able to pay \$100 for a course of treatment. A course of treatment at the moment is between \$20 and \$30 and most of these patients cannot afford that money. As a matter of policy, TB drugs are being given out for free. Any new drug that comes out needs to be cheap, otherwise neither the Global Fund nor the governments will be able to buy those drugs. The incentives have not been there and because of that the Global Drug Alliance has been formed and

is trying hard to find new drugs, but it is not obvious. If we found a new compound today that would be promising, we would need to organise clinical trials and it would take at least three, four, five years. We do not think we will have a new drug tested in a clinical trial before 2010/12, and that is an optimistic view. Countries have not invested in drug development.

Q1085 Lord Desai: Is it a matter of encouraging basic research?

Dr Billo: Yes. I have said, and I said this in Norway because there was a meeting on that topic, that governments have to invest more in basic science, in the development of drugs, but, more importantly, in vaccine development. In our opinion, the only thing that would really help us get to grips with the TB and AIDS epidemics is going to be a vaccine like we have seen in other diseases.

Q1086 Chairman: Vaccine is low profit, is it not?

Dr Billo: It has to be cheap.

Q1087 Chairman: What about differential pricing for drugs?

Dr Billo: This is very difficult because of the smuggling issues.

Q1088 Chairman: So the drug ends up being a corrupted drug?

Dr Billo: Yes.

Q1089 Chairman: You do not think that works?

Dr Billo: It is working. If you buy drugs in the UK or in the United States or Switzerland, TB drugs are much more expensive in the sector than if you buy it from the Global Drug Facility, which is housed in WHO, where a course of treatment at the moment is between \$20 and \$30, which is affordable for countries.

Q1090 Baroness Hooper: We have touched on this already and you have advocated an holistic approach and referred to the fact that TB is a disease of the poor, but looking at the wider picture and the need for more joined-up thinking between health, trade, economic development and organisations, whether IGOs or NGOs, WHO, WTO, OECD—and we talked earlier about the role of the WHO in all of this as the orchestrator perhaps of these—do you see enough appropriate action being taken outside the health sector between other organisations?

Dr Billo: I would say that a lot still needs to be done and that we are struggling with the basic technical health-related issues. We need to make sure that patients who have a disease have enough money to get to the health centre. As I said before, if they do not have the money to pay for their lorry or their taxi

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cab to get to the health centre, they will not come. I will take the example of pneumonia in children, where we have a very successful programme in Malawi. If the mothers do not see the advantage of going to a health centre because they will not find the drugs, they will just let the kid die and have another one. The economy is critical, and these links need to be much more addressed. Obviously removing poverty is not something that we can achieve from one day to another. We have tried several programmes where we gave incentives to TB patients, we gave them a kilogram of rice or a travel voucher so they would come and get the treatment they need. That certainly needs to be addressed much more forcefully. This is not only true for TB but for any other disease. WHO is addressing it, but getting WTO or other governmental organisations involved in health is critical, I would absolutely agree with you.

Q1091 Chairman: Can I take you back to the argument between the horizontal and the vertical.

Dr Billo: Yes.

Q1092 Chairman: It has become an issue for this Committee in a way because we have been told by some people that not enough is put into the horizontal healthcare system, the basic healthcare system, and maybe too much into the treatment of individual diseases. We have also been given another view that these two pictures are not a good picture of reality, that there needs to be a much more varied approach and that both are necessary. What is your view of it? How do you think the vertical treatment of disease should co-ordinate with the building up of basic healthcare systems?

Dr Billo: You are absolutely right. The theme of our World Conference this year is the importance of health system responses and global threats to lung health. Health systems are definitely deficient, there is not enough infrastructure and there is a huge human resource issue presently. A lot of good personnel in countries go to the UK, Switzerland, the United States and do not stay in their countries because they are not able to get a proper wage. That has not helped either. Stabilising health systems, improving the working conditions, making sure that health personnel are retained in their jobs, that there are incentives to advance in their jobs, this needs to be invested in first of all by governments themselves; it is not possible that DFID, the Swiss Development Corporation or USAID can fund that. The Global Fund can do quite a lot, but basically it is the governments that need to put more money into the infrastructure and health personnel to make sure that these programmes not only have an existence on paper with two or three people at the top in the capital but that all the centres, the cities, the

peripheral health facilities, are properly staffed, have adequate medicines available and adequate infrastructure. That is certainly a big, big issue.

Q1093 Chairman: Supposing I played the role of Devil's Advocate and said that the money that Bill and Melinda Gates are putting in is enormous but actually it would be better spent on providing basic healthcare structures, what would you say to that?

Dr Billo: The question is what do you mean by "basic".

Chairman: I mean the provision of basic clinics on the ground in areas where people can reach them, for example.

Baroness Falkner of Margravine: Primary care.

Q1094 Chairman: Would you agree with that?

Dr Billo: I think this is critical, but if you do not have somebody who co-ordinates drug distribution to those clinics, for instance, this infrastructure will not help.

Q1095 Chairman: You are saying that should be the government's role?

Dr Billo: Yes. You are talking about private clinics?

Q1096 Chairman: When you say it is critical that it is there, you could argue that Bill and Melinda Gates's money would be better used to provide that.

Dr Billo: Very often what will happen, and this is a very human thing, is that it is a business; and, if you have private clinics, those who have money will benefit from such a system but the poor will fall through the cracks, they will not get the attention. They will probably go to the private sector, and we have a lot of examples where they go first to the private sector, they pay the first two visits to the general practitioner or specialist but after a while they do not have money to pay and they discontinue their treatment. We need to really reinforce both systems. In India, for instance, the private sector is very large. I would say that 40 to 60 per cent of TB patients probably go first to a private practitioner to get their treatment. It is only when you have a really strong government system where people realise they get proper, decent treatment and drugs that they switch, but very often they approach the private practitioner first.

Q1097 Chairman: I understand that. That is helpful. Do you think there is a bigger role for the World Bank in investment in infrastructure, the infrastructure of the health system in a country? Have you thought about that?

Dr Billo: Yes. The responsibility is first and foremost with the governments. Certainly the World Bank should also invest in infrastructure. Development agencies invest heavily in roads, telecommunications,

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but I think infrastructure needs to be heavily supported also. I would very much agree with that.

Q1098 Chairman: One would obviously agree that governments matter, but the reality is that very often the governments are corrupt, despotic, incapable or non-existent in some cases.

Dr Billo: I agree. It should be supported heavily. It should go hand-in-hand with human resources because it does not help to have a nice clinic and no people who can work there.

Q1099 Baroness Hooper: Back to the co-ordination/collaboration issue which has been touched on, but perhaps looking at it from the perspective of a small developing country and the way in which intergovernmental associations co-operate with non-governmental associations, foundations, charities, and so on, is there a problem over competition between some of these organisations? NGOs particularly may be unwittingly reinventing the wheel because they do not know what is going on but they move in with the best of intentions perhaps. Therefore, is the International Health Partnership, which seems to be the vehicle for co-ordination, working or likely to improve the way these various agencies can cope?

Dr Billo: This is an excellent question, which is a real challenge. If you look at a TB programme manager or an AIDS manager, one of the major tasks is to organise visits for the WHO, UNICEF, NGOs, and they have hardly any time to work because they are constantly organising visits. There is a lack of co-ordination and I would very much agree with you that this has to be improved. Especially in the TB area, we have a system with WHO called the TBTEAM that co-ordinates the visits, so we make sure on travel and try to improve that co-ordination. We know when WHO goes, let us say, or another organisation goes to a country to address an issue, but it is still something that needs to be improved. If we are not able to get that better addressed, this will be a real issue for countries. Also, this co-ordination is hindered a lot of times by the fact that the Global Fund, DFID or NGOs demand different ways of reporting on how money is being used in countries. That is a huge burden on countries to report on what they are doing. Also, when they have to make applications, these applications are complex. So, on a Global Fund application, for instance, they spend two or three months and the whole system is burdened by that. This also needs to be addressed, how to apply for funds from different sources, how to report to different agencies, that is something that needs to be improved. You said is there a danger if they do not collaborate; and, yes, there is a danger if they do not collaborate with the government. There are many NGOs that have a little funding, they start a

little project and, when the funding stops, everything collapses. The ideal situation is where the government knows which NGO is working in which area and they work together. There are good opportunities for that, but it does not always work, unfortunately.

Q1100 Chairman: Therefore, do you think International Health Partnerships will help sort this out or not?

Dr Billo: Yes, I think these Partnerships are very helpful and a lot of things that we used to do completely independently in the 1990s are now much better co-ordinated, at least at the global level. The co-ordination at the regional level with, for instance, the regional Stop TB Partnerships, where the technical agencies, the governmental agencies, meet with the NGOs and the funding agencies, has helped a lot. At the local level, the country level, you have these Country Co-ordinating Mechanisms which are working quite well. I can give you an example. At the moment we are preparing a Global Fund application in India on the NGO side. There were about 20 NGOs that came together, meeting to see what the needs were and discussing with the government at the same time how they could fit into the overall Global Fund application. This co-ordination is being addressed much better these days but still could be improved.

Q1101 Chairman: Are you saying the International Health Partnership is crucial to that? I am not quite sure how much emphasis you are putting on the importance of it as a co-ordinating mechanism.

Dr Billo: I think it is critical, because otherwise there will be counterproductive actions if, let us say, an organisation buys 20 microscopes for a certain area to improve diagnostics and at the same time some other organisation does the same thing and all of a sudden the government has bought microscopes with the Global Funding, that is not co-ordinated and is not healthy.

Q1102 Lord Howarth of Newport: Can I just follow up on that one before going on? You mentioned that application procedures for funding can be burdensome, but presumably well-devised application procedures, while being demanding, could be helpful in, as it were, steering governments towards addressing the right questions?

Dr Billo: Yes, certainly. On the other hand, there are applications which demand the inclusion of certain things because at the moment the buzzwords need to be used. What happens very often is that governments hire a professional grant writer who helps them to write those grants, to use those words, and the buy-in is sometimes not there.

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Q1103 Lord Howarth of Newport: They do not think at all?

Dr Billo: Again, it is the lack of management, the lack of knowledge and how to think through what do we need, so somebody comes from outside and writes an application that will please the funders and come through. The problem after that is that the money will be available but the country will have difficulties in absorbing the money. It comes back to the issue of management, management skills in all areas, health, accounting, financing, budgeting, planning, that is not adequate and at national level not speaking to the sub-national or local levels. That needs to be improved, addressed and funded, because only then will we have a better buy-in from countries and they will apply for what they really need rather than things they do not really need, in fact.

Q1104 Lord Howarth of Newport: Can I come back to a point you made in the discussion about DOTS, and that is what more precisely your thinking is to prevent the uncontrolled supply and misuse of drugs for treating TB. The Stop TB Partnership told us that preventing the uncontrolled supply and misuse of prime drugs for treating TB, such as Rifampicin, is the best way of stopping drug-resistant TB. In your view, what can be done to limit the spread of multi and extremely drug-resistant TB, particularly in HIV—infected patients?

Dr Billo: At the moment everybody is talking about XDR and MDR-TB and we need to fund those programmes. That is important, but it is much more important to fund basic TB control to avoid these cases. I think what we are doing at the moment is a mistake, where funding agencies were scared by Mr Speaker who was travelling through the world and infecting Americans probably, a big disaster, and now they say, “Let us fund MDR-TB, or not even MDR but let us fund XDR-TB”. It is a panic reaction. I always say it is important to fund the basic things to prevent new cases. That needs to be addressed. Unfortunately, we do not have a standardised approach to treat MDR or XDR-TB, it is a lost cause in most of the AIDS communities anyway; we do not have that, it is much more complex, the treatment is much longer, the drugs are very toxic, so it is a complex issue to treat MDR and XDR-TB. It needs to be addressed for various reasons, for humanitarian reasons.

Q1105 Lord Desai: It is the same thing that it attracts much more public attention than ordinary TB.

Dr Billo: Obviously. One agency called and said “Can you do something for XDR-TB” and I said “Yes, but we need to do something for MDR-TB” and they said “No, we are not interested in MDR-TB, we are only interested in XDR-TB”. It is this lack of understanding that we need to prevent rather than

treat the most complex cases and XDR-TB, as I said, is hard to treat.

Q1106 Lord Howarth of Newport: You have spoken very energetically about the need for burden management, administrative capacity and infrastructure. Is it your view that in the balance of priorities and the balance of funding too much effort by certain intergovernmental organisations is going into treatment and not enough into detecting, identifying and preventing TB? If so, how would you get the shift that you might want to see?

Dr Billo: We need to improve case finding. You mentioned before the issue of the marginalised, the poor who are not getting the treatment or inadequate treatment because they do not get the service, and this needs to be improved. In our organisation we are trying to get funding especially to address that issue of how to address the poor. We have good links with the Liverpool School of Tropical Medicine and Dr Bertie Squire, who was very interested in that question, and other partners to address exactly that issue. If we are not able to service the marginalised, the poor, they will get a few drugs here and there, pay for it, not get properly treated, and then we may have these issues of MDR-TB.

Q1107 Lord Howarth of Newport: It is the vertical-horizontal dilemma again, is it not? While it is a false distinction in some ways, it does seem that not enough of the big money is going into the horizontal. Do you have thoughts as to how to get it there?

Dr Billo: Many development agencies favour the so-called “basket” funding, and I think DFID is one of those development agencies that gives money to the government and the government then decides how they will invest that money for whatever infrastructure and so on. Unfortunately, in many instances I would say the money sticks at the top. It maybe goes one level down but it does not trickle down to where it is really needed. That is the problem.

Q1108 Lord Howarth of Newport: Is that to do with inadequate procedures for contractual arrangements or for auditing? There would be ways, you could imagine, in which you could improve performance and do more to ensure that the money is appropriately spent, not just handed over and then not worry too much about what the end result is.

Dr Billo: Again, there is an issue of how to plan this, to budget, monitor it, audit it and report it. That needs to be improved. Also, the development that I have seen over the last ten years is that development agencies give more flexibility to countries, they have to decide what they do. Many development agencies do not attach many strings.

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Q1109 Lord Howarth of Newport: One can see that diplomatically it may be difficult to attach those strings, but are you aware of examples where this has been well-handled which could be a model?

Dr Billo: This is not dependent on the money they receive. Many countries have millions of dollars in the bank and are not using them, so they are not getting it to where it should be. One example where I have seen the government has put a lot of money into infrastructure is in Peru. By doing that, they have dramatically improved TB. Everybody asked why they have improved TB, and it is because they have improved the basic health services, and they invested in the late 1990s in beefing up health services; they had nurses, drugs, everything there, and had a reach-out to the community and things started to improve. That is a model I would see as positive. On the other hand, when the government changed this collapsed a little bit.

Q1110 Baroness Hooper: May I come in there. DFID, if we are just talking about the UK's involvement, removed its person in post from Peru, so that obviously affected the DFID funding; and similarly in Central America, where in Nicaragua they had a very good programme, not just health-related but rather more general, they have removed their field officer who controlled and managed it. If other countries are doing the same thing, then that is where things go wrong.

Dr Billo: It is interesting that you mentioned Nicaragua, which is a country where we have been for many years and they have an excellent TB programme. The Americans had a huge problem with TB in the early 1990s and I compared Nicaragua with New York, which had a big epidemic of TB because they had not invested in infrastructure, the same issue in New York, and did not have enough money to co-ordinate TB activities and said "This will be taken care of by whatever is available". It was a huge problem. In Nicaragua, with about \$300,000 they had an excellent programme because they had developed centralised services in all their provinces. In New York, with the same number of cases, approximately 3,000, they had to invest about \$50 million to get that back on track. They did it, but at a huge cost because they had abandoned the proper financing of the health services. I am not sure if in the UK you have a similar problem. You have to invest, otherwise these people who are difficult, very often homeless, alcoholics, diabetics, immigrants, do not have the facility to go to their GP, and that special infrastructure needs to be there.

Q1111 Lord Howarth of Newport: So it is less about the total of funding that you have available to invest as about intelligent investment and continuity?

Dr Billo: Absolutely. I do not think we have a huge lack of funding, we have a lack of intelligent investment of the funding we have.

Q1112 Baroness Falkner of Margravine: I should declare an interest because I ran an AIDS NGO working in southern and eastern Africa. To flesh out a little bit what Lord Howarth was saying, one of the problems we found with DFID's strategy, or the main agencies, CIDA and so on, of giving money to the ministry of health was that first, as you said, it stayed in the capital on the whole and, if you were lucky, it went to a few regional centres; but the other problem was that you had very differing results, so in Country X you had a very enlightened ministry of health, so the NGOs were able to do the work on the ground in the very poorest rural areas, and in the neighbouring country you had a different attitude from the ministry of health. So there was exactly the same source funding from the World Bank, DFID and CIDA, but it was being used in very different ways and in one case it would get stuck in a bottleneck and in another case some enlightened officials would make a decision to trust you to dispense it. Do you think that the mix between bureaucracy and the practitioners, the grassroots activists, in these very poor developing countries where you have a real problem is right? Or does the money get caught up in the bureaucracy and does not actually get out to the activists because of the problems of audit? Are developing countries risk averse in this area?

Dr Billo: The bureaucracy is a big obstacle to development. You should not mention governments in the first place, but look at the World Bank. Sometimes they take two, three or four years to get a grant out to a country. Some development agencies take a long time as well, it is a huge bureaucracy. I like what you said, "intelligent investment", but this is not happening; there is too much bureaucracy to get the funding to where it should be and it gets entangled in the bureaucracy. The money is there, it is in the bank accounts. I think the Global Fund has several hundreds of millions of dollars that are waiting to be disbursed, but they are not disbursed because the channels of distributing the funding are not well-defined and they are afraid they will get entangled with bureaucracy. That is something we absolutely need to improve. In the Union we have realised that and started to train technical people in management. We tell them how to plan, how to budget, how to monitor what they are doing and be more efficient in what they are doing. Obviously this is a drop in the ocean but we should convince other people to improve that governance issue which is really deficient in almost all the countries. In one

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country it may work better, but I do not think it is necessarily the ministry of health that is at fault, it is the administration of the country that is not able to work properly at federal level, the national level, and is not able to communicate well with the regional and local levels. That is one of the main obstacles and all of the other problems come with it.

Lord Desai: I look at it occasionally, Indian bureaucracy or the World Bank bureaucracy, and it is precisely because they have all the requirements of auditing, monitoring, such a lot of things to check off, that they get risk averse. They do not want to do this because, "If I do this, what happens when I get the money into the country?" There is a dilemma between doing what Lord Howarth said is quite right, we need the money well-spent, but that money has to be spent and quite a lot of them do not spend it because they do not want to get into the hassle of having to answer as to where it went. That is one of the problems. In India, apparently 85 per cent of any grant given to the poor ends up in civil service costs.

Chairman: Scary!

Q1113 Lord Avebury: You have mentioned several times differential access to treatment, particularly in countries where people's first point of access is through paid-for services. What I am wondering is, if governments were made to realise that failure to treat people in these categories led to a greater risk for the general population, then they might wish to invest in the services that these people are lacking. I am wondering whether the Global Fund, or somebody like that, ought to be undertaking this kind of motivational research, if you like, that would point governments in the direction of spreading the health services to those who do not get access to them at the moment. Is that what is lacking, that in the treatment of these marginalised groups governments are not seeing a sufficient incentive in terms of the protection of the general population that they cannot directly connect the infection of somebody who is a poor migrant worker, for example, with the threat to the health of the general population?

Dr Billo: That is a good question and it is complex. You were addressing the issue of the economy and accessing health and that is critical. If you look at the migratory worker, the migratory worker is not going to stay here and have access to the health centre that is there, this worker will move to the place where he will have work and will not think about his health, he will think about how to get money. Obviously this migration will not help to improve his access to health. To organise health services for these large quite populations, and in India there are large movements of people back and forth depending on where they are working—

Baroness Falkner of Margravine: Truck drivers with AIDS travelling in southern Africa all the way up the east coast of Africa.

Q1114 Lord Avebury: In Afghanistan the same thing, truck drivers.

Dr Billo: It is the same as if you have a heart infarction in Switzerland in the Alps. If you are unlucky enough to be on holiday on the Alps somewhere, you will not find an ambulance coming straight away. In many countries you cannot have access points everywhere because it is just not realistic. We need to have at least those services working where there is basic infrastructure and, if those work, then also invest heavily into the communities to make sure they set up their infrastructure. It would be unrealistic to think that we could guarantee up-to-date or state-of-the-art treatment for almost everybody. This is not realistic and will not be possible in our opinion.

Q1115 Baroness Hooper: This is a slightly different question. May I ask about your organisation and, indeed, maybe I ought to know the answer to this. Where does your funding come from? You referred to a grant from the Canadian Government for a project, but do you receive it from other sources? Are you ever in a position not only of perhaps managing a particular project but distributing funds on the ground?

Dr Billo: We have a budget of about €40 million a year. Funding comes mainly from USAID, the French Government, the Norwegian and Swiss Governments, the Canadian Development Agency and a large grant from the Bloomberg Philanthropists for Tobacco Control. These funds are project-related, it is not basket funding. It is for very specific things and we have to report on those activities. We have had the opportunity to do exactly what we are asking, which is to contract organisations in countries, and there was a project called FIDELIS, to find local solutions for improved access to TB treatment. We had over 50 grants given to governments but also to NGOs in high burden countries. We had quite good results with this, although also some failures. Some projects, where they said they would improve case finding among private practitioners, did not work, but in other areas it worked. We have a lot of experience in granting projects in different countries. This model is also used for tobacco control, where we are doing the same thing. The advantage is that you can really boost a local government or NGO and you do not have to pass through the national government, because that would often stall the whole system. We were in China and people said, "This FIDELIS project was really nice because we submitted the proposal, we got the OK and three months later we had the money and

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could start working. With the World Bank or Global Fund, we apply and then it takes forever until we can start". The motivation there is not so good. However, we cannot fund like the Global Fund or the World Bank. With small grants like this, you can create some crystallisation points and pilot test a few approaches and, if they are successful, they can apply for larger grants from the Global Fund. That was quite a good example. Our organisation works on TB, that is our main area of work. We work on HIV, tobacco control, on pneumonia, especially in children under-five which is a very neglected area, a lot of kids die, more than four million a year. We also work on asthma, a very neglected area which affects ten to 15 per cent of the population and is very expensive treatment for them. We have about 200 staff and consultants and several offices throughout the world, one in India, one in China, one in Egypt, Mexico, one in DR Congo, one in Uganda and probably one opening in South Africa very soon, and one in Russia.

Q1116 Chairman: Dr Billo, thank you very much indeed for your evidence and thank you for the work you are doing too. Is there anything else you would particularly like to add at this stage? Or have we covered everything we need to cover?

Dr Billo: No, you have asked excellent questions. My plea would be if you can influence what I liked hearing—more intelligent investment of what is being transferred to countries; and, if we can improve that, that would be brilliant.

Chairman: More intelligent decisions is always something that is open to interpretation by people who have different interpretations of intelligence, but I understand and hear what you say and it is important. Thank you very much. If you do get any other ideas or points you want to elaborate on, then please contact the Clerk and we will take those on board as well. As I said, you will see a transcript of this evidence and you will be able to correct any factual matters and then it will be published in due course. Thank you very much indeed.

TUESDAY 20 MAY 2008

Present	Avebury, L Desai, L Falkner of Margravine, B	Hooper, B Howarth of Newport, L Soley, L (Chairman)
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Memorandum by World Organisation for Animal Health (OIE)

The OIE was created in 1924 with the aim of sharing animal disease information and controlling the international spread of infectious animal diseases. Under our current strategic plan 2006–10, the OIE’s primary mission now is “to improve animal health worldwide”. This requires all 172 OIE Members to share the same commitment and political will. New institutional and technical mechanisms for preventing and controlling animal diseases will have to be developed at a national, regional and worldwide level.

Question 1: Opinion on the global situation with communicable diseases; and

Question 18: View on the global threat from new or previously unrecognised infectious diseases and from the transmission of infections from animals to humans.

1. As a result of globalisation and climate change the world is currently facing an unprecedented conjunction of emerging and re-emerging animal diseases and zoonoses (animal diseases transmissible to humans). Improving the governance of animal health systems in both the public and private sector is the most effective response to this alarming situation.

2. As agriculture increases in complexity and sophistication, routine costs associated with production decrease. However, the potential costs of disease increase. Agriculture is increasingly using concentrated production methods and, as animal densities increase, genetic diversity is decreased. Even in vertically integrated commercial farms, animals are constantly on the move. Some modern farming practices raise the stress levels of livestock, making them more susceptible to infectious agents.

3. The accelerating emergence of new diseases risks threatening human and animal populations globally has been the subject of considerable discussion, with particular reference to the risks presented by globalisation and the potential use of biological agents by terrorists.

4. The OIE and the World Bank, in collaboration with the FAO, held an international conference “Global Animal Health Initiative: the Way Forward” in October 2007, where the risks and sources of hazards to human health, as well as the recommended measures to address these, were discussed. In a keynote presentation to the Conference, Dr Lonnie King of the United States Centres for Disease Control, highlighted the following risk factors:

- Climate change and extreme weather events;
- Genetic changes and evolution of micro-organisms, including the emergence of pathogens that are resistant to commonly used antimicrobial agents and disease vectors that are resistant to parasiticides;
- Global movement (ie tourism and trade) of people and goods, in some cases leading to translocation of pathogens and their hosts, including insect vectors of disease;
- Changing behaviour of human populations, including in the selection and preparation of food;
- New technologies, including in global transport and processing and preparation of foods;
- Changes in the health status of the human population, including demographic changes and the emergence of immunosuppression associated with other chronic conditions and/or medical treatments;
- Expansion of human and animal populations into new ecological settings, setting the scene for closer interactions with novel pathogens and disease vectors;
- Changes to global ecology due to human interventions and other causes (eg global warming);
- Periods of civil unrest and war, which can cause large displacements of human and animal populations into new areas and, through the breakdown of established human health and animal health programmes, provide a situation where both new and old diseases can flourish;

- Intent on harming (bioterrorism, agroterrorisms, bioviolence).

5. This list is not exhaustive. Comprehensive reviews have been published on this topic, for example:

- Proceedings of the OIE/World Bank “Global Animal Health Initiative: The Way Forward. October 2007”. http://www.oie.int/eng/OIEWB_Conference_1007/en_Global_Animal_Health_Initiative.htm;
- Proceedings of the workshop on Global Climate Change and Extreme Weather Events: Understanding the Potential Contributions to the Emergence, Re-emergence and Spread of Infectious Disease. December 2007 (<http://www.iom.edu/CMS/3783/3924/45653.aspx>);
- Proceedings of the workshop on Vector-borne Diseases—Understanding the Environmental, Human Health, and Ecological Connections. June 2007 (<http://www.iom.edu/CMS/3783/3924/40713.aspx>).

6. Improving the governance of animal health systems in both the public and private sector is the most effective response to this alarming situation.

7. Animal diseases have a serious economic and social impact on the rural economy of rich and poor countries alike. The animal production industries in rich countries are often free of the serious livestock diseases. In many cases, and at great expense, the serious animal diseases, such as foot and mouth disease (FMD), have been eradicated, but free countries remain at risk of disease reintroduction from still endemic countries, with resulting enormous economic losses, not only limited to the agricultural sector. For developing countries, animal production is important to the survival of poor rural communities. Disease is a constant threat to animals raised in these countries and it is a serious problem for poor communities in rural and peri-urban areas. Such communities are currently incurring severe losses due to animal diseases and these losses are on the increase.

8. There can be no doubt that improving animal health is a global public good. More than 120 countries need help to reach a situation that is satisfactory for them and that reduces the sanitary risk to other countries. The current situation clearly calls for the expression of international solidarity in the global interest. The Veterinary Services in developed countries also need to be re-examined and in some cases new priorities need to be established. In the past, the majority of resources were directed towards the eradication of serious livestock diseases and in some countries the Veterinary Services have suffered from their success. As a result of successful disease eradication campaigns, some Veterinary Services have been downsized to a point that is unsustainable. To be capable of early detection of and rapid response to diseases of animal and/or public health importance, a sustainable veterinary infrastructure and scientific capability must be maintained.

9. Investing in new animal health systems throughout the world helps to protect countries from natural or bioterrorist threats linked to the reintroduction of infectious animal diseases and zoonotic diseases that they have succeeded in eliminating. It is also important to safeguard public human health, reduce poverty and open to all countries the possibility of trading their agricultural products internationally.

Question 2: What reliable data exist regarding the numbers of people infected globally with the four diseases on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in incidence and pattern?

The OIE comments relate to avian influenza.

10. As a partner with FAO and WHO the OIE has taken important steps to improve the reporting and dissemination of information relevant to cases of human infection with H5N1 HPAI (see paragraphs 11–17 for a description of relevant activities involving the OIE).

11. For zoonotic diseases, it is important to control them at the source, meaning in animals. It is well established that control of zoonoses in animals is cheaper and more effective than human pandemic preparedness cost. As regards HPAI, the OIE notes that all cases of human infection are directly related to infection in poultry. No human infections have been detected in regions where poultry are free of H5N1 disease and most infections are related to direct contact with infected birds. To date, more than 200 people have died, with the highest number of people in Indonesia. Human-to-human transmission is extremely rare, with only a few cases suspected to have occurred in Indonesia, Cambodia, Pakistan and Vietnam. For this reason, it is worrying to note that human cases of H5N1 infection continue to be reported in certain countries that are nonetheless silent on reports of infection in poultry. For this reason the OIE wrote to several countries in December 2007, reminding them of their official obligations as OIE Members to report all findings of highly pathogenic avian influenza in poultry and other avian species.

Question 3: What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? What improvements might be made?

12. The OIE manages the World Animal Health Information System (WAHIS), which depends on the commitment, linked with their OIE membership, of OIE Members to officially notify to the OIE their important animal diseases, including zoonoses. WAHIS includes an early warning system and a disease monitoring component. All OIE Members can provide, including by electronic means, direct input to the OIE early warning system and the OIE worldwide on line database on animal diseases (WAHID). The OIE is the key global organisation committed to providing official information on animal diseases, including highly pathogenic avian influenza, and on exceptional epidemiological events. While WAHIS is adequate for the time being, the OIE has established an ongoing program of upgrading in response to the needs identified by users. The OIE is currently emphasising the identification and training of responsible national officials (172 National focal points) for disease notification to maximise the value of information provided by OIE Members.

Question 4: Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years? and

Question 11: What intergovernmental action is planned or in hand for early detection of the transmission of avian flu from birds to humans and of human to human transmission in potential source countries? Is this proving sufficiently effective to prevent an influenza pandemic? What more could be done?

The OIE comments relate to highly pathogenic avian influenza and other major epizootic diseases of animals, including zoonotic diseases such as bovine spongiform encephalopathy (BSE) and bovine tuberculosis (TB).

13. Collaboration between the OIE, FAO and WHO is ongoing with regard to the prevention and control of major epizootic diseases of animals, including zoonotic diseases. With specific reference to avian influenza, over the next 10 years, the OIE will work towards significantly reducing H5N1 virus infection, based on:

- reducing the risk of human exposure to H5N1, thereby diminishing the threat of pandemic human influenza;
- mitigating the negative impact of the disease and its control on production, markets and trade in poultry products;
- supporting the livelihoods of poor communities that depend on poultry for income and food security.

14. The global strategy adopted by OIE and FAO sets out three concurrent priorities:

1. In endemically infected countries, the incidence of HPAI must be controlled to reduce the risk of human exposure to H5N1 infection and to limit the threat of virus dissemination to other countries.
2. In countries experiencing sporadic outbreaks, intensive efforts to eradicate the disease must be supported. Results will depend on progress made in reducing HPAI in endemically infected countries.
3. All countries are “at risk” of HPAI incursion. However, some countries, by virtue of geographic location, poultry production systems and level of economic development are at particularly high risk and would suffer particularly serious consequences. In these countries, surveillance, preparedness and response capacity must be improved.

15. OIE is also pursuing the goal of strengthening States’ capacities to rapidly detect the presence of HPAI and other emerging diseases and take appropriate emergency actions, thereby minimizing pathogen load and economic impact. It is important to ensure the efficacy of public services responsible for formulating the relevant legislation and effectively controlling its application. Efficient veterinary services, based on good cooperation between livestock owners and private veterinarians, are key to the early detection of animal diseases.

16. In 2005 the OIE and FAO established a joint network of expertise on avian influenza (OFFLU) which has as its most important objective improved sharing of virus isolates and their sequence data. Continuous analysis of strains is important to get a better understanding of AI epidemiology and to track possible mutations that may change the biological behaviour of the viruses. OFFLU also helps laboratories in infected and at risk countries and functions as the veterinary counterpart of the WHO influenza working group. By sharing strains and sequences with the WHO network, OFFLU supports the development of a human vaccine in case of a pandemic.

17. OFFLU is also a precious source of scientific expertise. It maintains a database of experts recognised for their excellence, who may be available for missions, under the overall management of the FAO/OIE Crisis Management Centre. Additionally, some specific missions requiring laboratory and scientific expertise may be carried out directly by the Network.

Question 4 (end of sentence): *What predictions can be made of (the four diseases) likely spread and pattern in the next 10 years?*

The OIE comments relate to highly pathogenic avian influenza.

18. Since outbreaks of H5N1 highly pathogenic avian influenza (HPAI) started in Asia in late 2003, the disease distribution and dynamics have evolved significantly. In Asia, some countries that suffered extensive dissemination of infection, including Vietnam, China and Thailand, have had great success in bringing the disease under control. Indonesia and Bangladesh still need to establish good control. Other countries in South East Asia have suffered outbreaks but have achieved control and in some cases eradication. Following spread of the disease to Europe and northern and western Africa late in 2005, many countries were able to eliminate the disease. Notable exceptions are Egypt and Nigeria where the disease is still endemic, and some other African countries, which are experiencing sporadic outbreaks. Some countries detected their first outbreaks in 2007, eg Togo, Benin and Poland.

19. The OIE sees a positive trend overall, in terms of States' performance in early warning, detection and response, as well as an improvement of the quality of veterinary services and a reduction in the number of outbreaks per country. However, more needs to be done to ensure that positive trends are maintained.

Question 5: *What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? How might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?*

20. The OIE comments relate to the main international blockages to achieving progress in the prevention and control of highly pathogenic avian influenza. The intergovernmental actions under way are described in paragraphs 13–17.

21. Highly pathogenic avian influenza remains largely a disease of poultry that occasionally spreads to humans and other mammals and the viruses that cause this disease have not yet developed the capacity for sustained human-to-human transmission. The risk of a human influenza pandemic will persist while influenza A viruses continue to circulate in animal populations unchecked. Therefore, control of this disease at source in poultry remains the priority intervention. It is well established that the control of zoonotic diseases in animals is both more effective and more cost effective than managing the effects of these diseases in humans. Better tools need to be developed to support diagnosis, early detection and effective management of avian influenza in poultry, through applied scientific research and collaboration.

22. Although humans appear to be exposed to avian H5N1 viruses primarily through contact with infected poultry, specific risk factors and alternative sources of human exposure remain undetermined and scientific research is needed to elucidate these factors and provide solutions.

23. Uninfected countries are also important participants in the global struggle against avian influenza. They must strengthen their preparations to deal with virus incursions into poultry. In the case of developing and in-transition countries, planning and preparedness must be supported by the international community.

24. Many countries do not have adequate preparedness plans to deal with pandemic influenza in the human population. All countries need to improve their capacity to deal with the emergence of a novel pandemic strain of influenza virus.

Question 6: *What role does the organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?*

The OIE comments relate to avian influenza and other epizootic animal diseases, including zoonotic diseases.

25. The prevention and control of zoonotic diseases by implementing OIE standards and guidelines within the framework of the World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) are an essential component of public health policies. The current H5N1 avian

influenza crisis is a perfect example of this, but there have been many other crises involving zoonotic diseases (such as severe acute respiratory syndrome [SARS], Nipah virus, bovine spongiform encephalopathy [BSE], Rift Valley fever and rabies). OIE standards cover disease control, diagnosis, surveillance and trade. They are science based standards that have been adopted by the OIE's 172 Members following well established democratic and transparent procedures.

26. In addition to elaborating standards, the OIE is responsible for compiling a list of Member Countries and Zones that are officially recognised as being free from certain animal diseases, comprising foot and mouth disease (FMD), rinderpest, contagious bovine pleuropneumonia and BSE. It has been suggested that this list should be expanded, to include, for example, highly pathogenic avian influenza. The International Committee (the General Assembly of National Delegates) is empowered to take such decision. It is clear that the OIE would need significant additional resources, both financial and staff, to respond to such a decision.

27. The OIE is responsible for the global provision of official information on animal diseases including zoonoses, based on the obligations of its Members to notify diseases and significant epidemiological events. These obligations are set out in Chapter 1.1.2 of the OIE *Terrestrial Animal Health Code* and Chapter 1.2.1 of the OIE *Aquatic Animal Health Code*.

28. One of the most important roles played by the OIE is in advocacy for the world's Veterinary Services. As mentioned above, a collective political commitment is needed if the world is to deal with serious animal diseases and zoonotic diseases more effectively. To secure this commitment, intergovernmental organizations, regional organizations and individual countries must be prepared to provide policy makers with the right information, arguments and tools. The OIE is a key player in this process. Convincing arguments must be based on a qualitative and quantitative evaluation of the political, social and economic benefits to be gained by investing more in new national, regional and worldwide animal health systems. Recent studies conducted by the OIE in conjunction with the World Bank and the FAO clearly demonstrate the significant economic advantage of investing in disease prevention rather than simply responding to disease incursions. Disease prevention, in turn, depends upon field networks for surveillance and for the administration of vaccines, where this is judged to be appropriate.

29. An important blockage to the effective control of serious animal diseases, including highly pathogenic avian influenza, is the lack of governance and limited effectiveness of national veterinary services, particularly in some developing countries where multiple government priorities (eg health, education, physical security) compete for scarce resources. Veterinary Services, including both public and private sector components, are in the front line when it comes to improving animal health and welfare. Increasing their effectiveness depends on the mobilisation of adequate human and financial resources. Good governance of Veterinary Services is a key element for success. Appropriate standards for good governance are described in the OIE *Terrestrial Animal Health Code*. Good governance requires both appropriate legislation and the necessary human and financial resources to apply it. Effective collaboration with other government sectors (human health and environmental management) and with stakeholders (livestock producers and community representatives) are important elements of good governance.

30. By evaluating VS compliance with the quality standards set out in the *Terrestrial Animal Health Standards Code*, the OIE can also identify priority areas for investment to obtain the needed improvements. The OIE aims to ensure that effective veterinary surveillance networks are in place everywhere, since early detection of diseases and quick, effective response are the keys to effective prevention and control of natural and deliberately introduced animal health disasters and this is accepted by all OIE Members.

31. In partnership with the World Bank and other major donors, the OIE is undertaking evaluations of the Performance of Veterinary Services (OIE-PVS) in more than one hundred countries, using experts trained and certified by the OIE. The World Animal Health and Welfare Fund, which was established by the OIE in 2004, is dedicated to this work of evaluation and analysis. The Fund is currently supported by Australia, Canada, the European Commission, France, Japan, Switzerland, the United Kingdom, the United States (US Department of Agriculture) and the World Bank. The importance of the complementary role that stakeholders (private sector and NGOs) play in carrying out animal disease surveillance is recognised in the OIE PVS process. The Fund also provides continuing education for national officials in charge of modernising the VS and maintaining relations with the OIE and for relevant private sector representatives.

Question 7: What are the main non-health causes of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas and what more needs to be done? Do you consider that there is sufficient “joined-up” thinking in approaching the problem?

32. As mentioned in paragraph 4, many non-health factors are contributing to the spread of infectious diseases, including zoonoses, globally and the actions of governments and intergovernmental organisations must address these underlying factors to the maximum extent possible. It is the view of the OIE that maintaining and in some cases strengthening the following activities will help to address some of the non-health factors listed in paragraph 4:

- Elaboration of standards for international trade in animals and animal products and helping all countries to implement the standards.
- Supporting countries in the diagnosis, early detection and reporting of diseases and unusual epidemiological events, including providing guidelines on disease surveillance in wildlife.
- Development and approval of new technologies to detect and control animal diseases and to protect the public from zoonotic diseases.
- Strengthening the legislative base and governance of Veterinary Services, including communications networks with Human Health Services at national, regional and global levels.
- Establishing standards for prudent antimicrobial usage in animals, respecting human health and animal production needs, and supporting countries’ implementation of these standards.

Questions 8, 9 and 10: *No OIE comment.*

Questions 12, 13 and 14: *No OIE comment.*

Question 15: What interchange exists between States in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?

The OIE comments relate to the control of avian influenza and other serious animal diseases, including zoonotic diseases.

33. Before the extensive spread of H5N1 HPAI in late 2003, FAO and OIE had already developed a Global Framework for the progressive control of Transboundary Animal Disease (GF-TADs), including a critical role for the WHO in relation to zoonotic diseases. It is the view of the OIE that the GF-TADs and other current activities described in paragraphs 34—38 needs to be maintained and supported by the international community.

34. The GF-TADs was developed with a strong emphasis on partnership with key regional organisations, including ASEAN and AU-IBAR. The GF-TADs has already shown itself to be an effective platform for global and regional coordination and collaboration of international and regional bodies in support of States engaged in the prevention and control of HPAI (and other serious animal diseases). The tools that have been developed and applied include:

- The Global Early Warning System (GLEWS), which provides disease intelligence and modelling for disease outbreak early warning;
- A Crisis Management Centre, for provision of a rapid response to disease events, for countries requesting support;
- A network of expertise on avian influenza including the OIE and FAO Influenza Reference Laboratories, and groups with HPAI epidemiological expertise, comprising OFFLU, to provide technical advice and training to national laboratories, to undertake research and to assist in the development of human vaccines; and
- The OIE World Trust Fund for Animal Health and Animal Welfare for supporting projects of international public good.

35. In addition, FAO and the OIE, together with regional agencies including AU-IBAR in Africa, are collaborating in the development of Regional Animal Health Centres to ensure that technical and operational personnel are accessible to national authorities to provide support in disease prevention and control programmes. Centres have been established in Nairobi, Bamako, Tunis, Gaborone and Beirut and more are planned.

36. Regional and sub-regional veterinary networks are being established and extended, engaging national laboratory and epidemiology personnel and those with expertise in socio-economic analysis, farming systems and biodiversity, in forums for the exchange of ideas and information with the goal of strengthening the quality and transparency of disease surveillance, detection and reporting. These networks need to be strengthened and sustained.

37. An effective laboratory infrastructure is critical in responding to serious disease threats because laboratory confirmation is generally required to confirm a diagnosis of a serious disease. Ideally, each country should have its own laboratory facilities but this is far from being the case. Some three quarters of the 172 OIE Members are developing countries and most of the OIE Reference Laboratories and Collaborating Centres, and associated scientific expertise, are found in the remaining one quarter of the OIE Membership.

38. All OIE Members are obliged to comply or at least move towards compliance with the international guidelines, recommendations and standards prescribed in the OIE Codes and Manuals for both terrestrial and aquatic animals. It is therefore very important to establish the necessary scientific expertise in these countries. The OIE has undertaken an important initiative to improve the geographical balance of scientific expertise to support the veterinary services in developing countries, thereby enabling them to fulfil their obligations as OIE Members. The main objective of twinning is to strengthen laboratory capacity in poorer countries with the aim that some could eventually have OIE Reference Laboratories established. In practice the program aims to link an existing OIE Reference Laboratory or Collaborating Centre with a laboratory in a developing or in-transition country with a view to exchanging scientific expertise and building capacity. The twinning concept could apply to a “north-south” or to a “south-south” relationship.

Question 16: The International Health Regulations 2005 are intended to provide a global framework for the rapid identification and containment of public health emergencies. How effective do you consider this response system to be? Do improvements need to be made?

39. The OIE is collaborating with the WHO in regard to disseminating reports received under the amended International Health Regulations 2005 (IHR). In 2007 the OIE informed all National Delegates that WHO notifications relevant to national Veterinary Services would be disseminated by the OIE on behalf of the WHO (see Annexes). The IHR are intended to improve the provision of official information on human diseases for the rapid identification and containment of public health emergencies. The OIE has much experience in this field. While the containment of animal health emergencies is a national responsibility, at a country's request the OIE assists by providing experts from its Reference Laboratories and Collaborating Centres to participate in field missions and provide advice and technical support. It is the OIE's view that the implementation of the IHR will help to strengthen transparency and to improve preparedness through dissemination of relevant information. However, States may still require assistance with response and containment activities, which may be provided by WHO or other international and regional organisations, as well as by developed countries working with donor organisations.

Question 17: What intergovernmental planning has been undertaken to cope with the impact of an outbreak of infectious disease caused by deliberate release of micro-organisms into the environment? Is there adequate liaison between the various agencies involved, including intelligence, law enforcement and health care professionals? How could action by intergovernmental bodies help further?

40. Preventing the spread of disease through international movements, accidental or intentional, is one of the OIE's key objectives. One of the OIE's most important activities relevant to this objective is the publication of international standards and guidelines aimed at, *inter alia*, preventing the importation of pathogens that are dangerous for animals and humans.

41. The OIE and FAO Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs) provides a framework for Members of these organisations to increase their capacity to manage disease occurrences, whether natural or deliberately introduced. However, compliance with OIE standards depends on the political will of national policy-makers, including the transfer of resources to developing countries to support good governance and appropriate policy implementation.

42. The OIE, FAO and WHO collectively provide advice to the United Nations on preparedness for the use of biological and toxin weapons, through participation in meetings of the Biological Weapons Convention and associated bodies, including the Expert Working Group set up to review the existing technical guidelines and procedures to investigate the alleged use of such weapons. The OIE has offered to provide experts to assist in investigations and to provide information to the UN in the event that it becomes aware of a suspected event of this nature.

43. The OIE has recommended that the United Nations consider passing a Resolution obliging Members to implement OIE standards. This would prove invaluable in strengthening disease prevention and response mechanisms and would provide the best safeguard against bioterrorism.

Question 18 is addressed with Question 1.

Question 19: *No OIE comment.*

Other relevant information:

Annex 1—“The Role of International Organisations in the Surveillance and Control of Epizootics” presented by the OIE Director general at the French Veterinary Academy of 5th October 2006 (English translation of an article originally published in French in Bull. Acad. Vet. France—2006—Tome 159—No.5 www.academie-veterinaire-france.fr);

Annex 2—“International organisations and their role in helping to protect the worldwide community against natural and intentional biological disasters”; B. Vallat, J. Pinto & A. Schudel, in Rev. Sci. Tech., OIE, 2006, 25 (1), 163–172;

Annex 3—Letter of 22nd June 2007 to all OIE Delegates on OIE-WAHIS and WHO-IHR: “Note on international disease information mechanisms”;

Annex 4—DVD overview of the OIE.

February 2008

Examination of Witnesses

Witnesses: DR BERNARD VALLAT, Director General, DR ALAIN DEHOVE, Co-ordinator, World Animal Health and Welfare Fund, DR SARAH KAHN, Head, International Trade Department, and DR ALEX THIERMANN, Advisor and President of the Terrestrial Animal Health Code, (Standard Setting Committee), OIE, examined.

Q1117 Chairman: First of all, may I thank you very much for your time this afternoon, we are very grateful. Personally, I am very pleased, as I am sure the Committee is, to be present at this office, which has a very established history—from, I believe, 1924. I think you have done a great deal of very important and very good work, so for that alone I would thank you. Our purpose as the House of Lords Committee on Intergovernmental Organisations is to look at the question of how intergovernmental organisations can work better and how we, in Britain, use taxpayers’ money to improve the working of these organisations to address the issue of contagious diseases. We are obviously more interested in the structure of the intergovernmental organisations and, with them, the non-governmental organisations than the actual diseases themselves, although that is very relevant. Part of this is the all-important aspect of where it overlaps with animal health. Can I say that these proceedings are recorded by our shorthand writer; they will be produced and you will see them in draft form and be able to make any factual corrections that you wish before they are published. They will be sent to you. Perhaps I should start by asking the members of the panel to introduce themselves and their roles. When we ask our questions, if anybody wants to come in and answer those, we would be glad to hear it. Our purpose is to get as much information as possible about the structure of the intergovernmental organisations and the need to address the animal health/human health

interface. Perhaps if we could start with an introduction from you and then we will start with questions.

Dr Vallat: Thank you. I would like to welcome you. As the UK is a very active member of the OIE, we consider your exercise very important and I decided to invite some members of the OIE staff to this exercise. I have invited people to participate with us and all British citizens working with us in the OIE in our headquarters in Paris. OIE was created before the United Nations, and that is why it is not part of the United Nations and is very proud to be independent from this body. You have proposed that the participants will present themselves, so I will ask my staff to do this.

Q1118 Chairman: If they could perhaps just introduce themselves and the roles that they play within your organisation and then we will start with the questions.

Dr Dehove: Good afternoon. I am Dr Alain Dehove. I am the Co-ordinator of the World Animal Health and Welfare Fund at the OIE.

Dr Kahn: Good afternoon. I am Dr Sarah Kahn. I am Head of the International Trade Department, a British citizen but most of my work career, in fact, has been in Australia and Canada, so Commonwealth countries. Since 2006 I have been responsible for the International Trade Department here at the OIE.

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Dr Thiermann: Good afternoon. My name is Alex Thiermann. I am not a member of the staff of the OIE, I am an elected member of the Code Commission, the Standard Setting Body of the OIE.

Q1119 Chairman: Thank you very much for that. Can I start with the first question, which is based on the evidence you gave us—that you see, not unreasonably, your primary mission to improve animal health worldwide, not least because of the crucial aspect it plays in human disease. You talk about the need for “new institutional and technical mechanisms for preventing and controlling animal diseases” spreading nationally, regionally and worldwide. What sort of institutional mechanism would you like to see introduced in order to improve that? Perhaps in answering that you could also tell me what the position is in relation to the United Nations. I think you were asking if they would pass a resolution requiring all 172 members of the OIE, but also more widely than that, to set the same standards that you set in veterinary services.

Dr Vallat: Thank you. Our fundamental text gives power to the national representatives nominated by governments to decide on the policies of the organisation through resolutions. We have an annual General Assembly and the members vote on resolutions. Each country has one voice. Currently we have 172 members (countries and territories). Two years ago they voted for a strategic plan. This is an exercise that we conduct every five years to ensure that we are implementing the strategic plan adopted by vote by our 172 members. The new strategic plan has put as the main objective of our organisation to improve animal health worldwide. I would like to inform you that this strategic plan was voted by unanimity by all member countries. To implement this objective we try to influence all members, and to do that we use different tools. One of the important tools is international conferences organised with other organisations, such as FAO, WHO, the World Bank. We participate in all international conferences which include objectives related to health or animal welfare. We obtain a position to express our opinion on this at international conferences and, of course, we try to influence resolutions always voted on by participants. This is a very efficient way to influence the international community to give more interest to our objectives. We also use official visits to different countries, contacts with governments and their administrations. We have official agreements with different international organisations with influence, such as the World Bank. We have an official agreement endorsed by our member countries and World Bank members and this is very useful to convince donors at a worldwide level to consider the animal health programme in developing countries as important in the competition we have between

different topics to be found in developing countries. Also, we try to convince governments of developed countries to invest in-country where there is a reservoir of pathogens, bacteria, virus, parasites, that it is more cost-efficient than trying to protect only the borders of a country.

Q1120 Chairman: Thank you. If there was one intergovernmental organisation that could put most pressure on countries to develop the standards in veterinary care that you seek to achieve, what would that organisation be? Would it be the United Nations? Who would it be?

Dr Vallat: We think that the United Nations could be one of the more efficient ways of convincing governments, but, as you know, internationally there are a lot of different bodies involved in health and we have to try to convince those bodies. We have the WHO and the FAO, but a better way is the United Nations in New York. It is difficult to have a statement made by the General Secretary of the United Nations. We got a very important statement three years ago during the avian influenza crisis because of the risk of a pandemic, not because of the risk to poultry. Thanks to that, the United Nations' General Secretary nominated a co-ordinator in New York, Dr David Nabarro, and this was useful for co-ordination between different United Nations bodies. Thanks to this crisis, the outcome was that our organisation had more influence on governments to convince them to make more available for prevention and control of animal diseases but, unfortunately, mainly for diseases transmissible to humans. We would like to convince governments to address all animal diseases.

Chairman: Thank you. I would like to bring Lord Desai in here because there is a crucial question about the political will and the ability to carry it out.

Q1121 Lord Desai: Thank you, my Lord Chairman. Dr Vallat, you say in your evidence: “an important blockage to the effective control of serious animal diseases . . . is a lack of governance and limited effectiveness of national veterinary services, particularly in some developing countries where multiple government priorities . . . compete for scarce resources”. Do you think it is your role to encourage individual countries to prioritise animal health as against other competing demands for resources? Secondly, do you think the World Bank should do more to fund the priority for animal health in their agenda of governance?

Dr Vallat: As soon as our member countries vote a mandate to improve animal health worldwide, it is our duty to provide the relevant information to all governments to convince them that they have to address these threats mainly because the world is changing and the globalisation of trade and the

movement of people is unprecedented. We need to provide this information because we are convinced that the threats are increasing because of the new factors of globalisation and climatic change. We provide all information to governments as to why they have to invest more than before in the field of animal diseases. Developing countries cannot fund this by their own resources, they need external resources, and it is in the interests of countries to have a disease-free environment after investments over years and they now understand it is more cost-efficient to invest in poor countries to protect themselves than to invest it all in border protection. That is why a specialised organisation, the World Bank, accepted working with us and using our technical inputs to develop programmes in several developing countries in the field of animal health. A lot of developing countries are using funds from the World Bank or the EC. The EC is a very active partner worldwide in the field of animal health investment.

Q1122 Chairman: Just before we go on to International Health Regulations, on the World Bank issue we have heard a number of times that there is a need for greater investment in the infrastructure of health systems in countries, and I wonder if the World Bank does not give sufficient attention to investment in veterinary systems in countries. Would you welcome a much greater emphasis on that? What could, and should, the World Bank do in relation to veterinary services that it is not doing already?

Dr Vallat: It is true that for 30 years the World Bank has considered priorities other than health and culture. The Bank funded more infrastructures in industry and not in health, but for the last five years the World Bank has been changing its priorities. We think they have to do more because the issues of sectoral investment have changed, but not sufficiently. We would like the World Bank to take that more seriously.

Q1123 Chairman: What would the investment be in veterinary services that you think the World Bank could do?

Dr Vallat: We are promoting a concept directed first at employment of governance. Governance includes appropriate legislation and appropriate resources to implement the right legislation to prevent and respond to sanitary events. First, any efficient investment needs appropriate governance. For example, if you found some material to address animal diseases in poor countries without appropriate staff trained for that you will lose your money. That is why we first need to be sure that governance is appropriate before putting money into infrastructure. That is why we try to convince

governments first to adopt the right governance and then to ask for loans or grants to carry out actions in the field.

Q1124 Chairman: If any other members of your panel want to come in on these questions, then please indicate.

Dr Thiermann: I would like to comment on the first question regarding enforcement. As you know, the OIE does not have the legal mandate to enforce adherence to the international standards, but the legal basis for that is in the World Trade Organisation. I think the World Trade Organisation, by having recognised the OIE as the standard-setting organisation for issues on animal health and zoonotic diseases, is where the obligations come for countries that do not adhere and properly justify their position in accordance with the standards of the OIE.

Q1125 Chairman: In some respects the World Trade Organisation is more important than the World Bank in terms of delivering the sort of structures you want, is that right?

Dr Thiermann: Not so much the structures but in terms of enforcement. The courthouse, if you will, for countries that do not use the international standards coming from the OIE to determine legislation in terms of international trade resides in the WTO, and the WTO in a case would seek the expertise on the international standards from the OIE to resolve that. The legal aspect comes from the WTO while the financial support and enforcement that Dr Vallat indicated will come from the World Bank.

Dr Kahn: I will just make a quick comment. I think the OIE is in quite a unique role because at the same time we are responsible for standard setting, and the standards relate to the control, management and reporting of diseases, and to trade. The standard-setting activity, as you can imagine, has a strong input from the developed countries. The reference laboratories and collaborating centres are largely in the developed countries. When you look at the membership, the 172 members of the OIE, two-thirds or more are developing countries and least developed countries. In a sense, if the standard-setting is driven by the more developed countries, what about the implementation of the standards? This is really the challenge for the developing countries. The OIE has got a two-fold role. It is the standard-setting, certainly, but it is also how to reinforce the capacities in the developing countries and how to encourage them and help to give them the tools to implement standards. Of course, there is the technical side, the technical capacity, and also the administrative and legislative, the governance aspects that Dr Vallat was talking about. In our minds, there is always the standard-setting role but, very importantly, how to support particularly the poor countries in putting

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these standards into place and the ultimate goal, certainly, to improve food security, to fight against poverty, but in a self-interested way for many of the members it is about removing the threats to their disease status, whether it is animal diseases or diseases that affect humans.

Q1126 Lord Desai: This leads me to the governance question. Dr Vallat, you have criticised the International Health Regulations because they “do not include specific measures, where zoonoses are concerned, that would enable the appropriate synergies to be developed with other international organisations”. Could you expand on that comment. How would you like other international health organisations to be improved now that the IHR are in force? How do they achieve the appropriate synergies between national and other international organisations?

Dr Vallat: I am still very frustrated by the content of the International Health Regulations because, if you read them (and I think there are 60 or 70 pages), the words “zoonoses”, “veterinary”, “veterinarian” do not appear. This is very surprising because it means that the role of zoonoses is not mentioned in this document. Why, because this document introduced new obligations for members of WHO ignoring the fact that the prevention of zoonoses is mentioned through different tools, managed commonly by OIE, FAO and WTO. One of the more frustrating parts of the IHR are that, under WTO obligations, the OIE provides obligations to our members, with the support of the WTO, to give certifications of safety of animal origin products regarding all zoonoses. The IHR do not mention the existence of this safety tool. It puts new obligations on the control of commodities which are not described in our standards. During the negotiations we tried to influence members and got the support of the staff of the WHO but not the support of the member countries’ representatives which was surprising to us.

Q1127 Chairman: Did they give a reason for that?

Dr Vallat: We think that the collaboration between the medical services and veterinarians worldwide has to be improved. We need to improve this collaboration and dialogue.

Q1128 Chairman: It suggests that they just saw it, for whatever reason, as two totally separate compartments. Is that how you see it?

Dr Vallat: Yes.

Q1129 Lord Avebury: Immediately to follow that point up, what opportunities do you see in the future of influencing the IHR so that they would incorporate some of your concerns? Are you lobbying member countries of the OIE to raise this

when they have the opportunity? At what point in the cycle of international meetings would there be a chance to inject some of the concerns that you have expressed?

Dr Vallat: The adoption of the current version of the IHR was made before the big crisis of avian influenza, which helped to bring about a better dialogue between veterinary and medical authorities worldwide. Thanks to this crisis, I think that, if there is a decision to be made in this sense, we could improve the IHR agreement.

Q1130 Lord Avebury: Where? At what point?

Dr Vallat: We could introduce some formal obligations in this agreement for member countries to improve the collaboration between people working in animal health and public health. We need a better mechanism for collaboration.

Q1131 Lord Desai: Just to continue with the IHR. As you know, the IHR has a surveillance system which has moved away from a fixed list of notifiable diseases towards a more flexible approach, requiring states to report “public health emergencies of international concern”. Does OIE continue to rely on a fixed list of notifiable diseases? Or do you have a flexible approach, such as in the IHR?

Dr Vallat: The list of notifiable diseases is voted by our member countries and currently we use 100 diseases, which are established using a decision tree which includes multiple parameters, including the zoonotic potential threat but also potential economic damage. We know that with globalisation we have emerging diseases and every year we have new diseases and that is why our system is flexible. Our members have an obligation to notify unknown events in case of doubt. There is a new obligation on that. We have a list of diseases because there can be a very important consequence for trade. There is an obligation of surveillance by countries, because any country can say, “I am free” if they cannot demonstrate they are making investigations. We know of at least 400 diseases and a country will not carry out surveys for 400 diseases, which is why we selected the more important on our list. In the case of new evidence there is now an obligation that exists in the OIE for emerging diseases.

Q1132 Lord Desai: Can I follow that up. We learned that in the IHR the WHO now has powers to use evidence from the media to be able to tell a government “you have such and such a problem”, even though the government has not reported. Does the OIE have such powers to be able to notify?

Dr Vallat: Yes. It is a complex subject. The OIE cannot make an official statement without the agreement of the government. The risk of a mistake is important. Sometimes the media puts news out

which is not verified, so the risk of making a wrong notification is high. We cannot do that, we would lose our credibility. We never publish information without the agreement of the government, so the government is sovereign. We know that some governments are lying and that is why we have a system called a tracking system. We use some software which is able to provide us with all information linked with media publications worldwide. All of the small publications for small villages in China we can have through the Internet. We have a common platform with WHO and FAO and the name is GLEWS—Global Early Warning System—and we exchange our tracking information. When we have information, we immediately contact the government and say “This is the information, please could you tell us if this is true or not”. We now solve 95 per cent of the events. We can have evidence that it is a mistake but when it is true, probably because of democracy in the world, the government cannot play with that and we consider that, thanks to tracking, thanks to communication with governments, we are able to give a very good picture of the situation worldwide.

Chairman: Thank you. I give the same option to your colleagues if they want to come in on any of these questions. Can I now bring in Lady Hooper, please.

Q1133 Baroness Hooper: Thank you. My name is Gloria Hooper, I am a Conservative Member of the House of Lords and of this Ad Hoc Committee. In your written submission, for which many thanks, you wrote: “it is well established that the control of zoonotic diseases in animals is both more effective and more cost-effective than managing the effects of these diseases in humans”. This reflects very much the views of other witnesses we have heard during other sessions, who have suggested that too much emphasis has been placed on treating infectious diseases as opposed to prevention efforts, and that we ought to be picking up new zoonoses from animals rather than waiting for them to leap the species barrier to humans. I know that you have already touched on this and stated that there is a need for more collaboration, but perhaps you would comment in terms of directing resources. Has there been too much emphasis on treating the effects of zoonoses and not enough on preventing or controlling the problem at source?

Dr Vallat: Thank you. We have a panel of 172 members and we know the situation of resources directed to animal health in many of them. We think that ministers in charge of human health have more success when they negotiate budgets than ministers in charge of animal health and they win the competition. I can give you an example. Worldwide we have more or less 50,000 people dying from rabies—mainly children, in India, China, Asia and

Africa—and the resources used by governments for the control of rabies are 95 per cent on post-bite treatments because dogs are the main source of rabies worldwide. We know too that, if less than ten per cent of this money was used to vaccinate dogs, we could eradicate rabies. This is because in the resource negotiations in parliaments or in front of policy-makers the human health aspect wins over the animal health aspect. There are other cases. For example, with avian influenza the money for the prevention of the pandemic is more important than the money for eradication of the disease in animals. We know that, if we eradicate this virus in animals, the risk of a pandemic will be reduced. This is why we think we need to work politically to put that on the table in all countries.

Chairman: That is an important point.

Baroness Hooper: Well, I hope that, as politicians, that we will be able to raise this issue in the various fora that we work in because on the figures it is incredible. Thank you.

Q1134 Lord Howarth of Newport: Good afternoon. I want to go back over ground that we trod on in your response to my Lord Chairman’s questions about what you might expect the World Bank to do and also partially in your response to Lady Hooper’s question just now. This is about the dilemma between disease-specific strategies and strategies to strengthen infrastructure more generally. In your evidence you say: “as a result of successful disease eradication campaigns, some veterinary services have been downsized to a point that is unsustainable. To be capable of early detection of and rapid response to diseases of animal and/or public health importance, a sustainable veterinary infrastructure and scientific capability must be maintained”. I have two questions that follow, one just on a point of information. Which disease eradication campaigns did you have in mind? Where has this occurred? Secondly, have you experienced the same difficulties as have been experienced in the field of human health, that an excessive proportion of available funding goes in programmes to address particular diseases and an insufficient proportion goes in programmes to support a broad-based capacity for healthcare and disease eradication at source?

Dr Vallat: Thank you. That is a very complex question. I always start by talking about the money invested in Europe for the eradication of some diseases. For example, in the case of bovine tuberculosis Europe funded 50 per cent of the cost of eradication in EU member countries. This started in 1970. Billions of euros were invested in the eradication of tuberculosis. As soon as the situation became acceptable in countries, all the effort that had been made stopped. This gave the possibility for the disease to be reintroduced. In the UK you now have

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a big debate on tuberculosis. Investment will have to be re-made for this problem. There is the case of foot and mouth disease. In 1970, Europe, not the UK but the Continent, was heavily infected by FMD and the policy was to vaccinate all animals for eradication, and that was successful. After that nothing was invested for prevention. What is prevention? It is how can we be sure that a free country will remain free or will be able to limit any re-infection to a very, very short period. We have to work within the concept of early detection and this is relevant for any accidental or intentional introduction of pathogens. Early detection is the capacity of a country to maintain a network of surveillance mainly by the training of farmers and a network of veterinarians working closely with this network of farmers. If something appears in a farm, or even in a city, the warning will be made the same day, or very, very soon after, in order to allow a rapid response. What is a rapid response? It is a specialised team able to go immediately to where the event is suspected or confirmed to implement biosecurity measures, which are to block the pathogen when it appears and to stamp it out if there is no other route to kill the pathogen, to disinfect, control the movement and be sure the pathogen, the factor of the new element, disappears. This has a cost. The government has a responsibility and this has to be shared by public but also private providers, because it is in the interests of farmers for it to be prevented. It is clearly also a public good because it is in the interests of all citizens to be protected. There is a sharing of the costs between the different beneficiaries. This is the policy that OIE would like to promote in all our member countries, to convince governments that prevention has a cost and it is the responsibility of the government to decide by negotiation with all beneficiaries who has to pay. In all cases it is in the public good that government has to participate. This cost is mainly what we call a cost for a horizontal system, because 90 per cent of any investment in animal health can cover prevention of all diseases and only ten per cent is an additional cost to be focused on a specific disease. We always promote these systems first.

Q1135 Lord Howarth of Newport: Would you say that historically part of the explanation as to why there has been under-investment in veterinary infrastructure has been because it has been seen as the responsibility of agriculture departments, or ministries, and there has been an insufficient appreciation among politicians and in governments that there is an essential intimate link between animal health and human health, but that perhaps there is now a more widespread recognition of that?

Dr Vallat: Yes. I think many governments were not sufficiently focused on the sustainability of investment for detection and rapid response. A very small cost linked with the mechanism of surveillance would have avoided a lot of crises with a very high cost. Surveillance systems are an insurance to be paid by all beneficiaries and it is a better way to avoid crises which have very, very high costs.

Q1136 Lord Howarth of Newport: Do any of your colleagues want to add anything on these issues?

Dr Thiermann: Possibly the other reason could be that, when countries were affected by bovine tuberculosis, brucellosis or foot and mouth, as you say, it was clearly an economic issue for the agricultural sector and it was easy to justify a rapid reaction to solve the problem. As we all witnessed, the difficulty is determining how good your insurance should be when you are not sick. It is a bit more than having to fund crises and imminent problems rather than putting the money in a preventative system that will only prove its use once you demonstrate you have prevented a crisis like the one we are seeing with avian influenza.

Q1137 Chairman: That is a good analogy.

Dr Dehove: I would like to draw the attention of this Committee to the fact that, since the written evidence from this organisation, the OIE has published three economic studies on that topic. The results of these studies were presented during an international conference held in Washington in October 2007. The first study compared the cost of prevention against the cost of crisis. The second study was on the feasibility of a global emergency compensation scheme. The third study was on the pre-feasibility study for the possible use of insurance mechanisms for certain animal diseases. We are currently carrying out a fourth study focusing on the cost of prevention to demonstrate that this is not so expensive and is clearly a saving when compared with the cost of crisis. In addition to that, we have had a clear signal from the European Commission that we will work together on a fifth study on the categorisation of diseases to identify where the priority should be, what is a global public good, what is maybe less important, where money from the private sector could be used and where clearly public money should be focused.

Q1138 Lord Avebury: You have already touched on this to some extent. We have been told that OIE is about enforcing the ability of developing countries to comply with standards. Given the evidence which has been accumulated by these studies that have just been mentioned, is there a growing political will, at least in developing countries, to adopt the standards which simply has to be reinforced by the injection of money

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from the developed world to enable them to carry out their duties in compliance?

Dr Vallat: Yes. One of the main problems we are facing to implement our mandate is how to convince all governments to follow the standards that they have democratically adopted. Many developing countries vote on standards in the full knowledge that they cannot implement them, but they think it is a good decision and they will receive support from other countries to implement these standards. As we said before, we know that, if we would like to improve the situation of animal health worldwide and reduce the risk for free countries, such as EU countries, regarding animal diseases, we need to convince governments and international organisations, including the World Bank and financial organisations, DG Development in the EC, to consider compliance of developing countries with OIE standards in the field of animal health. They have to be considered as one of the priorities of the development agenda. Because of zoonoses, we can justify that the directions made for animal health are also of benefit for human health. This is a very great argument that we can use. Compliance with OIE standards will have an effect on human health, of course, but also in this current problem of food security, the loss of food, the weight of animal diseases for poor people is more than 20 per cent of the production of animal proteins, which are very important for children—eggs, milk and so on. We have more than one billion people worldwide who are poor and need small animals to survive. The weight on the production of these animals, the weight of animal diseases, is very heavy. If we improve the situation, we can win more than 20 per cent of production in this category of people. This is very important. The link between animal health and the alleviation of poverty is important. The link with public health is important. The link with market access is important because, if a country is complying with standards, they will market access for everybody. We have more than 100 countries which have no access to the world market of animal products because they are infected by epizootics. The control of epizootics is also of economic benefit for free trade for everybody. This is very important for the economic growth of the world. Animal health is a great component of animal welfare because animals which are not healthy are not in a good situation of welfare, so the impact of improving animal health or animal welfare is also very important. That is why our member countries have asked the OIE to provide standards on animal welfare. This compliance with standards is a political problem because it is not only a decision of the United States but of all governments worldwide. We think that communication is really important and economic surveys also, as described by my colleague, to demonstrate the benefits of

animal health are really important for our communication.

Q1139 Lord Avebury: Can I just follow that up. You pointed to reasons of self-interest as to why developing countries should comply with the standards, but also in your evidence you think this should be reinforced by the transfer of resources. You have not said very much about the scale on which this needs to be done. If there is a political will and if countries are convinced by the arguments you have just been advancing as to why it would be to their own advantage to adopt the standards, they may still not have the resources to do so and you are implying in your written evidence that there is a question of lack of resources. I am wondering what recommendations you would make to see where countries have not got the capacity that the aid donors step in and provide them with the necessary resources.

Dr Vallat: I can give you an example of the strategy we are currently developing for that. Our members adopted standards on the quality of veterinary services, what are the criteria to be efficient, and using those we made an evaluation tool, and the name is the Performance of Veterinary Services, and we use—

Dr Dehove: We have 41 critical competences.

Dr Vallat: --- 41 critical competences. Each competence has five levels of quality, from one to five. We train, more or less, 135 experts coming from all over the world. We send these experts, on request from developing countries, to make independent evaluations of their compliance with standards on quality. 72 countries have asked us to do that over one and a half years. Today we have got 54 reports from these experts, who spent two to three weeks in the country. We have a peer review system and send the report to the country. If the country accepts the final version of the evaluation, we have got an agreement with the World Bank and the World Bank uses that report to design the investment programme for the country. This is very successful, and we think the global impact will be important to improve the situation in developing countries and also to provide appropriate investment and not investment made without an independent vision of the situation.

Q1140 Lord Howarth of Newport: I am just wondering whether the worldwide increase in food prices that has been so spectacular in recent months may mean that the moment is ripe to strengthen the drive to improve compliance with standards country-by-country, because that 20 per cent loss of output that you referred to in consequence of poor animal health represents an enormous opportunity if we know how to seize it in these circumstances.

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Dr Vallat: Yes. As you know, this impression of the lack of food worldwide is very recent. At the moment we use the human health risk more as an argument to invest than this argument, but now we will use this argument more and more—that we can save 20 per cent of animal production if countries comply with standards on the fight against animal diseases worldwide.

Q1141 *Baroness Falkner of Margravine:* This is really about standards and your plea that the UN should pass a resolution obliging members to implement OIE standards. I want to go into bioterrorism and biosecurity as well. Are you aware of other international organisation standards? And to what extent do you co-operate with them? I am talking specifically here about the OECD's best practice guidelines for biological research centres and things like that. This leads into biosecurity. While you have standards that you want adopted, to what extent are you working with other organisations in areas where you have synergies to bring about common standards or to have implementation, at least, of common standards?

Dr Vallat: We are a unique organisation worldwide entirely dedicated to animal health. For example, FAO have activities on animal health but their mandate is food, to improve production of food in poor countries. We have an agreement with FAO which allows synergies in this field and we have a lot of common actions. We have formal offices in Africa, for instance, the Centre for Animal Health, which is commonly managed between OIE and FAO. Our mandate is global standard-setting. We have a network of more than 200 reference laboratories and

collaborating centres entirely dedicated to providing us with better methods to control and prevent animal diseases. We think everybody recognises that we are the leader worldwide in animal health and we provide to other organisations what they need to implement specific programmes in the world. In the field of bioterrorism, we have very good relations with the Convention on Biological Weapons and we demonstrated to this organisation that, if a country complies with standards on animal health prevention published by the OIE, in the case of intentional introduction of a pathogen in a country the early detection will allow the event to be stopped very, very quickly. In a country without a surveillance network we would have a disaster because the spread of the pathogen would not be rapidly stopped.

Chairman: Thank you. I am afraid I am going to have to stop it there. I am sorry, Lady Falkner, you got squeezed at the end, but we will literally miss our train, which is a very great pity, because what you are saying is immensely important. If you think there is anything that we have left out, anything you would like to elaborate on, any particularly important points, then please write to the Clerk, Mr Preston, because we really would like to hear it. With the expansion of global trade, I think we are beginning to realise the immense importance of the link between animal health and human health, and that is one of the things that will come out in our report. Please, do not hesitate to contact us with any further information that you or your colleagues might have. Can I thank you once again for your time. I would like to congratulate you on your excellent English, which I have to tell you is far, far in advance of my French. Thank you very much indeed.

MONDAY 23 JUNE 2008

Present	Avebury, L (Chairman) Desai, L Geddes, L Howarth of Newport, L	Jay of Ewelme, L Steinberg, L Whitaker, B
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Examination of Witnesses

Witnesses: DAWN PRIMAROLO, a Member of the House of Commons, Minister of State for Public Health, Department of Health, and GILLIAN MERRON, a Member of the House of Commons, Parliamentary Under-Secretary of State for International Development, DFID, gave evidence.

Q1142 Chairman: Ministers, I know that Lord Soley has been in touch with you to explain that he is unavoidably absent this afternoon and has invited me to take the chair. First, may I thank you both very warmly for coming to give evidence to us and for the paper that the Government submitted earlier on in our inquiry and also for the evidence that we have already taken from officials. This session is being recorded and you will receive transcripts so that errors can be corrected. We will aim to finish by 1730 if that is all right. If at the end of the day you feel you have missed anything out, we would be grateful for any further notes you may care to let us have. As you may know, there have been a number of key issues that have emerged in this inquiry and the central question of global health governance has been referred to many times, including in the Government's evidence, where they say "The current architecture"—that is, of international health—"is crowded and poorly coordinated. Within the diverse group of organisations there is no agreed vision or clarity over roles." I wonder if you can tell us whether the Government has a strategy for addressing this problem and, in particular, do you think that the international community needs a formal structure to agree which different organisations will accept different complementary roles? Could this encompass the very large private and single-State organisations like for instance the \$45 billion Gates Foundation or the \$15 billion US Presidential PEPFAR fund on AIDS? If so, how could this be accomplished?

Gillian Merron: Thank you very much for inviting us to be here. We are very glad to be here together to demonstrate joined-up government, as indeed we have on this issue. To apply myself specifically to the question, first of all, it is a situation that we know needs to be remedied. It is a question that I think it is important to ask: is it possible to create a formal structure in which people will accept different but complementary roles? Yes, it is possible and, yes, it is difficult. For me, the reason we are in the crowded situation that we describe is because many organisations have evolved over many years,

sometimes in the absence of others. Now, we find ourselves in a different situation, with new challenges and a lot of new players. You mentioned some yourself—for example, the Gates Foundation. Indeed, there is a role for them to play. It is a fragmented place and, if I can refer first of all to the United Nations, the development of the UN over 50 years, the UN that we have today is very different to the UN that we had 50 years ago. I think therefore it has grown up in a somewhat fragmented way which is not now serving as well as it should do. There is very much scope to improve the effectiveness and coherence of intergovernmental organisations that are working on health and communicable diseases. Our work is to strengthen their performance and their accountability and to encourage more effective cooperation between agencies. Our particular focus, as you will know, is the International Health Partnership, which is about combining health system strengthening, which is absolutely crucial as you will have seen, I am sure, in our updated HIV and AIDS strategy. That is a very good example of joint government working in the UK, because it is a UK Government document, not just a DFID document. I think that is its strength. The IHP is about strengthening health systems, improved alignment by donors and international health agencies. In the medium term we would like to see mergers happening but we are realistic that that is not likely to happen in the short term. We are very much supportive of the H8 and the leadership of the World Health Organisation is very important. I myself met with Margaret Chan, and I pay tribute to her in her role. She is completely focused on the need to get results through the International Health Partnership and to bring organisations together. There is a lot of money, as you know, going into health globally but we are not seeing the levels of results that we would want to see. I just offer those as a few comments on the points that you make.

Q1143 Chairman: We will come on to the IHPs. But, just on what you have said so far about strengthening performance and accountability, do you think there

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is any formal mechanism by which this should be done? Should that be led by the WHO?

Gillian Merron: Yes, the WHO certainly has the mandate to lead on technical health issues. It is the correct place for intergovernmental agreement on health. Margaret Chan, as the Director-General, is very committed. We have seen improvements in the WHO but it cannot act alone and that is important to stress. We need to see UN reform. We need to see the other agencies all working together. For me, we need to see UN country plans. It is obvious; it needs to be re-stated and we need to be working to achieve that.

Q1144 Lord Howarth of Newport: I wonder whether you could give us a slightly fuller sense of where the need to achieve greater coherence, greater strategic impact, less duplication, more effectiveness really ranks in our own Government's scale of priorities. How important is this to the Government? How hard are we working on this? How much does it matter? What are you really doing to effect change?

Gillian Merron: I could give a very specific assurance to the Committee that our departments—the Department of Health, DFID and the FCO—are working together on the WHO institutional strategy. We are finalising that, and that is the UK's engagement with the World Health Organisation, which of course the Department of Health takes the lead on. If I could clarify the kinds of areas where we would want to see performance improved, I assure you, Lord Howarth, and the rest of the Committee, if it is only one lesson I can leave you with, it is that results are what matter. The amount of resources we commit is important. I believe we have proved ourselves in that regard. However, the UK plays a very important part in galvanising others, bringing them to the table. Leadership and coordination are crucial, because whilst I would like to see more resources coming into health, as much as that, I want to see resources used better for greater effect. I believe that the IHP is going to be helpful in that. The H8 gives leadership, and the WHO of course is the main technical leader. I would not expect them to be a funder. Just to mention some of the improvements that we are looking at for the World Health Organisation, perhaps to give some indication, because that is what will come out of the institutional strategy, we would like to see improving the way that there is work done at country level, particularly with other multilateral agencies, including the UN. We want to see more effective support to governments in development and implementation, national plans on health, and closer integration for the World Health Organisation's own approach on that. Important in all this is making sure we have the right mix and quality of WHO staff at country level. We also want to see a properly functioning performance management system for WHO staff, and a

performance framework of course should include the WHO's own indicators on communicable diseases. All of this we are working to ensure through our institutional strategy which, for me, is the best example I can give you of cross-government working in the UK to get cross-international agency working globally. If you ask me for my sense as a Minister, we are extremely focused on it and we need to do more. I am very hopeful that the Committee's deliberations will assist us in that.

Q1145 Chairman: Shall we move on to the International Health Partnership, which you have already mentioned, and which was prominent in the Government's written evidence, where you refer to the launch by the Prime Minister last September to strengthen health systems and improve alignment by donors and agencies, including those with a disease specific mandate, of which I remember Dr Tyson told us that there were more than 100? How does the Government envisage the IHPs integrating with the Global Fund Country Coordinating Mechanisms and also with 'One UN' model that we were told about which was being piloted in eight countries bringing together donors, ministers and other stakeholders?

Gillian Merron: For me, the launch of the IHP was something of an important political milestone. I think it is the first time the global health community have come together with a clear signal that we cannot go on as we are. It is important to recognise we have a crowded market place and we are not making as much progress as we would like. That political commitment that was shown was very important. In my own discussions, I am quite clear that what the IHP cannot be is just a talking shop. What it has to be is something that is implemented and very real, that will contribute towards us meeting the Millennium Development Goals. Three principles aimed at improving the health of the poor, I feel, are important to elaborate. Country-led national health strategies is the first point. Secondly, funding is coordinated around these strategies. That does require organisations like the World Bank, the Global Fund, GAVI and the bilateral donors, like DFID and others, to sign up to that. Interestingly, there are also moves to fund and support national strategies. Again, that is a shift. The third point of course is the strengthening of health systems. I have already mentioned our updated HIV and AIDS strategy, which makes a commitment over seven years. The strongest way we can deal with HIV and AIDS is to strengthen health care systems. That is one side of it, but the other side of it is that the developing country governments have to agree to invest more to address bottle necks and to strengthen their planning and accountability systems. The IHP is the organising framework for support but it is

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requiring all the relevant players to come to the table. I was in Zambia last week. The interesting thing there was seeing the important role of civil society that I would want to highlight to the Committee, because there the IHP is encouraging civil society to work more closely with the Ministry of Health, to address the needs of the people in local communities. I am happy to give more detail about examples of improvements that we have seen already, but the IHP is international organisations and those countries that have signed up—we hope that more will—saying, “We will commit ourselves to coordinate, to work together on those three principles.”

Q1146 Chairman: You mentioned the need for coordination. I was wondering how the IHPs can work with the Country Coordinating Mechanisms. Is that a possibility for a further merger? We have only heard about one merger between organisations at country level during the whole of our evidence. I think that was a case of maternal and infant health. Do you think that the IHPs could take on that role with the Country Coordinating Mechanism? And can you think of any other multilateral initiatives that require the attention of donors and recipients at country level that might also be dealt with through the IHPs? What about, for instance, the Global Early Warning Response System or the Global Influenza Surveillance Network? Do we need separate organisations to do all those jobs?

Dawn Primarolo: That is a very good point in trying to respond to what is the interaction between in-country and the multilateral bodies. What we are trying to do around discussions, whether it be animal and human health or the balance of investment, is to firstly start from the principle that what we need is that each organisation is very clearly focused on its core remit. We need them. They do vast jobs which are important, and there is cross-over, as you would see in a Venn diagram. The first thing that we would want to make sure is that we do not lose the focus on the core remit, which is part of the discussions that we are having both as Government through the Global Health Strategy and at the WHO through the Institutional Strategy, and also looking at the balance of funding. Then we need to move on from that to make sure that, having satisfied ourselves that we will not lose that core focus, there can be coordination and that it is sensible in country, so there is not duplication. It is a slightly different way of approaching the point that you made earlier, Lord Avebury, about making sure there is not duplication here, but equally we should not underestimate—I know your Lordships have not and certainly Gillian and I do not as Ministers—the vastness of the challenges for global health development and the very great difficulties in setting priorities. I think it is a very fine balance. Through our efforts, supported

by the Foreign and Commonwealth Office as well through Lord Malloch-Brown, the three of us working very tightly together trying to advance these arguments, that is really where we are trying to get to. Clearly we see the WHO as the best placed with the skills and we have huge confidence in them as an organisation to manage those protocols and those bilateral arrangements.

Q1147 Baroness Whitaker: I suppose this is really a DFID question. I was very pleased to hear you say, Minister, that civil society was particularly important in implementing health policy. I saw some evidence from the International HIV/AIDS Alliance hoping that DFID might make more substantial investments in civil society in their responses. Perhaps you could tell us a little bit about DFID’s view of what should be done to encourage civil society.

Gillian Merron: Civil society is crucial because it is about securing political will. The thing that I have learned—and I am sure many Members of the Committee would agree—is that often where we come to the biggest block to progress is political will. We would probably all understand as politicians that when people in our countries speak and demand we listen. Without that voice, it is harder to make the case. That is why civil society is so important to us. In Malawi this week just gone, where I was also visiting, I saw perhaps one of the best examples of community engagement that I could imagine, which was DFID-supported. In visiting a community, it was based on our work in Nepal which has been highly successful in reducing maternal mortality, because it was giving a voice to the people in that community who, with the greatest confidence, I think would have impressed all Members of the Committee. It certainly took my breath away. Young women stood up and said, “This is why we are dying in childbirth. This is what needs to be done. This is what has improved and this is what now needs to improve.” To be quite honest with you, it would be hard not to listen to that because they just spoke sense. Civil society has to develop that voice and then politicians have to hear it. When I meet with ministers, when I visit various countries, I have various messages to take there, as doubtless people bring to us too, but it is not sufficient that I say, “We need to work harder on maternal mortality.” The men and women of that country also need to do that. I hope through that you can hear that we have in-country very specific plans for developing that voice because, without it, I do not think we can secure that political will to greatest effect. I am increasingly seeing how powerful that is in making change. I think here civil society is very strong and we almost take that for granted. When we go to developing countries, we are talking about sometimes a very new voice. Again, our level of expectation has to be there,

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but certainly DFID is very clear about the role and importance of it, yes.

Q1148 Lord Geddes: Dawn Primarolo, you made a very interesting comment a couple of minutes ago on promoting—my words, not yours—the WHO as being the obvious body, the natural body, to lead. The thing that has worried me throughout this inquiry is that, sometimes for very understandable reasons, there are an awful lot of chiefs and relatively few indians. What mechanism could be used to try and reduce the number of chiefs and increase the number of indians so that you really get a focused, international, global strategy on this subject?

Dawn Primarolo: Our view is that by the discussions that we are having now with the WHO on the institutional strategy, it seems to me, it is how we interlock as well and how we hold, as members of the WHO, the WHO accountable for what it delivers. We all of us recognise our limited resources with massive challenges and expectations so that it is necessary that the WHO is able to prioritise and then to be accountable for that. If we look at our relationship as one member, but also as Ministers, we see this in the UK as well. For us as Ministers, we have to be accountable for the resources that have been spent and to explain why that happened. It seems to me that by the institutional strategy, by agreeing on some clearly identified objectives, goals, coupled with recognising what needs to be done in country and cooperation with other international bodies that also might be working, in that way we can have a dynamic that pushes that forward. We recognise what the pressures are. I think that will bring it about. A point was made about reform and development globally in terms of other funds, the Gates Fund for instance, and how that interaction would then occur. It seems to me that a WHO that wants to be able to embrace and engage with something like the vast resources that we are talking about being available in the Gates Fund does require it to be clear on its core remit, focused on delivering that and then be able to coordinate and be flexible where it is necessary. I think that will start the process of what you are suggesting. I have to put in a caveat. We are talking about a huge challenge for the organisation where each member is trying to say, “These are our priorities. This is what we want you to do” and pulling them from one end to the other. I think that is a way to deliver what you are seeking.

Gillian Merron: The Prime Minister launched an initiative on the reform of international institutions in January, which is key to the point that you are raising, which is quite understandable. There are three main areas to DFID’s work on this. First of all, about gathering and strengthening the base of evidence. That is particularly important in respect of accountability. Secondly, promoting reforms of

various agencies and, thirdly, seeking to increase effectiveness at country level. I would say, particularly when you look at the United Nations, that is very key to seeing them operating as One Country plans. It just makes so much sense. We need to encourage that to happen. I mentioned the long term, about seeing mergers. We would like to see mergers amongst some of the international initiatives. We also recognise that is longer term but just to give the Committee an idea we feel we should brainstorm around mergers—for example, the Global Fund and GAVI—and, in the future, UNAIDS. Then, of course, there is the UN country programme. It is a big challenge. These are big beasts and we believe that the fact that they are big beasts will not put us off. It is all the more reason to work with them and with others to secure institutional reform, because I do feel that is going to be crucial to delivering the results and improving the lives of poor people. That is what we are here for, not to create huge organisations that sustain themselves. I feel quite strongly on that.

Q1149 Lord Jay of Ewelme: I was very glad to hear that last answer. I was going to ask whether you had any specific examples to give us and what the mergers in the medium term might be. I would like to bring us back to Whitehall and joined-up government and the institutional approach which you are taking here in pursuit of the government’s Global Health Strategy. Health is one of those classic issues which cuts across many different departments—I suppose, in particular here, the Department of Health, DFID and the Foreign Office. You have already said you are an example of joined-up government by being here together and you have talked about the importance also of working with the Foreign Office. But I just wondered whether you could go a little bit beyond that and say how you envisage the structure which will emerge from these deliberations. Do you see there being, for example, a lead department among the three? We were quite interested when we were in Switzerland to see that the Swiss were giving their Foreign Ministry the lead in international health issues. DFID having the lead would be another one. I suppose another model would be the equivalent of a Climate Change Office which brings together officials in different departments to handle a specific issue. I just wondered if you could say something to us about how you see the results emerging from the discussions you are having to ensure effective Whitehall coordination, which is crucial to this.

Dawn Primarolo: Currently we are working on developing a joint strategy for the government, a Global Health Strategy which is about how the whole of government should be interacting and working with the WHO. That includes the Department of Health, DFID, the Foreign and Commonwealth

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Office but does reach across to some other departments as well, depending on what we are considering, the BERR or the MoD under some circumstances.

Q1150 Lord Jay of Ewelme: And Defra on animals, presumably, too?

Dawn Primarolo: Indeed. There is an Inter-Ministerial Group on Global Health, which is chaired by myself in the Department of Health. I hesitate to say the lead department. I would describe it as the department with responsibility to coordinate. That is rather long.

Q1151 Lord Jay of Ewelme: Why do you hesitate to say the lead department?

Dawn Primarolo: Because I think that what is important in developing the Global Health Strategy is that, whilst the Department of Health clearly has a very big role to play, particularly with its expertise in terms of health protection and health security and our experience in the domestic situation, it is not only about health and should not only be left to health. It is important that we look for the policy synergies in other departments as well and we are working together. That is what it is designed to do. I suppose, as I am Public Health Minister, if the Government thinks that the only person who deals with public health is the Public Health Minister, we would be missing a beat: transport, environment, housing, and it is the same here. The Department of Health is the lead department in that sense. It is coordinating and working with in partnership and parallel through the Inter-Ministerial Group. Clearly, the Foreign and Commonwealth Office has a great interest as well in this for global security as well as other issues. That strategy which we are finalising as Ministers now and agreeing will set the outline for how the departments should work together through the Inter-Ministerial Group. We will be able to bring in departments as we need them if there is a cut-across into that department. I think it recognises what everyone is bringing to the table. Of course, the Department of Health has very considerable expertise but the partnership, particularly between DFID, the Foreign and Commonwealth Office and the Department, is important here.

Gillian Merron: I want to mention a particular area which I think will be a good one and show joined-up working, although I have already mentioned the HIV and AIDS updated strategy. We have some evidence of us working together, but global shortage of health workers is a huge challenge and a huge possibility for working together. I have been in discussion with Lord Crisp about his report and where we can go. Clearly, we have to work very closely together. I think the Committee can be reassured that not just goodwill but the structures are in place to do it.

Obviously, the Department of Health has the seat on the WHO and we work quite happily with that. We are just seeking to maximise the benefits out of our working together.

Dawn Primarolo: A recent example with the work that we did with the Departments of Education and Health was with regard to professionals—in this case health and educational professionals—who are going to do a placement. There were some arrangements that were necessary with a great amount of effort by government that were very important to those individuals around a consideration of pensions and maintaining them in the national insurance scheme for obvious reasons for them individually. You can go from quite small but nonetheless important issues like that right the way through to the workforce.

Q1152 Chairman: When we heard evidence from Dr Silberschmidt, from the Swiss Federal Office of Public Health, he made great virtue out of the fact that health is an explicit part of the foreign policy of the Swiss Government. I notice that in the *Health is Global* document, which was presumably for discussion, the question was asked: “How can global health be more explicitly integrated into UK foreign policy?” I wonder how far you have got in your thinking on that subject and whether in particular you are going to respond to the Royal College of Physicians’ discussion on communicable diseases at their conference which was held on 29 April.

Gillian Merron: We are very happy to respond to their views. There is a further question. That is the role of health in respect of economic growth. If I could revert back to my comments on political will, my view is that in the UK we take for granted that people understand that a healthy, well-educated population is essential to growth. I am not convinced that is the case in developing countries. I believe it is an argument we cannot avoid having. Referring to Baroness Whitaker’s comments, the role of civil society is crucially important in holding the government to account. There can be a tendency, which we have to overcome, that health is isolated. It is not. It is a contributor to other policies and well-being and that includes political and economic. This is an area that we need to be developing more but I do feel civil society has a role there.

Dawn Primarolo: There is a slightly different approach from us and the Swiss. The Swiss were looking at how they can make sure that government action was coordinated, absolutely vital. What our Global Health Strategy is doing is looking at areas of policy as part of our global health policy that we want the departments not only to be coordinated but to focus on. It is responding to the same propositions about the need to coordinate, but it is putting in as well the idea of policy objectives, fair and free trade, development of effective health systems, so we can

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begin to see then how that would pull a number of government departments into that, to make sure that we were not inadvertently crossing over an objective that we had set somewhere else. Obviously that is a very big objective for us and this is right at the beginning, but we are quite hopeful that this strategy will provide that first stage.

Q1153 Lord Howarth of Newport: We are talking about how to enlist the most useful contributions from a variety of departments. One of the suggestions that Dr Silberschmidt made to us was that it would be of outstanding benefit to developing countries if they had more of what he called Health Diplomats, people who were trained to negotiate with the IGOs, with the big NGOs, with the bilateral donors, because one of the difficulties for a recipient country is that there is this bombardment of goodwill coming from all these different directions and it is extremely difficult to assimilate all this help, to coordinate, to prioritise and to make sure that you do get the right kinds of help and that you are best placed to use it most effectively. He thought that, if developing countries more often had skilled negotiators who could field and absorb the support that was being offered, that would be a good thing. Is that something that we have thought about? Have we thought that, for example, our own Foreign Office, perhaps in combination with DFID or the Department of Health, would be able to assist in training people who would then go back to their own countries to perform that kind of role?

Gillian Merron: It might be interesting for the Committee's considerations that we have taken the view—and it is the Committee's starting point—that we think it is very crowded out there and to acquire that level of expertise, rather than getting developing countries to respond to our architecture, we feel the right thing to do is to revise and reform our architecture. A very specific example is in Zambia. Whilst we are not the biggest donor on health, we are the Zambian Government's preferred partner to deal with. There is a great discipline there. They only deal with the UK. The WHO represents the constituency of other countries. It works very effectively. My instinct is that we should be tackling the problem rather than expecting others to respond to us. I was reading that Vietnam had had over 700 missions come through the country. That is probably a full-time job for a team of people. Is it the best use of resources that we have a full-time team of people to accommodate us and every other country that wants to come and see or is it better that we organise ourselves? My strong feeling is we should be organising ourselves and exerting greater discipline, and it is happening. The African Development Bank uses this very well. We do have a constituency where we have a lead country and they are represented. The

other point in all of this that matters is that it should be country-led rather than us telling countries how to reform themselves. I can see why somebody would suggest that but that would not be my instinct. Interesting, though!

Q1154 Baroness Whitaker: We have heard that three-quarters of emerging infectious diseases originate from animals but that the international systems for human and animal health operated by WHO and OIE are not integrated, so we tend to find out about new animal diseases—for instance, H5N1 avian influenza—only after they have jumped across the species barrier and infected humans. The Prime Minister, when he was stating what the national security strategy was going to be, said, “On disease and global pandemics, our priority is to improve early warning systems.” Is there not a strong case for bringing together international human and animal disease surveillance onto a common basis? And, if so, what is the Government doing about it?

Dawn Primarolo: I think there is a case for better coordination. If we look at the activities at an international level, whether it be the WHO dealing with human pathogens or OIE dealing with animals, and then we see the collaboration between those two agencies and the links to the Food and Agricultural Organisation, and all of those feeding into groups, we can see that in that architecture there is a possibility for the exchange of information. Of course, there is an argument for there to be better communication between those. The real problem is the data that is available to the system in the first place. That is the surveillance, the corner stone of it. We can see that there are quite significant problems in countries for getting us that early warning surveillance. Again, we cannot underestimate the huge scale that we are dealing with here. Those are dependent on very difficult things like accuracy of diagnosis of the disease, reports through reliable infrastructures, capture of health data and demonstrating politically that the will to share early suspicions of diseases is very important. The challenge internationally is that the information still remains incomplete. Yes, there is therefore a case to strengthen the capability of developing countries in particular to have the internationally agreed protocols of notification. Again, that is something that we perceive that the WHO has a key role in. It is very important for us to support them and encourage them wherever we can. The separation of animal and human diseases in different agencies is not unique internationally. We do it here for good reasons. It comes back to the point I was making earlier about a core focus but looking for the synergies. The work that we do to support the WHO in its efforts, whether it be the veterinary laboratories at Weybridge which are one of the international places and certainly the European or

the HPA laboratories for human pathogens at Mill Hill, the work we are doing on pandemic planning both for ourselves and engaging with the WHO and sharing our experience. I think today at an international meeting we were talking about what the UK is doing and whether that can be translated into an international dimension and example. That is the way we are going to have to proceed. We have to recognise the challenges that that gives us, and that makes it all the more important that the work Gillian was talking about in building capacity in country, using the networks, particularly civil society and connecting that fits together. I suppose that is a very long answer. Our problem is not coordination at the international level; it is making sure we get the surveillance in country and the timely information, which is a different problem.

Q1155 Baroness Whitaker: The work that we do diplomatically in the WHO is presumably related to the surveillance of human disease. The WHO cannot be expected to reorganise OIE and FAO to make sure that there is more accurate prediction of animal diseases of this sort which are likely to be dangerous to humans. Does your being joined-up also extend to the animal health side internationally?

Dawn Primarolo: I think there is that cross-over when it is necessary and when it is identified that H5N1 and the possibility of a mutation into humans that the ability to be able to forecast that or to map it is absolutely dependent on having received timely and accurate information from the country concerned. That goes back to the institutional questions as well about who is the most appropriate and where is the information and whether the international architecture could do with some change in terms of the UN has a system for influenza coordination and there are these other bodies involved. What we want to make sure is not that they all try and do the same thing. They do what is appropriate and timely information goes to the right place. That is broadly there if we can get the information in and people focus on what they should be doing, not what they think they should be doing.

Q1156 Lord Howarth of Newport: Does our government play a part in programmes to strengthen the infrastructure in developing countries of animal health care, as we seek to do with human health care, and to ensure that within those countries the strategies are coordinated?

Dawn Primarolo: The answer to that must be Yes—through the OIE, but I would need to check that. My understanding, dealing in the UK between HPA and Defra, is the necessity for the interaction when it is appropriate.

Gillian Merron: I think we should let you have a note on this.

Q1157 Lord Geddes: Is the experience of the Department of Health in particular that the instances of nations coming up front and advising international authorities of animal disease and indeed the jumping across to the human side—is there a lessening of reluctance or an increase of reluctance to divulge that? One can quite understand that for economic reasons countries might say, “We want to keep quiet on this.” What is the experience of the Department of Health?

Dawn Primarolo: The experience is that with these great challenges—SARS is another example—countries recognise that early detection and prevention is the best way to deal with it. The expertise and the support that they need to advance that is something that can be accessed through the WHO or with the UN, through its system of influenza coordination. I am not saying that is absolutely everywhere but that is recognising that the best way to deal with these highly contagious, dangerous infections is early intervention which means you have to have early identification so that the countermeasures can be deployed. I attend on behalf of the Government the G8 Global Health Security meetings, and the discussions that we have there give me no reason to believe that that is not the case. Of course, it is a challenge, as you rightly say. If you have one farmer with a few chickens and the whole family livelihood depends on it and some of them are sick, there are issues there that need to be recognised and dealt with.

Q1158 Lord Desai: TB is the biggest killer of people who are HIV-positive. We have been told that. We need to have some coordination and synergy between the two. We have been told that neither TB nor TB/HIV co-infection is fully incorporated into DFID’s strategy for tackling HIV/AIDS. You talk about Government support for more integration in the latest document. What are you specifically doing about it?

Gillian Merron: I am aware that the Committee has been told this. I was rather surprised, not least of all because I was looking back at the requests from the various lobby groups. We had a very considerable, very open public consultation and it informed us immensely in terms of our updated strategy. One of the requests from the lobby was to address TB and TB/HIV co-infection in the updated strategy. That is what the updated strategy is all about. AIDS is certainly closely associated with other diseases and health issues. TB and HIV are certainly fuelling each other. We are well aware of that and I would certainly agree it is the leading cause of death amongst people living with HIV. The need for integration is quite clear because of the challenge in drug-resistant TB infections on top of that situation. We are fully aware that we need to do more to bring services together.

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We are not just supporting the integration of AIDS services with other health services, including those for TB; our updated HIV/AIDS strategy sets out firstly a health spending target over seven years which I referred to earlier of £6 billion. That is all about the importance of stronger health systems and full coordination and integration of HIV and TB services. What it means in reality is having the health workers, the drugs and the facilities in place to be able to bring those two together. I can give particular examples. The Committee will be aware that we support many programmes in this whole area. For example, our commitment to the Global Fund to fight AIDS, TB and Malaria and UNITAID, the new drugs purchase facility. We also have very specific programmes to tackle AIDS and TB in specific countries: China, India and South Africa. In a number of countries where DFID is working, including Zambia and Malawi where I have just returned from, there is a very well established coordination of TB and HIV programmes. If the Committee would like more information, I would be very glad to supply that. Our whole line is about the best way to deal with HIV, TB and a number of others, to strengthen health concessionaire systems.

Q1159 Chairman: We would be grateful to have that.

Gillian Merron: I would be pleased to supply it because I feel it would give the Committee a very clear indication of how we are working and doing it well.

Q1160 Lord Desai: One of the things we were told was that TB testing facilities were some miles from HIV testing facilities. Very often, even if you knew that this person had it, it took a long time before the person went off. At country level you need a lot of joined up thinking or whatever it is.

Gillian Merron: You do. What that illustrates is that of course the testing facility needs to be in the right place. It may well be the case that there have been some health systems that exist but that is not our preferred option and it is not our policy and it is not where we are working. I hope it will be helpful to the Committee that we can give some good examples of very positive working but please be assured—you will find it fundamentally in the updated HIV and AIDS strategy—the coordination with TB services is very central. I think our commitment to the Global Fund shows that, so not just intent but action and resources.

Q1161 Lord Howarth of Newport: I would like to ask you how we are making sure that the bilateral funding that our Government provides is used to best effect. We were told by DFID officials, “In many countries, such as Tanzania, Uganda, Malawi, we are

providing substantial resources into the budget or health budget of the country to enable the government to deliver on its priorities as reflected in the national plan. In essence, we are putting money into the government’s systems, so how governments spend that is of great interest to us.” How can you be sure, and how can the taxpayer be sure, that the very significant sums of money that have been provided to developing countries are being used properly and efficiently, that they are being targeted where they will do most good and that the money is not staying in the capital cities but is getting out to the people who need it most? For example, Gillian Merron, you have talked of problems of political will in countries, and that is clearly a factor. There are problems perhaps also of limited administrative capacity, problems of corruption, problems of tribalism. What do we do to make sure that our bilateral funding gets past those kinds of possible difficulties and is really used most efficiently?

Gillian Merron: First of all, it is crucial to all that we do that money is used properly and gets to where it is needed and it is used to tackle poverty, that is the first point. When we provide budget support as aid direct to governments, it is one of a range of mechanisms that we will use and we will only use it. It is a preferred option, ultimately, in that it is the way to build up the systems that we have just been speaking of, which are government services, but we use it where we believe it will have more impact by going directly to a government than other ways. We do identify with our partner governments what we expect for that, and we monitor progress to make sure it is going to the right place. If I could be specific about what we do to make sure that money gets where it should. I do believe that is a very fair question from taxpayers in the UK which I am always willing to answer. The first thing is we assess the risk before we commit ourselves to budget support and we audit the use of the funds afterwards. The main assessment is the fiduciary risk assessment, a very detailed investigation and analysis of the public financial management and accountability system of the partner government. It assesses the risk, it makes sure that funds will be used for the intended purposes, that they will be accounted for and that they will achieve value for money. Then we use a whole variety of mechanisms to check on the use of funds during project implementations. We do not just give the money and go away, we are constantly working. Audits are undertaken by the partner government, international agencies and directly by DFID, including by the UK National Audit Office, and the audits are supplemented by public expenditure tracking surveys and other surveys which identify exactly how funds are used to ensure the money is getting there. For example, tracking through government systems to make sure the salary payment is made or the item is procured,

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whatever the judgment is. I would agree, Lord Howarth, that the question of capacity is crucial, and that is why part of our work often is about building capacity, as I mentioned earlier, within governments, not after the event but before the event. Our job, as I say, is to assess risk, to monitor and review progress with all the partners and we have all of those systems in place. It is probably also worth assuring the Committee that we take action if funds are not used properly. In 2007-08 we did reduce budget support to three countries—Sierra Leone, Ghana and Rwanda—because of issues that were related to public financial management and we also delayed budget support to Malawi and Sierra Leone pending receipt of audit reports. I feel we have very robust and responsive measures and a good assessment of risk before we start. However, it is the result that we are looking for and I think probably what I should express to the Committee is that each country is different. There is a statement in the House now about Zimbabwe, which is a very different situation to Malawi—to use two extremes. It is right to use that as an illustration of what we would do. In Zimbabwe we do not give money to the government, obviously, but I think it is important to state that because people are not aware of that. We do it through the most effective mechanisms. I should say, also, we only use budget support where there is a commitment by the partner government to reduce poverty, respect human rights, improve their financial management and their good governance, and that we are convinced it will be the greatest impact.

Q1162 Lord Howarth of Newport: From that answer, I am encouraged that you are clearly using all the bureaucratic means at your disposal and applying what would seem to be appropriate criteria. Can I just ask you about a particular case in point, of which I was personally aware? This goes back to 2005 and I should be comforted to be told that the situation has greatly improved. I visited Uganda, one of the countries mentioned by your officials in the paper to us, and there we were indeed providing a very substantial proportion of our assistance through budget support. I went up to northern Uganda, where there has been a substantial and appalling humanitarian crisis for a very long period. We found there was a morass of UN agencies and NGOs operating with huge energy and goodwill, but disappointing lack of effectiveness. The British Government's, the British taxpayer's, contribution was going to the Government in Kampala. There was a great deal of evidence that the Government in Kampala was not the least interested in ensuring that the humanitarian crisis in northern Uganda was relieved or that the civil war was finished. The Acholi people do not vote for President Museveni. In addition, there were some serious problems of

corruption in the Ugandan administration and yet we had taken a decision that we would trust this regime and the money was going to them. Obviously, I cannot expect you to know the particular circumstances that applied at that time but it left me very worried. I would just like to press you a little bit more about your systems of monitoring and your systems of evaluating the effectiveness of budget support provided by our own Government to countries that are in that kind of difficulty.

Gillian Merron: There are two points, perhaps, I can make in response to Lord Howarth's points. If there is something that happens which brings into doubt the arrangement that we have, then we reassess if budget support is appropriate. I feel what I must say to the Committee is flexibility—flexibility is perhaps not the right word—responsiveness to situations is for me very important. If necessary, we will reduce or suspend aid or deliver it in a different way appropriate to the situation. That will be one point that I would make. Also, the National Audit Office did conduct a study about budget support and they did report that, through the right sort of budget support, and taking into account all of the financial safeguards that I have mentioned, we did increase the capacity of partner governments to deliver, we did result in partner governments providing more services and it often enabled partner governments to increase their own expenditure on priority areas, which I think is also important. On the particular issue, again if it would be helpful, I would be very happy to come back to the Committee with details on how we responded to that particular situation that Lord Howarth refers to.

Q1163 Lord Howarth of Newport: To be fair, there had been some small reduction in budget support because the Government was unhappy about the political situation within Uganda at that time. I recognise these are very, very difficult judgments.

Gillian Merron: Yes.

Q1164 Lord Howarth of Newport: Just how you apply these criteria and how you apply your systems would be helpful to know more about.

Gillian Merron: At the end of it all, it is the poorest people in the countries we are talking about who must not be left to suffer twice.

Q1165 Lord Geddes: To an extent you have answered a lot of the question. I have just two points. You have twice prayed in aid—if I can use that expression—the National Audit Office. We have had evidence, also, that the National Audit Office is not all sweetness and light as far as DFID is concerned. They did highlight some weaknesses with DFID's performance, as indeed did the Common's International Development Committee. I just

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wonder if you can update us on that. The other thing is really more a statement than a question. We have, if you like, a working title, if I can call it that, at the moment, which is “Controlling the global spread of infectious diseases”, but in point of fact what this Committee is doing is looking at the value for money that the United Kingdom Government is getting out of its investment in IGOs and NGOs. That is key to our entire inquiry. When we see evidence from the National Audit Office or whatever which says there are weaknesses, what have you done and are you doing to address those?

Gillian Merron: We are working hard to improve our assessment of multilateral effectiveness, first of all to provide the evidence that is necessary to have the discussions with multilaterals on their performance and also to inform our own decisions about where we allocate our own aid. There are three strands to our work that I would like to highlight, which I am reiterating, in fact, which are strengthening the evidence, so that we can have informed discussions and promoting agency reforms, as we discussed at a corporate level but also at a country level. The new point, perhaps, I can mention for the benefit of the Committee, which I have not mentioned earlier, is that we are developing a common approach to multilateral effectiveness with ten other donors through a network called MOPAN. We are developing a set of indicators and we will be piloting it at the end of the year. It is expected to replace some of our previous work to make it more effective, so I am hopeful—not just hopeful—I am fully aware of our efforts to improve our situation in terms of making sure we do have the effectiveness that we are always seeking. On the issue of IGOs tackling communicable diseases, I would say that perhaps a corner stone in the Global Fund model is that it is actively measuring its grant performance based on sets of nationally proposed and owned indicators. I think we are seeing improvements in terms of assessments and, indeed, I have a number of figures which the Committee are very welcome to see, which show—although the Committee may already be aware of it—for example as of December 2007 Global Fund support meant that we had 1.4 million people on ARV treatment, 3.3 million on TB treatment and 46 million insecticide-treated bed nets being distributed. So there are very clear indicators of what is coming out of the efforts rather than just what is going in. I do think that is important. It is true to say, though, that although we have got the efforts of IGOs such as the Global Fund, on measuring their performance, it is not yet possible, desirable though it is, to assess the impact on development of multilateral organisations. Some of that is because it is difficult to attribute who, what and why is responsible for a change, and that is just a fact of the matter. We do need, and we are clear on the need for

agencies to be improving the quality of their evaluation and the rigour and consistency with which they are reporting results. I happen to think that is not only just important to us as a Government, it is important to UK taxpayers, because we are putting money into multilateral organisations and people do want to know. I want to be able to say, and this is if not directly the UK but in supporting this, this is the change we have made. That is the way in which we are working to improve the situation in a way, rightly, you are raising with me.

Q1166 Lord Geddes: You mentioned ten other donors, are they national or international? That was a fascinating remark.

Gillian Merron: Other donors such as ourselves.

Q1167 Lord Geddes: You said “ten other donors”.

Gillian Merron: I can let you have the list of countries.

Q1168 Baroness Whitaker: WHO funding. Less than a quarter of the funding available to WHO for 2008-09 falls within its core budget, out of which they have to fund their operating costs and programmes which they consider to be a high priority. This budget comes in the form of voluntary contributions, as of course you know, which are largely earmarked by their donors for particular purposes. In Geneva WHO have told us that this leaves them with little room for manoeuvre to invest in global health programmes, such as the ones that were mentioned, building up disease surveillance capabilities in developing countries. We would like to know what the Government’s view of this is and whether you think their funding systems need to be modified and, if so, how.

Dawn Primarolo: Yes. We are sympathetic to the problem that the WHO identifies. I think as you pointed out, over the last ten years earmarked funds from Member States have steadily increased. I think, first of all, we can understand why there has been a tendency to earmark, which is to be able to set priorities, to have that accountability of the money, but it does produce the sort of challenges that you have identified. The WHO cannot be confident of what their core budget might be. Clearly what we want, and we recognise this as Member States, we recognise that WHO has limited monies and has to set priorities but we need to have confidence in the framework that they go about setting those priorities and, picking up very much on the points that Gillian was making, about accountability of taxpayers’ money. The UK is currently discussing with them how we can most effectively ensure that our performance management arrangements, being able to account to Parliament for the monies we have given and how it has been used, can be arranged in a way that also provides the greater flexibility in

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funding that they are requesting. That is where the Institutional Strategy comes in, which is jointly managed by DFID, the Department of Health and the Foreign and Commonwealth Office, because what we are proposing to do is to indicate and support the mutual goals and objectives and, therefore, be able to demonstrate or ensure value for money. This over-arching framework, a sort of contract agreement with the WHO, would then be the basis for our funding. I have just received the figures for 2006 and 2007, and the UK paid the second largest subscription, £54.7 million in voluntary, which is quite difficult to breakdown between earmarked and not, £303.5m. The sort of things we will be looking at are how can we ensure there is an improvement in the work at a country level, working effectively with other multilateral actors, the points we touched on in earlier questions, trying to make sure they are using the synergies without the duplication, making sure there is a clear division of labour, delivery of health, advice and support to governments, effective support in the development and implementation of the national plans on health, and this might include closer integration with WHO's own planning instruments, making sure that they have the right mix and quality of staff—again coming back to the point Lord Geddes was referring to earlier on—that the quality of staff at country level is there, that there is a transparency of process and recruitment of staff, and also looking to make sure that the right incentives are in place, to ensure that their staff are engaged in the UN reform programme and co-operating, and, finally, to make sure the framework cuts across, so we have indications and indicators of what the main goals will be, particularly on the communicable diseases: Malaria, Polio, TB, HIV. In that way, seeking to establish a framework that is transparent for the UK, hopefully a model for others, in terms of accountability of resources, able to detect value for money, to demonstrate value for money, pursuing objectives which are our objectives but providing it in a way that gives the WHO the flexibility they need for that longer planning and being able to do some of the things which this Committee has rightly touched on as being necessary in developing countries.

Q1169 Chairman: Can I ask you if the international community is convinced of the importance of the WHO as a central player, 'conductor of the orchestra' as somebody has put it, in international health, why is it so difficult to increase the amount of compulsory contributions? And is that an objective of the Government or not?

Dawn Primarolo: Why it is difficult is because all Member States that are contributing want to say specifically what they expect to be done, and this is the huge challenge for the WHO, be accountable to

its members and respond, have strategic priorities and make sure that they are in line with the objectives of the donor countries. What we are trying to do is provide a model, certainly we believe it will work for us, that hopefully then will work for other contributors so that they can clearly see the accountability of their money. The wider political debate about why it is important for all countries to engage with the WHO is still one which needs to be addressed and does take us back to the Global Health Strategy and indeed the Global Security Strategy, in terms of recognising what the challenges are. I think there is some movement there. Whether it will end up with countries agreeing to making block grants, well that has not been the history in a number of multilateral organisations. I think that, if we have got transparency for ourselves, strategic objectives, we can give the flexibility to the WHO that they require but we can still see progress on what we consider and agree are the challenges. I think that is a good base to be on.

Q1170 Lord Desai: This is about vertical and horizontal investments. Obviously the vertical ones are business-specific, and it partly goes back to what we were saying about value for money. If you want to show value for money, you go for a specific vertical investment rather than a horizontal. We also know, however, that disease is due to poverty and water supply and so on, so horizontal investment is needed. It has been put to us that maybe the World Bank should be much more into horizontal investment in health. Are you urging the World Bank to do more for health investment rather than just building more dams?

Gillian Merron: Yes, is the simple answer, Lord Desai. To make the important point, of course, horizontal investment is about the building blocks of health systems, so that is the workforce and the drug procurement systems, the whole infrastructure, and without the building blocks being in place then you cannot get value for money from the vertical funding because there is nothing to root it in. We do need to find ways to increase funding for horizontal investment and we are pursuing several channels in addition to the World Bank. We are also pursuing the European Commission, GAVI and the Global Fund as well. There is a bit of an issue that the Committee might be aware of, which is that the World Bank's main funding is through the International Development Association and, of course, Ministries of Finance who see large grants for health coming from other places are a bit reluctant to use that World Bank funding because they see that infrastructure is even harder to fund. We are working with the World Bank to remedy the situation and we do want to create incentives with the Bank to use IDA resources for health. There is the role, of course, of the African

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Development Bank who do have a very strong specialist role in terms of infrastructure. It is probably a very good example of a more joined-up approach on the international stage to make sure that funding is getting to all of the right places. But, yes, I would certainly share your view that the World Bank does need to up its game, and we are seeking to assist.

Q1171 Lord Jay of Ewelme: A word about prevention and treatment, another of the great dilemmas. We have noticed that the Government said in its AIDS Strategy document that “prevention is far more cost-effective than treatment, largely because of the high price of medicines, but also because the disease is not curable—so treatment is for life”. Dawn Primarolo has already said earlier, in answer to a question from Lord Geddes, that as far as influenza is concerned again prevention is the best way of nipping the disease in the bud. We have also had some suggestion that the emphasis of the international community still tends to be too much more on treatment, for example, particularly antiretroviral treatment for HIV/AIDS rather than on prevention. I suppose this is also a case partly caused by the need to be able to show, and you can show, results more clearly in terms of treatment than you can in prevention. But I just wonder whether you thought we have got the balance right between treatment and prevention or whether, in our own aid programmes or in the pressure we put on international organisations, we should be arguing for more emphasis on prevention than treatment and, in particular, stressing the need for better information systems, better for disease surveillance systems, so that we are better able to know what is going on and can thereby put the prevention in place. I would be interested to hear your views on that.

Dawn Primarolo: I think, Lord Jay, as you acknowledge, it is not an either/or, it is getting the balance right. But we are absolutely clear, through our own *Achieving Universal Access* and the UK Strategy for halting and reversing the spread of HIV in the developing world, we recognise absolutely that, unless more is done on prevention, the epidemic will continue to grow faster than our efforts to control it and the cost of treatment for care and support will continue to escalate. We see that on a much smaller scale, tiny scale, in comparison in the UK. Our efforts are on prevention and commitments to intensify those efforts particularly, as Gillian touched on earlier, mother-to-child transmission, family planning and harm reduction. We recognise nonetheless that there is still a need for a greater effort but it has to be set within a universal access. HMG was the third largest provider of contraceptives and commodities to the developing countries in the period 1996 to 2004, so we are pushing ahead on that. But also, as you said, we have to have evidence on a

sound understanding of the local epidemic. We saw this recently in reports from the UN Conference in New York, the importance of knowing your epidemic, if I can put it that way, understanding what is driving it, the social, cultural and economic forces, including gender inequality, and how people’s behaviour is influenced in order to increase people’s ability to make the healthy choices. There clearly needs to be more done internationally on that in recognising and being able to deal with the growing epidemic. That is certainly the approach that we have taken. That is why, if you come back domestically and you look at what are the priorities for Britain—for England I should say—for England’s health service but equally true for Scotland, Wales and Northern Ireland, we are focused very much on understanding the epidemic and how we get to prevention, including screening, and we are pushing that very hard in our international strategies as well. We have a lot of people to convince though.

Q1172 Lord Geddes: Yet another dilemma—medicines. In your opinion, how can we get the right balance between encouraging the pharmaceutical companies, normally from developed countries, to research into medicines and, on the other hand, the affordability of the results of that research in countries that need them which are normally developing countries? We have had a lot of evidence on this and it is a real nightmare. I would be fascinated to hear your views on such initiatives as the International Finance Facility for Immunisation and Advance Market Commitments. Do you see any role for the Medicines Transparency Alliance?

Gillian Merron: Yes, very much so.

Q1173 Lord Geddes: Good.

Gillian Merron: You are right that these are tricky questions that we are dealing with. Certainly on MeTA, I am very optimistic about it. We are funding it in seven countries, to improve transparency and accountability for price, quality availability and the promotion of medicines. What it will do is it will help countries to identify and address the inefficiencies which are currently leading to higher prices and limited availability. On the basis that, as we know, the price of medicines can be very important, and it is affected by a number of factors, (including manufacturer, level of competition, the cost of passing things through the delivery chain) all of these things are affecting services to the consumer, and that is why I believe that MeTA will make a good contribution. On the other points which are raised, we have been a prominent supporter, as the Committee will be aware, of what we believe to be new and very innovative forms of financing and incentive mechanisms because financing and incentives are absolutely crucial, and that does

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include the IFFIm and Advance Market Commitments, because they are increasing confidence that there will be viable markets, which mean that pharmaceutical companies will be prepared to invest their own resources to develop products at affordable prices for the poorest people in the world. It is about acknowledging the reality of the market whilst seeking to serve the poorest. As a Government, we do both through DFID and the Medical Research Council make very direct and significant investment into research and development that meets the needs of developing countries. Access to medicines is absolutely crucial; it is part of the horizontal work that we are talking about. It is the building blocks of the health care system.

Q1174 Lord Geddes: Could you let us know who the seven countries are—not now, but you are going to give us other information, so if you would send that, that would be helpful.

Gillian Merron: Of course.

Q1175 Chairman: I think we are one of the most substantial contributors to Pneumo-ADIP which is the single example of the Advance Market Commitment which is actually coming into operation. Does the Government see that particular mechanism as being applicable to any other forms of development of vaccines or other medications?

Gillian Merron: I cannot really comment about the broader application but to say that what we are trying to do is to encourage an environment where companies are prepared to invest, research and develop with the confidence to the future to deliver and whilst balancing that in a fair and free market. If that can work elsewhere, then we will be interested.

Chairman: Ministers, you have been very full in your answers and we thank you most warmly, not only for that but for the further information which you have agreed to provide. Thank you very much for your help.

Letter to the Chairman from Gillain Merron MP, Department for International Development

HOUSE OF LORDS SELECT COMMITTEE ON AD HOC INTERGOVERNMENTAL ORGANISATIONS

At the joint Ministerial evidence session on Monday 23 June, I agreed to provide the Committee with additional information on five specific points. The responses are attached.

I look forward to reading the Committee's final report in due course.

Annex

1. Q. 1142 *Whether the UK Government plays a part in programmes to strengthen the infrastructure for animal health care and to ensure that within those countries the strategies are coordinated.*

The UK strengthens animal health care in developing countries through applied research and the promotion of policies and institutions that support poor livestock keepers. For example, the European Union's animal health infrastructure and capacity building programmes are supported via UK contributions to the European Commission including the recent €72 million, 32 country, Programme for the Pan African Control of Epizootics.

DFID provides direct support to the Pro-Poor Livestock Policy Initiative within the UN's Food and Agriculture Organisation (FAO). This programme was mentioned in the independent external evaluation of FAO as influential and an example of best practice. In 2007, DFID established a public-private partnership, the Global Alliance for Livestock Vaccines (GALV) to develop, commercialise and deliver new vaccine technologies for diseases that affect the poorest livestock keepers.

The Alliance will soon receive \$24 million of co-funding from the Bill and Melinda Gates Foundation. The threat of highly pathogenic avian influenza is being addressed through national level control and surveillance projects in selected countries such as Kenya and Ethiopia. DFID also supports research on the best policy options for developing countries faced with avian flu epizootics. In 2007 DFID seconded an expert for three years to the World Organisation for Animal Health (OIE) to strengthen developing county laboratories by twinning them with World Reference Laboratories.

2. Q. 1159 *What the UK is doing to ensure that programmes to treat TB and HIV/AIDS are integrated.*

The Department for International Development (DFID) is working with the global health partnerships and international financial institutions to improve programme integration in developing countries. Two examples from the bilateral programme:

In Zambia DFID is implementing two joint HIV/Tuberculosis projects under the auspices of the Zambia AIDS Related Tuberculosis (ZAMBART) Project a collaborative effort between the University of Zambia, School of Medicine and the London School of Hygiene and Tropical Medicine. Funding initially came from DFID-UK only and now includes the Bill and Melinda Gates Foundation, EC, The Beit Trust and WHO. Zambia has benefited from recommendations for improving HIV care that includes the policy to test all HIV positive patients for TB and vice versa.

£100 million UK funding to the Malawi health Sector Wide Approach (SWAp) supports the implementation of the national TB protocol, and guidelines that prioritise the integration of HIV and TB services. Until 2005, the National TB Programme operated largely independently from the main health system, but since then, TB funding from DFID and the Global Fund has been pooled as funding for delivery of the overall Essential Health Package. The TB and HIV units work together to cross-refer patients for testing and coordinate treatment regimens, although recent findings show that due to limited access to district hospitals there is a low uptake of Anti Retroviral Treatment (ART) by many HIV+ patients referred on from TB treatment. The Ministry of Health and National AIDS commission continue to work hard to increase the number of facilities able to offer ART. By December 2007, 146,000 people had commenced ART in Malawi.

3. Q. 1162–1164 *How the UK Government applies its criteria to decide whether to reduce or suspend aid to a recipient country government or to deliver it in a different way (by-passing the national government) to ensure the aid reaches people who need it. In particular, how did the UK provide aid in response to the humanitarian crisis in Uganda in 2005. Did the UK Government continue to provide aid through the Government in Kampala even though it was clear that this Government was not interested in ensuring that the money got through to the people in Northern Uganda who needed it?*

DFID only uses Poverty Reducing Budget Support (PRBS) with partner governments committed to poverty reduction, improving public financial management, good governance and human rights and when PRBS will achieve greater impact than other forms of aid.

DFID is alert to the risk of corruption or misuse. DFID protects its funds in three ways:

- Assessing risks carefully before we give budget support.
- Addressing underlying problems—support to strengthen public financial management systems.
- If necessary, using short-term safeguards eg extra audits.

If something happens to bring into significant doubt the partner government's commitment to public financial management reform and accountability, DFID will then reassess if budget support remains appropriate. If necessary, we reduce or suspend aid, or deliver it in a different way.

In December 2005 DFID reallocated £15 million of the bilateral aid programme to help the UN provide humanitarian relief in northern Uganda (bringing our total expenditure on the humanitarian effort in the North to £20 million in 2005–06). At the same time we decided to reduce our planned disbursement through the Government by £15 million.

Since early 2006 the government system of allocating resources has resulted in a significant increase in financing to the North. It is estimated that regular central government transfers to northern districts affected by the conflict with the Lord's Resistance Army increased from about US\$ 97 million in 2005–06 to about US\$ 114 million in 2006–07.

4. Q. 1165–1167 *A list of the ten other donors that the UK is working with, through MOPAN, to develop a common approach to multi-lateral effectiveness.*

The 10 donors are Austria, Canada, Denmark, Finland, France, Ireland, The Netherlands, Norway, Sweden, Switzerland. The Republic of Korea, Spain and Australia have recently applied for membership and have been invited to join as observers.

5. Q. 1174 *The seven countries where the UK is funding/piloting the Medicines Transparency Alliance.*

Ghana
Uganda
Zambia

Jordan
Kyrgyzstan
Peru
Philippines.

Written Evidence

Memorandum by the Academy of Medical Sciences

1. The Academy welcomes the opportunity to respond to the House of Lords Ad Hoc Committee on Intergovernmental Organisations following its call for evidence on “Acting through Intergovernmental Organisations to Control the Spread of Communicable Diseases”. The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are translated as quickly as possible into benefits for society. The Academy has previously addressed issues relating to pandemic influenza in its joint report with the Royal Society *Pandemic Influenza: Science to Policy*,¹ and recent follow-up symposium (a report of which will be published in Spring 2008). Our Fellows have a wealth of expertise in basic and clinical malaria, TB and HIV research. We have chosen to address specific questions, with reference to each communicable disease where possible. We would be pleased to expand on any other points made in this submission.

2. *A recent report on Communicable Diseases by the UK Department of Health stated that “post-war optimism that their conquest was near has proved dramatically unfounded”. What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Is it exaggeration to talk of a crisis? (1)*

With regard to avian influenza, the Academy considers that greater effort is required at an international level to prevent spread of avian disease. A recent symposium, held by the Academy of Medical Sciences and Royal Society, identified the need for particular efforts in South East Asia and Africa, where poultry and humans live in close proximity and live poultry markets are thought to contribute to the maintenance and dissemination of avian influenza viruses. With avian influenza endemic in poultry in three continents, management and control of this reservoir is key to managing pandemic potential. Thus, we recommend investment in avian vaccines, particularly standardisation of antigen content, in combination with greater research into new vaccines. Consistent use of the chosen vaccine must also be ensured. In addition, it may be necessary to improve surveillance and monitoring systems in African countries, where levels of infection in animals and birds are unknown. To date, surveillance via detection of H5N1 in dead birds has proved to be useful; support is needed for monitoring efforts in all countries.

3. The Academy is aware that progress has been made in reducing TB infection in some regions (Asia, Latin America and the Caribbean)² through the implementation of highly effective “Directly Observed Treatment Short Course” (DOTS).³ This has been supported by the World Health Organisation (WHO) and the International Union Against Tuberculosis and Lung Disease (IUATLD), together with strong commitment, dedicated funding and co-ordinated action of global networks and organisations including the “Stop TB Partnership” and the “Global Fund to fight AIDS, TB and Malaria”. However, successes in certain areas are offset by the increase in TB infections in Sub-Saharan Africa.⁴ Predisposition to TB by HIV is a key determinant of global spread and progress has been held back by the marked global rise in HIV infection. It is clear that greater progress in control of HIV is a crucial step in limiting the spread of TB infection. Moreover, the rise in the spread of the multi-drug resistant TB strains, MDR and XDR, should be urgently addressed. The development and spread of TB strains resistant to all antibiotics would lead to a public health crisis. Efforts to stem this rise, through improved monitoring of infection, expansion of DOTS and the development of more potent drugs that would reduce the duration of treatment and thus improve adherence, are imperative.

4. Significant funds and efforts are being directed towards a reduction in HIV infection and data indicate downwards trends in prevalence in some countries.⁵ However, sustained and co-ordinated support will be crucial to prevent further rises in infection. The roll out of effective antiretroviral therapy (ART) has made an impact on mortality and morbidity in developed countries and progress in reducing/stabilising mortality is beginning to become evident in resource poor countries where the programmes are effective.⁶ However,

¹ Academy of Medical Sciences and Royal Society (2006). *Pandemic Influenza, Science to Policy*. www.acmedsci.ac.uk/p99puid89.html

² DFID (2007). Tuberculosis (TB). <http://www.dfid.gov.uk/Pubs/files/mdg-factsheets/tuberculosisfactsheet.pdf>

³ WHO and Stop TB Partnership (2006). *The Stop TB Strategy. Building on and enhancing DOTS to meet the TB-related Millennium Development Goals*. http://www.who.int/tb/publications/2006/who_tbm_t2006_368.pdf

⁴ <http://www.dfid.gov.uk/Pubs/files/mdg-factsheets/tuberculosisfactsheet.pdf>

⁵ UNAIDS and WHO (2007). *AIDS Epidemic Update*. http://data.unaids.org/pub/EPISlides/2007/2007_epiupdate_en.pdf

⁶ Ibid.

the major disadvantage of ART is that treatment must be continued for life, thus development of resistance is a serious risk if adherence to treatment is poor. Additionally, in the absence of improvements in infrastructure necessary to ensure accessibility of HIV treatments, HIV and TB infection rates in developing countries will increase.

5. In contrast to TB and HIV, progress in reducing malaria-related mortality and morbidity is evident in a number of countries, such as Vietnam and South Africa⁷⁸ and use of insecticide-treated bednets has increased in many African countries.⁹ Continued provision of effective prevention and control measures, including combination antimalarial chemotherapies and insect control, will be essential to continue this trend and to reduce the disease burden where transmission rates and infection levels remain high.

6. *What reliable data exist regarding the numbers of people infected globally with the four diseases on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?* (2)

Where communications are good, WHO data regarding cases of human influenza infection are reliable, although infection data are difficult to obtain from more remote rural areas of some Asian and African countries. Extensive surveillance efforts and early reporting of confirmed cases is needed to ensure full reliability of data. As mentioned above, there is little information regarding prevalence of influenza infection in mammals, such as pigs, and greater efforts are required to assess infection levels in birds and animals in Africa.

7. In well-resourced countries, data for TB, malaria and HIV infection are reasonably reliable. For instance, data have demonstrated an increase in TB infection rates in the UK over recent years.¹⁰ Yet, latent TB infection may be carried for many years before visible disease occurs and skin tests designed to detect latent infection lack specificity and sensitivity. Infection figures could thus be far higher than currently thought. Full validation and development of new diagnostic tests are essential to ensure improved accuracy of data.

8. Additionally, reliable data are lacking where fewer resources are dedicated to TB surveillance. The accuracy of infection data and temporal patterns will only be increased if diagnostic methodologies for malaria and TB improve and are taken up more widely. Similar reliability problems compound data collection for HIV infection, given its latency in earlier stages of infection, such that most data are based on cases of HIV-related disease, rather than initial latent infection. In the absence of improved surveillance, testing and adherence to treatment in many developing countries, it is likely that infection will increase.

9. *What intergovernmental surveillance systems exist to give early warning of outbreaks? Are these systems adequate? And what improvements might be made?* (3)

What intergovernmental action is planned or in hand for early detection of avian flu transmission from birds to humans and from human to human in potential source countries—is this sufficiently effective to prevent a pandemic? What more could be done? (11)

WHO is responsible for oversight of global influenza surveillance systems (through the WHO Collaborating Centres and the Global Outbreak Alert and Response Network [GOARN]), setting international recommendations for surveillance and investigating and responding to clusters of disease. We consider this to be an effective system.¹¹ GOARN provides the response arm for global outbreaks and has responded to a number of events in over 20 countries.¹² We are aware that steps are being taken to improve surveillance and welcome such activity.

10. The Academy notes that the Global Early Warning and Response System for Major Animal Diseases, including Zoonoses (GLEWS) surveillance system, operated through the Food and Agriculture Organisation of the United Nations (FAO), World Organisation for Animal Health (OIE) and WHO, plays a key role in worldwide avian influenza monitoring. However, although information is received through National Influenza Centres, there is an urgent need to support improvements in the capacity of infrastructure of national surveillance systems around the world.

⁷ http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_4985739

⁸ Sharp, Kleinschmidt, Streat et al., (2007). Seven Years of Regional Malaria Control Collaboration Mozambique, South Africa and Swaziland. *Am J Trop Med Hyg* 76(1): 42-47.

⁹ UNICEF (2000). Malaria and Children. Progress in Intervention Coverage. <http://www.unicef.org/health/files/MalariaOct6forwebfinal.pdf> 10

¹⁰ HPA (2006). Tuberculosis Update

http://www.hpa.org.uk/infections/topics_az/tb/pdf/newsletter_2006_pdf; Euro Surveill (2006). Epidemiology and response to the growing problem of tuberculosis in London. <http://www.eurosurveillance.org/em/v11n03/1103-228.asp>

¹¹ Royal Society and Academy of Medical Sciences (2006). Pandemic Influenza: Science to Policy. www.acmedsci.ac.uk/p99puid89.html

¹² Merianos A and Peiris M (2005). International Health Regulations (2005). *Lancet* 366:1249-1251

11. Improvements could also be made to ensure that surveillance is carried out in healthy animals including pigs, wild birds and poultry, in farms, back yards and live poultry markets. The latter are of particular importance since they are thought to maintain, amplify and disseminate avian influenza viruses and the FAO could focus more heavily on this issue. The Academy considers it important to strengthen worldwide surveillance structures for cluster and syndromal detection and we welcome the steps taken by WHO to address this. By inclusion of a requirement for member countries to develop their core capacity, the International Health Regulations may help to develop these systems where required.¹³ However, we consider that improvements in multilateral funding may be required for such developments in capacity and infrastructure.

12. Further to cluster detection, an additional sentinel system could be useful to join farming communities or areas where pigs, poultry and people live in high density so that outbreaks can be identified before they spread to other areas.

13. Within the UK, the Academy considers that the Department of Health (DH) and Department for Environment, Food and Rural Affairs (DEFRA) must continue to work closely with WHO to enable effective surveillance and diagnosis of cases of influenza. In the long-term, this capacity might be relevant to other infectious diseases. In the event of outbreaks and/or a possible pandemic, we recommend that collection and sharing of data in real time is co-ordinated through intergovernmental organisations at the EU, EU-G8 and WHO/UN level.

14. *Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years? (4)*

Whilst mathematical modelling is able to give quantitative estimates of the pattern and speed of spread of a pandemic strain of avian influenza once it has emerged, spread will depend largely on the extent to which surveillance networks and control measures are implemented and/or developed around the world. Whilst the UK and many EU member states may have well-developed pandemic response frameworks, outbreaks in rural African or South East-Asian countries could spread extensively prior to detection or treatment. Variation in monitoring and preparedness make predictions of likely spread difficult.

15. Through the influence of national and international programmes to control the spread of malaria through interventions such as insecticide-treated bednets, indoor spraying and Artemisinin-based combination therapy, it could be predicted that spread of malaria may decrease over the next 10 years. However, a key determinant of the likely pattern of malaria spread will be the drug resistance profile of the parasites in different parts of the world. Areas that have seen significant reductions in disease through national and international programmes could see a re-emergence of infection if Artemisinin-resistance becomes established. Similarly, drug resistance significantly affects control of TB and HIV infection. Although new HIV drugs are in development, there is concern that strains that have become resistant to current ART drugs may transmit widely in the population.

16. Within the UK, the likely pattern of spread of TB will depend to a large extent on the political commitment to focus on issues such as diagnosis, control programmes, treatment regimens and poverty. The frequency of migration of individuals from areas of high endemicity to low endemicity may also affect further spread.

17. *What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better targeted or better co-ordinated intergovernmental action? (5)*

One blockage to progress in control of influenza is the lack of a unified and standardised approach to influenza virus vaccination timings and doses. This is, in part, through a lack of opportunities for comparing one formulation directly with another, which prevents awareness of the benefits of particular approaches. We recommend that WHO leads an initiative to ensure that samples are shared and that comparative experiments are carried out to encourage development of a standardised approach.

18. The overall intensity of effort in preparing for an influenza outbreak serves as a model to demonstrate how preparedness can be heightened in both resource-rich and poor countries. Thus giving similar priority to infectious diseases such as TB and malaria could be of significant benefit. Establishing a panel, similar to the inter-governmental panel on climate change, would enable similar approaches to be used to manage threats from communicable diseases.

¹³ <http://www.who.int/csr/ihr/capacity/en/index.html>

19. In TB infection, the main blockages are the difficulty in diagnosis, the lack of a universally effective vaccine and the need to treat for six months or longer for resistant strains. There is a critical need to encourage medical research to develop new treatments to counter the rise in multi-drug resistance and simultaneously to utilise currently available diagnostic and treatment tools as effectively as possible. Continued funding is required, combined with technical expertise and implementation of diagnostic and control measures. Whilst collaboration between TB and HIV services has not been successful in the past, owing to concerns that the stigma surrounding HIV infection would prevent people from attending a clinic for TB treatment, the Academy considers that improvements in collaborative activity between these services could be strengthened.

20. It will also be necessary to address the stigma surrounding HIV to improve attendance at TB treatment centres, but also to encourage a greater proportion of individuals to be tested specifically for HIV—the main blockage to better control of HIV infection. Further blockages in developing countries that should be addressed urgently include the implementation of prevention techniques that have the acceptance of the relevant populations and meeting the cost of sustaining effective ART programmes (both in terms of providing drugs and human resources for dispensing and monitoring of patients).

21. Many of the same factors are also blockages to progress in malaria control. Widespread access to effective treatment, monitoring and diagnosis, adequate funding and sustained efforts are required. Co-ordinated efforts to monitor the development of parasite resistance (through WHO) and to support research into the next generation of antimalarial treatments are urgent priorities.

22. In all cases, intergovernmental action can encourage co-ordinated and continued funding and efforts on the part of governments in developing and developed countries. It can also encourage best use of scientific advances in policy and the provision of policy guidance. Furthermore, intergovernmental action can encourage the development of internationally agreed targets, implementation of prevention and control strategies in health programmes, data collection and monitoring of disease and management of drug supplies. Moreover, intergovernmental organisations can effectively bring together non-governmental organisations (NGOs), technical experts, governments and other stakeholders to manage any blockages and make the best use of resources.

23. *What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? What more needs to be done? Do you consider that there is sufficient joined-up thinking in approaching the problem? (7)*

The link between climate change and human health is being increasingly recognised. Vectors of disease, including the Plasmodium parasite responsible for transmission of malaria, are increasingly able to invade previously void areas with a steady alteration of temperature and/or meteorological conditions. Moreover, global trade is increasing the volume and speed of movement of people and animals, thereby increasing the likelihood of rapid spread. The SARS outbreak of 2003 was limited by quarantine measures but an outbreak of pandemic influenza, if it was only detected after it had become established, could have dire consequences.

24. Lifestyle and cultural factors are also critical in affecting the spread of these diseases. For instance, whilst education may be a key component of control measures, it remains difficult to change behaviour about the risks of influenza transmission from proximity to farm animals, when risks are not perceived as related to exposure. Overcrowding and poor nutrition increase the risk of TB infection and progression to disease and the stigma of HIV can prevent people presenting for treatment of their TB. Good leadership, education and engagement with technical experts are necessary, in combination with sufficient funding. Multi-disciplinary approaches to containment are essential and depend on co-ordinated efforts.

25. *Cases of TB fell progressively in the UK until the mid-1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of TB infections in Britain? And how could intergovernmental action help to reverse the trend? (8)*

Within the UK, immigration and international travel strongly influence TB infection rates. For instance, rates of infection between 2000 and 2004 increased in the non-UK born population but remained stable in the UK-born population. The majority of cases were reported in individuals from South Asia or sub-Saharan Africa.¹⁴ As described above, inadequate adherence to treatment and the difficulty of diagnosing a latent

¹⁴ HPA (2006). Migrant Health. Infectious Diseases in non-UK born populations in England, Wales and Northern Ireland. A baseline report. http://www.hpa.org.uk/publications/2006/migrant_health/default.htm; French CE, Antoine D, Gelb D et al., (2007). Tuberculosis in non-UK-born persons, England and Wales, 2001-2003. *Int J Tuberc Lung Dis* 11(5): 577-84.

infection, which does not present with symptoms for many years, have also played a role in encouraging a rise in infection. In particular, poor adherence to treatment encourages the transmission of multi-drug resistant strains.

26. *What interchange exists between states in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?* (15)

The main source of education and co-ordination of knowledge regarding TB has been through WHO and the IUATLD, whilst the International AIDS Society, Global Fund to Fight AIDS, TB and Malaria, WHO, the United States President's Emergency Plan for AIDS Relief (PEPFAR) and the Joint United Nations Programme of HIV/AIDS (UNAIDS) are all actively involved in training in the diagnosis and treatment of HIV. We consider that the link between training in TB and HIV could be strengthened in order to address the growing burden of these increasingly linked diseases. Crucial to these efforts will be sustained, consistent activity by all organisations involved and a focus on surveillance, for cases to be detected at all.

The Academy of Medical Sciences is particularly grateful to Sir John Skehel FRS FMedSci, Professor Janet Darbyshire OBE FMedSci and Professor Sanjeev Krishna FMedSci for their contribution to this response.

THE ACADEMY OF MEDICAL SCIENCES

The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are converted into healthcare benefits for society. Our fellows are the UK's leading medical scientists from hospitals and general practice, academia, industry and the public service.

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1 February 2008

Memorandum by the Association of Port Health Authorities

INTRODUCTION

The Association of Port Health Authorities represents the overwhelming majority of local and port health authorities having international trade or passenger flows at sea and airports within their areas. Legislation currently in force in the UK to control the spread of communicable diseases, both within the UK and potentially entering from abroad, places enforcement responsibilities on our member authorities, which therefore provide the necessary services to discharge those duties both adequately and effectively.

Our member authorities are in the front line in protecting the UK from imported communicable diseases. We are therefore pleased and grateful to be invited to submit evidence to the Ad Hoc Committee's inquiry.

We have addressed our evidence to the inquiry by responding to those numbered issues in the invitation only where we believe that we have the competencies to do so. However, we would firstly like to make a general point regarding the scope of the enquiry.

The inquiry is focussed on four particular diseases (HIV/AIDS, Avian Influenza, Malaria and Tuberculosis) as well as generally. Indeed 11 of the 20 issues in the call for evidence relate solely to one or more of the four specified diseases. We do not believe that the focus should be so constrained to those diseases. Previous UK and international legislation on the control of communicable diseases has been prescriptive about the diseases covered and the necessary controls to combat their spread. This approach has been proved to be entirely inadequate in relation to emerging diseases and the Association believes that international and UK controls to combat the spread of communicable diseases must focus on modes and pathways of transmission rather than on specific diseases. Only by adopting this approach can we respond to, and deal with, existing and emerging disease threats.

The Association has participated actively in the World Health Organisation (WHO) review of the International Health Regulations, leading to the passing of the International Health Regulations 2005. We continue to be contributing actively to the associated guidance currently being developed by WHO.

As the control and enforcement authorities, we are also contributing to the review of UK legislation currently in progress through Parliament in the Health and Social Care Bill.

There are a number of Port Health Authorities constituted in legislation covering seaports. There are no Port Health Authorities constituted for airports. For both airports and seaports where there is no constituted port health authority, it is the local authority in whose area the port is that is given responsibilities under port health legislation. In our submission of evidence we will refer to all of these as port health authorities.

Turning to our more specific evidence, we refer now to the issues and to the numbering of those issues in the call for evidence.

Issue 1

We agree with the conclusion in the UK Department of Health report on communicable diseases that the post-war optimism of the conquest of infectious diseases has proved dramatically unfounded. Our experience is that, with few exceptions, existing diseases have not been controlled nor eradicated and further that other newly emerging diseases over the latter half of the 20th century demonstrate that controls are more than ever necessary. In our view the recent revision of the International Health Regulations go a long way towards providing those controls.

We believe that it is the increased international mobility of increasing numbers of people over the last 30 or 40 years, through ever cheaper air transport, that presents the risk of existing and new diseases being rapidly spread across the globe.

We therefore conclude that the global situation is certainly changing, but we would not consider it to be a crisis, provided that international controls have sufficient flexibility to deal with both existing and newly emerging threats.

Issue 3

Port health authorities, in conjunction with the Health Protection Agency, provide port health services at sea and airports to control the potential import of communicable diseases. In undertaking these statutory duties we must rely on intergovernmental surveillance systems to provide us with the necessary information on the current disease situation throughout the world.

The WHO provides such information to port health authorities, either through the Department of Health as specific communications, or through information on their website. There are also other information systems on disease surveillance available to port health authorities that port health authorities can refer to.

However, the Association would welcome the establishment of a single reference point containing all the available information that port health authorities need in order to fulfil their statutory duties and to enforce legislation.

Issue 6

We have outlined our role in the control of the spread of Malaria under issue 7 below. We also have a role in controlling the spread of both Avian Influenza and Tuberculosis.

In regard to Avian Influenza Port Health and Local Authorities are responsible for the control of all products of animal origin entering the EU through the UK's sea and airports. When controls are put on products from a third country due to the presence of Avian Influenza it is our members who must put those controls in place. In undertaking these controls we work closely with both UK and EU competent authorities as well as colleagues throughout the EU. In our view, this is an area where the intergovernmental collaboration works well.

In regard to Tuberculosis entering the UK through sea and airports it is Port Health and Local Authorities that enforce the relevant legislation. The medical input to these controls are provided by the Health Protection Agency, whose doctors are appointed as authorised officers of the local or port health authority. Indeed at the major airports the local authority will run the TB screening, including X-rays, where this is generally funded through the HPA.

The Association believes that a Chest X-ray is a must for all new entrants as Pulmonary TB is the only form that is easily transmissible to others. It not only helps to diagnose active illness but also latent TB. It is well known that a large number of recent immigrants develop the illness after being in the country for some months to few years. It is mainly due to activation of Latent TB.

Currently chest X-rays and pre-entry screening are advocated for new entrants before offering a visa for entry to the UK in certain countries. Experience at Heathrow is that a significant number of new entrants are coming with abnormal chest X-rays and marked sputum for TB negative, while it is well known this test depends on the quality of the specimen supplied, on the person who performs the test and it take 2—3 months the organism grows in the culture. Then treatment is for 6—9 months with standard regimen. But new entrants are allowed to come with these abnormal certificates. Heathrow also has evidence of abuse of Visa medical system with an element of corrupt practices.

Recent statistics for TB monitoring at Heathrow Airport are given in the following table:

<i>Year</i>	<i>Number of New Entrants seen</i>	<i>Number of Chest X-rays (CXR) done</i>	<i>Probable TB referred for further management with abnormal CXR</i>	<i>Active TB Confirmed among abnormal CXR by Consultant Radiologist</i>	<i>Active TB Diagnosed among the Results received from community</i>
2003/04	175,039	70,805	848	205	80
2004/05	189,623	74,382	1,599	294	224
2005/06	190,685	74,060	1,521	587	Received only 4% results

2006/07 stats not ready 184,217 new entrants were screened, 66,812 chest x-rays were carried out

58% of these referred during the last 18 months are on TB treatment or on Chemoprophylaxis as for Latent TB.

Issue 7

Non—health causes of the spread of communicable diseases are well documented and no doubt others will give evidence of these. However, the Association has concerns and can give evidence on some of these.

Cases of “airport malaria” in Europe are well documented and Port Health Authorities in the UK are at the forefront in preventing infected mosquitoes entering through our international airports by advising on and enforcing the disinsection of aircraft. The UK does not have the species of mosquito that could transmit malaria, but it has done in the past. With climate warming generally accepted as happening now and into the foreseeable future, the risk of malaria becoming indigenous in the UK is increasing.

There are other insect vector-borne communicable diseases already becoming a concern internationally and the increasing mobility of people and goods via air and sea raises the risk of those vectors and diseases entering the UK.

This increase in mobility, fuelled by both the increase in affluence of a large part of the population and by the reducing cost of travel in real terms, also means that more and more people are travelling further and further afield, and to places where they would not have gone, even a generation ago. This lifestyle change results in people travelling to areas with a greater risk of contracting communicable diseases.

With the ever more diverse nature of the population there is also an increase in the numbers of people travelling to visit the countries of their origin where some communicable diseases are endemic and returning to the UK infected themselves.

Issue 16

The Association has been closely involved with WHO on the development of the International Health Regulations 2005 and we believe they provided a considerably improved framework for the international control of communicable diseases. In particular they provide a flexible response to be made to particular diseases that can cope with new diseases as they emerge.

Turning the Regulations into the practicalities of comprehensive and effective control at points of entry is the key to the effectiveness of the Regulations. If countries get that right then our view is that the Regulations will provide effective global controls. We therefore contribute to the review of legislation undertaken by the Department of Health and with the WHO in drawing up guidance documents.

Issue 17

Port health and local authorities are Category 1 responders under the Civil Contingencies Act 2004, and therefore must have plans in place for dealing with emergencies.

We believe, however, that a closer link between the Civil Contingencies Act and the control of infectious disease at points of entry should be established to build upon much good progress that has been made in recent years. This would also enable local authorities with Ports within their area to hold proper practice exercises as regards control infectious disease to complement work already done concerning terrorism and natural disasters.

Issue 19

The Association is mainly funded by subscriptions from member authorities. One of the functions of the Association is to provide training for authorities and their officers.

Member authorities do provide, at their own expense, members and officers to attend and contribute to meetings of the Association.

Local authorities receive government general financial support through the RSG. This funding is based on a needs assessment and for those authorities that have ports we are given to understand that includes an element for port health services. However, Authorities are often unable to determine the amount of any resource included in the overall support. Whilst we feel that local authorities are best placed to determine locally what services to provide and how to provide them and financial support should not be ring-fenced, we feel that a greater clarity on exactly what element of the general support relates to the sea or airport would better enable our members to judge whether that element was adequate.

Some port health services at airports are funded by the Department of Health by direct reimbursement of costs, and the provision of Medical expertise is provided by the Health Protection Agency at no cost to authorities.

February 2008

Memorandum by the British Association for Sexual Health and HIV

Prepared by Dr Karen Rogstad¹ and Dr Adrian Palfreeman²

1. Chairman of BASHH Education Committee and Chairman of BASHH Adolescent Special Interest Group, Consultant Physician Sheffield Teaching Hospitals NHS Trust

2. Chairman of BASHH HIV Special Interest Group, Consultant Physician, Leicester Teaching Hospitals

The British Association for Sexual Health and HIV represents health care professionals with an interest in sexually transmitted infections. This includes clinical care, laboratory expertise, prevention and research. Most clinician members are based in Genitourinary Medicine clinics, where the majority of sexually transmitted infections including HIV are diagnosed and managed, and also provide inpatient HIV care. Although most Consultants in GUM are not TB physicians, there is a high rate of co-infection with TB and HIV therefore they care for many dually infected patients.

Q1. A recent report on Communicable Diseases by the UK Department of Health stated that “post-war optimism that their conquest was near has proved dramatically unfounded”. What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis?

A1. HIV and STI disease control requires both the identification of individuals with and without symptoms, appropriate treatment for them, partner notification and preventative programmes to reduce onward transmission either between sexual partners or from mother to child. These systems are inadequate in the UK but even more so in countries with less well resourced health care systems, both for treatment and surveillance. Poverty and war contribute to further spread.

2. What reliable data exist regarding the numbers of people infected globally with the four diseases¹⁵ on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?

A2. Data is available from the World Health Association and the Health Protection Agency.

3. What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? And what improvements might be made?

A3. This can be answered by the Health Protection Agency

4. Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years?

A4. Data can be obtained from WHO and the HPA. HIV in the UK is likely to continue to increase because of ongoing transmission particularly in MSM, but also IVDUs, heterosexuals, and mother to child transmission. This is exacerbated by the large proportion of approximately one third of infected persons in the UK being unaware of their positive status. Immigration of infected persons to the UK will also contribute to increasing prevalence of HIV and TB. As people with HIV live longer in the UK as a result of better therapy, then the overall number of infected people living with HIV would increase even if the rate of new infections (incidence) remained the same.

5. What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?

6. What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?

A6. BASHH is involved with the detection, treatment and prevention of HIV through our members. BASHH is also responsible for policy formation, service delivery development, and education for HIV.

Q7. What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient “joined-up” thinking in approaching the problem?

A7. Poverty, war, urbanisation and resultant social disruption and migration are drivers of HIV and thus also TB transmission. They are also a major cause of STI increases, which are known to increase HIV acquisition. A significant numbers of STIs and HIV diagnosed in the UK are due to UK residents acquiring infections whilst abroad either for leisure, work or visiting families. Risk factors for STI and therefore HIV acquisition whilst abroad include risky behavior in the UK prior to travel, drug and alcohol use.

Q8. Cases of Tuberculosis fell progressively in the UK until the mid-1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of Tuberculosis infections in Britain? And how could intergovernmental action help to reverse the trend?

A8. One major driver of increased TB is because of coinfection with HIV, particularly in those who have recently moved to the UK having acquired HIV infection in their country of birth, where there is also higher risk of exposure to TB.

Q9. Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions—eg HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?

A9. TB is often associated with HIV. There must be support for countries with high prevalences to detect cases of HIV and TB prior to the onset of clinical disease, which requires adequate screening. However case finding must be linked to adequate availability of effective drugs for both, and an infrastructure to provide and deliver these.

Q10. To what extent do you believe that the 2004 Stockholm Convention limiting the use of DDT against Malaria-carrying mosquitoes has been a factor of increases in the spread of the disease? Has any risk analysis been carried out comparing the relative dangers to human health posed by DDT and Malaria?

A10. Not applicable to BASHH.

¹⁵ HIV/AIDS, Tuberculosis, Malaria and Avian Influenza.

Q11. What intergovernmental action is planned or in hand for early detection of the transmission of Avian Flu from birds to humans and of human-to-human transmission in potential source countries? Is this proving sufficiently effective to prevent an Influenza pandemic? What more could be done?

A10. Not applicable to BASHH.

Q12. To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?

A12. There is increasing resistance to HIV in developed countries, and there is increasing evidence of the transmission of resistant virus. The problem of resistance in third world countries is likely to become a major health issue over the next few years as HIV drugs are supplied to these countries, but in many cases without the support mechanisms for patients regarding adherence and the problems with an uninterrupted supply of drugs, particularly for rural areas. The same factors are also relevant to TB drug resistance.

Q13. In a number of countries, including the UK, there is a problem with hospital-acquired infections. What intergovernmental sharing of knowledge is taking place to help bring this problem under control?

A13. Not applicable to BASHH.

Q14. Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?

A14. There is improvement in supply of HIV drugs to under developed countries, but this is still limited and usually the more modern, more effective drugs are unavailable.

Q15. What interchange exists between States in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?

A15. More could be done with regard to training health care professionals in the 3rd World by wealthier nations. This support could include internet based learning, although access to IT systems is often limited. Opportunities for training in UK clinics could be provided. Immigration restraints have made it more difficult for people to attend specialist STI and HIV training courses in the UK

Q16. The International Health Regulations 2005 are intended to provide a global framework for the rapid identification and containment of public health emergencies. How effective do you consider this response system to be? Do improvements need to be made?

A16. No opinion.

Q17. What intergovernmental planning has been undertaken to cope with the impact of an outbreak of infectious disease caused by deliberate release of micro-organisms into the environment? Is there adequate liaison between the various agencies involved, including intelligence, law enforcement and health care professionals? How could action by intergovernmental bodies help further?

A17. No opinion.

Q18. Though our remit is focused specifically on known infectious diseases, we would be interested to know how you view the global threat from new or previously unrecognised ones and from the transmission of infections from animals to humans.

A18. There is a need to have adequate surveillance systems in different nations for all sexually transmitted infections, in order to predict spread through and between communities and countries. Diseases that were uncommon can rapidly re-surge and spread, particularly when there is deterioration in health systems and/or increasing poverty, eg as was seen with increase in syphilis in the former states of the USSR, which then spread to Western European countries as a result of increased travel between countries and migration. There has also been a rapid rise in Lymphogranuloma venereum (LGV) in Westernised countries in recent years. This disease was previously regarded as largely restricted to the tropics, but has spread rapidly in men who have sex with men (MSM), and is particularly associated with HIV positivity.

Q19. What resources (subscriptions, staff, training, medicines etc) does the UK Government commit to intergovernmental bodies to help in the fight against the four diseases listed?

A19. The Department of Health used to support Registrars in Genitourinary medicine travelling to other countries to gain additional experience in countries of high prevalence for STIs. This would be beneficial educationally to the trainee and the unit they subsequently were appointed to as Consultant. It would also often foster long-term links between the medical units in the 2 countries. This funding was withdrawn a number of years ago.

Q20. Do you wish to provide any other relevant information in addition to what you have said in answer to the above?

A 20.

STIs as a major risk factor for HIV, and adolescent health issues

It is essential that the link between sexually transmitted infections and HIV transmission is fully appreciated by governments and intergovernmental organisations. Too often there is a dissociation of the two by policy makers and providers of care both in the UK and elsewhere. Any attempts to control HIV must be linked to STI prevention and treatment programmes. Issues of stigmatisation, poverty, social upheaval must all be addressed. There must be a focus on adolescent health issues, as infection although not detected till later adulthood is often acquired in adolescence, particularly in the third world. Also education programmes on prevention are most effective if given in childhood and early adolescence. The needs of those surviving into adolescence with vertically acquired disease is becoming an increasing issue due to effective therapies.

HIV in the UK

There are a number of challenges both in those of us caring for individuals affected by HIV and those living with these infections in the United Kingdom.

- The number of undiagnosed infections remains at approximately 30% of the 70,000 individuals infected in the United Kingdom and barriers to testing in care still exist. Those perceptions reinforced by recent government announcements that individuals whose asylum status is either uncertain or have been refused asylum should not be entitled to receive medical care. This may deter many individuals from seeking testing and care.
- The consequences of this are that many patients now present late to care with complications of HIV, needing costly emergency treatment and prolonged hospital admission. Recently reported cases such include that of a woman in London who was denied HAART because she was not considered eligible and was worried about the cost, and ended admitted as an emergency to ITU. The cost of the ITU admission was conservatively measured as equivalent to about 3.5 years of HAART.
- Patients who are deterred from seeking medical care and remain unaware of their HIV status risk passing on their virus to others. In the USA over 50% of new infections are estimated to come from individuals unaware of their status, and it has been shown in studies that knowledge of positive status reduces risk behaviour.
- Patients who are co-infected with other serious infections such as Tuberculosis cannot receive effective treatment for these infections unless their HIV is treated at the same time. They are therefore more likely to pass on Tuberculosis to other members of the community.
- The emergence of Multi drug resistant TB in populations co infected with HIV has been a public health disaster in South Africa. The key to control of this problem is to treat both infections and contact trace and apply appropriate public health measures. We need to learn from that experience.
- The dramatic success of the prevention of mother to child transmission of HIV in reducing the number of babies born with this infection in the United Kingdom to less than 1.2% in the UK and Ireland. Of note, the audit by the NHS AIAU (Audit Information Analysis Unit) which looked at transmission that **did** occur, made recommendations in an executive Summary October 2007 where they noted that some transmissions had occurred because of confusion about entitlement to care for pregnant women. The DoH states that treatment cannot be refused in this situation but these women may still be liable for charges subsequently. The audit goes further and in recommendation 31 states that “At the next policy review, the DH should consider classifying HIV prophylaxis for prevention of MTCT, and appropriate support in pregnancy and for her infant, as emergency care. As such, care should be free, regardless of immigration, asylum or residence status”.

February 2008

Memorandum by the British Infection Society

1. This statement is largely correct. The idea that new antimicrobial agents and improved disease control strategies would largely eradicate infections was unfounded. Although there has been great success in reducing the burden of certain conditions (such as smallpox and leprosy), attempts to eradicate other conditions such as malaria have not proved nearly so successful. Unforeseen problems have arisen, with the emergence of new infections and the development of antimicrobial resistance in already established diseases. Lack of interest in antimicrobial discovery/development by some major drug manufacturers has delayed, and continues to delay, progress. Research into new antimicrobial drugs is essential, and this is an area where intergovernmental action could be useful.

Future progress in reducing the burden of disease depends largely on the amount of resource and effort applied. This is illustrated by WHO predictions on mortality from HIV/AIDS, where the likely trends vary enormously depending on the intervention measures that are taken. However, even with the most optimistic modelling the burden of HIV/AIDS is likely to continue to increase over the next 20 years. For many other infectious diseases the global burden is likely to fall very slowly, assuming that there is continued investment in disease control and treatment programmes. However, it is impossible to allow for the effect of new and emerging diseases, or for dramatic changes in antimicrobial resistance. Similarly an unexpected interruption or failure of an established disease control programme (for example due to civil or political upheaval, or withdrawal of funding) could have a dramatic effect on the burden of infectious disease. Conversely, giving greater international priority to control programmes could speed the reduction or eradication of certain infectious diseases. Modelling of some of these factors can be found in the WHO report on the projections of global mortality.

2. Extensive data exist on HIV/AIDS, tuberculosis, and malaria. The best available statistics are compiled by the WHO, although at best these are (by the nature of the diseases, and the countries in which they are common) estimates (<http://www.who.int/whosis/en/>). Both HIV and tuberculosis can cause a wide range of clinical syndromes from asymptomatic infection to serious disease, and while the latter is relatively easy to recognise asymptomatic infection can often not be detected without specific screening (which is not available in much of the world). These overall figures also fail to take account of vital information such as the prevalence of drug resistant tuberculosis or HIV.

Avian influenza is currently a very rare cause of human disease. The main concern is that there may be a change in the behaviour of the virus such that it becomes more transmissible from person to person: The likelihood of this happening, and the impact that it would have, is difficult to predict. It should also be borne in mind that the next influenza pandemic could be another strain entirely, with little avian connection.

3. There are examples in specific countries or areas of relatively successful programmes to control malaria and tuberculosis. However on a global basis success to date has been limited and it is hard to be optimistic about the future. At best it seems likely that continuing current levels of funding may prevent a significant increase in the incidence and prevalence of these diseases. Most estimates suggest that for HIV, even an optimistic view of the next 10 years will still see a significant increase in prevalence. It is possible that there will be some minor changes in the pattern of disease, but the biggest burden is still likely to fall the developing countries of Africa and Asia. Pandemic influenza is rather different, in that an emergency response rather than an ongoing control programme will be needed. If a potential outbreak is to be controlled there will need to be an extremely rapid response at the country of origin in the face of the emergence of a new strain of influenza. This would require not only an adequate surveillance system but also prior agreement for a great number of countries to divert significant resources to a resource poor nation. This is clearly an area where intergovernmental cooperation would be essential.

4. Published WHO data and modelling probably provides the best estimates of these.

5. Many technical problems limit progress in the prevention and control of infections. However the biggest factor is economic and social deprivation. With more money, and better social conditions, many of these diseases would disappear. This is illustrated by changes in the western world in previous centuries, when malaria and TB were largely eradicated without any major medical breakthroughs. Instead the diseases gradually disappeared as a result of better living conditions and improvements in general public health.

6. The British Infection Society is a charitable organisation which brings together specialists in various fields of infection prevention, control, diagnosis, and treatment. It supports and promotes research in infectious diseases (including the important international diseases), and works to improve teaching and training of infection specialists. However, it does not have a front line role in dealing with diseases that are largely based internationally.

7. In global terms poverty is the most important factor allowing the continuing spread of these four infections. Other factors that could be listed, for example overcrowding, sharing living space with animal reservoirs, poor hygiene, etc. can all be traced back to poverty. Concerted international action on global poverty could have a huge impact on mortality from infectious diseases, but this would need to be on a far greater scale than anything that is currently being considered. Lifestyle and increased global mobility may play a small part in introducing diseases such as tuberculosis, malaria, and HIV to this country, but this is not of great significance overall.

The situation for pandemic influenza is rather different, in that the speed and frequency of international travel could play an important role in disseminating an outbreak worldwide. In the past it has taken many weeks for pandemics to become global, but experience with SARS has shown that in the age of mass travel airborne infections can spread around the world within a matter of days. We need to have the flexibility to be able to cope with such situations.

8. The main factors driving the rise in tuberculosis in the UK are migration and poverty with relatively little contribution from HIV. Restriction of access of migrants, refugees and asylum seekers to health services both in primary and secondary care encourages the spread of tuberculosis in the community. This approach is not ethical and significant financial savings to the NHS cannot be made by preventing refugees and asylum seekers accessing healthcare but the health detriment is significant. This trend could and should be reversed if there is a serious intention to combat the rise of TB in the UK; such people should be encouraged to have health checks independently from immigration procedures. The prospect of financing this by appropriate charging of outpatient and primary care use by those who should pay (eg US visitors & others with whom there is no reciprocal health care arrangement) needs investigation. This requires governmental rather than intergovernmental action.

9. There are many reasons why tuberculosis appears to be on the increase. Approximately 50% of patients with the disease are not diagnosed. The standard test used for diagnosis world wide is microscopy, which has only 50% of the sensitivity of culture (the standard used in more affluent countries). This is despite the fact that there are tests available which are both cheap and culture based. The crowding of people together in poor urban centres increases transmission of tuberculosis generally. There is a major interplay between tuberculosis and HIV. HIV increases the rate of reactivation of tuberculosis and conversely tuberculosis drives the HIV genome to replicate.

Intergovernmental action could be used to support the development of TB control programmes, encompassing appropriate diagnostics, and new short course regimens for treatment, with drugs quality controlled and free to patients. Other essential requirements which could be promoted by such action include: laboratories in resource poor environments which are equipped adequately to protect the workers from the diseases in which they encounter, improved healthcare facilities designed to reduce nosocomial transmission of disease in outpatient and inpatient settings, and ending the black market in antimicrobial drugs which threatens TB control programmes in many developing countries. Action is also needed (whether on a governmental or intergovernmental level) to reduce disease transmission in prisons, which are acting as an amplifier for drug resistant infections.

10. In certain situations the benefit of DDT for controlling malarial vector mosquitoes outweighs the danger of the compound for human health. This assumes that DDT is used in strict compliance to guidance, and that alternative agents are used whenever appropriate. The relative risks and benefits of using DDT are summarised in the WHO DDT position paper. This document takes account of the 2005 Stockholm Convention, and we are not sure that it is helpful to consider the Stockholm Convention as an obstruction to the control of malaria.

11. The Committee should talk about pandemic influenza rather than specifically about avian influenza. Although there has been considerable focus on the H5N1 form of the virus, it is entirely possible that a different strain will cause the next pandemic, and may not be associated with birds at all. Any control mechanisms must take this contingency into account. The International Health Regulations (see para 16) are intended to form an important part of the identification and control process for infections such as pandemic influenza. In principle the IHR framework is a good one, and potentially very important for global security against pandemic influenza. However, the IHR depends on the will of international governments to implement the agreed actions, and this is one area where better intergovernmental cooperation could be very important. There needs to be better sharing of information, and also of resources. Some countries, notably in South East Asia, have made great effort to develop their own pandemic preparedness plans. However the fact that many developed countries (including the UK) are putting a great deal of effort into plans to protect their own populations from pandemic flu suggests that there is a (probably realistic) assumption that intergovernmental efforts to prevent the spread of influenza are unlikely to be effective.

12. Resistance to available antimicrobial treatment is a well-recognised problem in malaria, tuberculosis, and HIV. It may also be an issue with antiviral drugs for the treatment of influenza, although this is less well documented at present. In terms of HIV and tuberculosis, the greatest problem remains providing even basic treatment for the majority of infected people in developing countries. Although the emergence of drug resistance is worrying, and may become a bigger problem in the future, the main priority is to ensure adequate treatment for standard disease. The picture with malaria is rather different, and there is an important role for intergovernmental cooperation in establishing the best drug regimens for treating drug resistant malaria and minimising the emergence of new resistance. (For example, there have been insufficient efforts to regulate the inappropriate promotion of monotherapy of malaria using artemisinin related compounds in much of Africa.) An intergovernmental approach could also help to improve and standardise the quality of 'legitimate' drugs, and reduce the trade in black market medications.

13. In the last few years British Departments of Health have paid rather more attention to healthcare associated infections (HCAIs), with some improvement in outcome. More could be done, mainly in terms of improving buildings and facilities, and promoting research. This is largely a governmental rather than an intergovernmental issue. Some countries (including the UK) were slow to learn lessons from other areas with both very high and very low levels of HCAIs, and there is a role for improved intergovernmental sharing of knowledge to plan future changes. There is a little evidence that the British Department of Health is collaborating with other governments in order to learn lessons for the future.

14. Many new diagnostic tests are based on patented molecular approaches which will almost certainly be too expensive for the parts of the world where they are most needed. A shareware approach should be encouraged. Intergovernmental action to suspend patent issues for resource-poor countries (possibly compensating companies) should be considered. Support for the purchasing of equipment by affluent country health systems could be directly linked to providing similar equipment at reduced prices for poorer countries.

15. Education of the public is essential in the context of health programmes which can provide necessary diagnosis and treatment. In some areas of the world there are conflicts between local beliefs (religious, political, or superstitious), and the actual facts. Worldwide provision of internet based learning opportunities for those in healthcare are required. Support for education would benefit from intergovernmental co-operation

16. The International Health Regulations are discussed in para 11. As IHR 2005 only came into place in June 2007 it is too early to assess how effective it will be. A lengthy review process was completed before the current implementation phase and it would not be appropriate to make any changes until the regulations have been placed for a while and properly assessed.

17. It would be wrong to focus specifically on bioterrorism, and we do not think that this should be a priority area for the committee. However, many of the responses would be the same for either deliberate or “natural” release of a highly contagious virus (such as pandemic influenza or SARS). Experience with planning exercises for bioterrorist release have not suggested that the UK is particularly well prepared to deal with a serious contagious disease threat, and further work is needed. This is largely a governmental rather than an intergovernmental issue, and requires considerable local and regional effort in order to maintain a viable response. This implies continued central Departmental encouragement and the provision of adequate resources if local multidisciplinary and intersectoral teams are to undergo the necessary cycles of exercises and review. The development of “top down” plans for outbreak control, including central and international cooperation is required, but provides a false sense of national security unless regional and local teams are genuinely educated, involved and supported so that such plans can actually be implemented.

18. There will inevitably be new infectious agents emerging, both as a result of evolution of current pathogens (as with influenza), and due to the appearance of genuinely new and unknown diseases (often zoonotic in origin). However, it is likely that any such infections will be transmitted through the same routes as our current major infectious diseases (eg airborne, blood-borne, sexually transmitted, or vector spread). If we have robust mechanisms in place to limit the spread of currently known infections it is likely that these have would provide a good foundation for dealing with a new threat. Similarly good surveillance systems could be easily modified in the face of a new or emerging infection.

20. The UK is at the forefront of international health and infectious disease (ID) research internationally and this research base needs to be protected. Increased numbers of academic ID and epidemiology physicians and scientists are required. We also have a strong tradition of training doctors and scientists in international health and tropical medicine, and this should be supported and expanded. There are a number of specialist ID centres in teaching hospitals in Britain. Which are centres of excellence in managing infectious disease. They also play a key role in setting standards for antimicrobial stewardship and infection control, which are essential elements in preventing the emergence of antimicrobial resistance. While this may appear to be a domestic problem, global mobility means that resistant organisms will rapidly spread around the world, and maintaining high standards is an international as well as a national priority. Existing ID centres should be supported and expanded, and there should be a drive to introduce more infection specialists into district general hospitals as well as in large teaching centres. This would require an increase in posts in all infection specialties, encompassing physicians, researchers, and microbiologists. The UK has very few ID doctors per head of population (compared to the US, Scandinavia etc) and expansion of training and consultant numbers is urgently required.

Memorandum by the Centre for Global Development

COLLABORATION OF IGOs/GOVERNANCE

1. Earlier this year, UK Government Officials told us, “*If we look at a typical, highly donor dependent country, we might see 20 UN agencies, 35 bilateral agencies, 20 global, regional banks or financial institutions and 90 global health initiatives*”.¹⁶ To what extent do IGOs collaborate within countries, in implementing HIV/AIDS, TB and malaria programmes? If improvements could be made, what are they, and how can they be achieved?

The Center for Global Development’s HIV/AIDS Monitor is examining HIV/AIDS donors such as PEPFAR, The Global Fund and The World Bank MAP in three countries Mozambique, Uganda and Zambia. A comparative analysis of financial flows¹⁷ for HIV/AIDS in these three countries shows that each of these three major donors supports the national response using its unique financing approach, but could improve their coordination and sharing of information with each other to enhance efficiency of the response and increase the effectiveness of aid. The study recommended that the three donors jointly coordinate and plan activities to support the National AIDS Plan. All three donors should coordinate to avoid duplication, and ensure that resources are distributed across the range of programming needs. Coordination should be based on supporting the strategies articulated in each country’s National AIDS Plan. All three donors should work—either directly or through their Recipient Organizations—with other country-level stakeholders to finance activities that are consistent with the national plan. Where a host country’s plan is weak or has gaps, donors should coordinate efforts to assist the government and other country-level stakeholders to strengthen it.

More broadly, other work at CGD suggests that multilateral agencies serve two broad functions in the delivery of aid:

- (i) Achieving collective action in the presence of heterogeneous preferences among donors or between donors and recipients.
- (ii) Economies of scale and scope, especially in information gathering and analysis.

One benefit for recipient countries of the multilateral agency system is the partial restoring of the broken feedback loop that is typical of bilateral aid where it is usually the donors who can influence the political decision making process. That is, it gives recipient countries a voice in decision making. Of course, the voice of recipient countries in these agencies is dependent on the voting systems in the multilateral agency. One example is the need to address the governance of the World Bank in order to better engage developing countries. In a 2005 working group report, one of the recommendations was “to push the Bank’s member governments to make the Bank’s governance more representative and thus more legitimate.”¹⁸

In the specific example of the Global Fund to Fight Aids, TB and Malaria (GFTAM), the 2006 CGD working group report¹⁹ made a variety of recommendations that would allow for more effective collaboration with other international agencies and recipient countries. These include:

- (i) The ED initiates a regular meeting, with at a minimum, the Director General of the WHO, the ED of UNAIDS, and the President of the World Bank to discuss complementary roles and activities, including mutual support for operations on the ground, technical assistance, procurements, monitoring and evaluation, alignment and harmonization around country operations.
- (ii) The GFATM move beyond a one-size-fits all approach and design a range of operational models in different countries. Differentiated models would help provide principal recipients and country coordinating mechanisms with incentives for strong performance and provide pooled financing where appropriate.

ADDITIONAL SOURCES

Birdsall, Nancy. 2007. “Do No Harm: Aid, Weak Institutions, and the Missing Middle in Africa”. CGD Working Paper 113. <http://www.cgdev.org/content/publications/detail/13115>.

_____. 2003. Why It Matters Who Runs the IMF and the World Bank. CGD Working Paper 22. <http://www.cgdev.org/content/publications/detail/2768>

¹⁶ Dr Stewart Tyson (DFID), Oral Evidence, Q 1.

¹⁷ See Oomman, N, M Bernstein and S Rosenzweig, “Following the Funding: A Comparative Analysis of the Funding Practices of PEPFAR, the Global Fund and World Bank MAP in Mozambique, Uganda and Zambia. Center for Global Development. 2007 available at <http://www.cgdev.org/content/publications/detail/14569/>

¹⁸ Center for Global Development. 2005. “The Hardest Job in the World: Five Crucial Tasks for the Next President of the World Bank”. CGD Working Group Report. <http://www.cgdev.org/content/publications/detail/2868>

¹⁹ _____. 2006 “Challenges and Opportunities for the New Executive Director of the Global Fund”. CGD Working Group Report. <http://www.cgdev.org/content/publications/detail/10948>

2. Many organizations told us that the only effective way to coordinate external donors and multilateral partners is to put the recipient country in charge of the coordination and management of financial aid. How do you assess recipient countries' capacity to negotiate with intergovernmental organizations such as the GFATM, WB and other and to effectively coordinate various programmes?

One means of assessing and improving recipient countries' capacity to effectively coordinate programmes with multilateral agencies like the World Bank is to enhance their voice and representation in these agencies to signal more ownership of programmes and projects, as described above.

The management of all of these donors is extraordinarily difficult for recipient countries. But sometimes the cure of "coordination" is worse than the disease, especially from the recipient's point of view. Suppose that all of the donors were truly coordinated a donor agency set up for that purpose. That is likely to mean that all the donors must meet and agree before the recipient country can get anything. This would be an interminably unwieldy and inefficient process. Furthermore, donors are unequal. Those with money and prestige will wield more power and ultimately do an end run around the donor coordinating agency in order to strike side-bargains with the government. (There is anecdotal evidence that World Bank task managers frequently felt forced to do such end runs around UNAIDS.)

Alternatively, many recipient governments could instead shop their ideas and proposals across a wide variety of donors, until they find a donor with a desire and capability to help with a particular project or program. Assessing a recipient country's capacity to negotiate with an IGO like the GFATM or the WB could begin with fixing a knowledge asymmetry (over and above an inherent resource asymmetry) between the two. By providing more complete and timely information about donors, recipients can make decisions about requesting specific donors for support for specific programs and minimize the coordination of multiple donors.

BALANCE OF INVESTMENT

3. UK Government Officials also suggested that "*within the AIDS opus there is an imbalance between money going into prevention, treatment, care and palliative care*".²⁰ Have IGOs been placing too much emphasis on the treatment of HIV/AIDS, and not enough on prevention? Should IGOs revise their priorities?

Different IGOs have revealed different preferences with respect to the trade off between treatment and prevention. The World Bank has been much slower to fund treatment, preferring to fund prevention and health systems support mechanisms and community based development styled support for patients and orphans. Figure 6 of the CGD working paper on PEPFAR (<http://www.cgdev.org/content/publications/detail/15973/>) demonstrates that the US PEPFAR program shifted its funding somewhat away from prevention and towards treatment between 2005 and 2006.

Research from the HIV/AIDS Monitor indicates that:

Programmatic activities supported through Global Fund grants varied significantly by country. Prevention, for example, made up only a small share of total Global Fund monies to Uganda but a substantial share of funding to Zambia. Even within funding categories, resources often go to different types of interventions. For instance, 41% of disbursements for prevention in 2004, and 88% in 2005, went toward condom distribution in Uganda, while the available data for Zambia show an emphasis on outreach and behavior change, and only small amounts for condom distribution.

The variation notwithstanding, a significant and increasingly larger share of Global Fund money is being allocated for treatment activities. The percentage of disbursements going to ARV treatment and services in Uganda went from 21% in 2004 to 33% in 2005 and 72% in 2006.²¹ While no programmatic data are available for overall Global Fund disbursements in Zambia, data from two ROs, ZNAN and CHAZ, reflect the trend toward funding for ARV treatment—ZNAN disbursements for treatment went from 0% of total disbursements in 2004 to 51% in 2006, while CHAZ saw an increase from 0% to 15% of funding in the same period. In addition, the Chief of Party for the MOH's component of the grant has noted that most money going to his ministry was programmed for ARV treatment.

Specific Recommendation provided to the Global Fund based on the above evidence:

²⁰ Dr Stewart Tyson (DFID), Oral Evidence, Q 6.

²¹ Some of this large increase in ARV treatment and services as a percentage of total disbursements in 2006 in Uganda can be attributed to the suspension of Uganda's grants in 2005, and the Global Fund's decision to continue funding most facilities that were providing life-saving ARV drugs.

Keep the focus on funding gaps. The Global Fund is right to focus on filling funding gaps. It should continue to ask Country Coordinating Mechanisms (CCMs), as part of the grant application process, to identify all major AIDS activities ongoing in their country. This will help ensure that Global Fund money is made available, where warranted, to support under-resourced priorities such as prevention activities.

For further information please see: <http://www.cgdev.org/content/publications/detail/14569>

HORIZONTAL VERSUS VERTICAL HEALTH PROGRAMMES

4. In its 2007 report, *Help Wanted*, MSF wrote, “efforts to further increase access to [antiretroviral therapy (ART)] and maintain and improve quality of care are coming up against a wall due to the severe shortage of health workers”.²² What is the impact of the implementation of vertical programmes on the wider health care systems? Should IGOs be doing more to ensure that horizontal and vertical health programmes are successfully integrated, and should they be placing more emphasis on horizontal issues such as workforce shortages?

Current research (paper is expected to be released in August 2008) suggests that the Global Funds health system strengthening inputs vary by country and depend on the country’s identified needs for this type of support. While results from this analysis are still preliminary, a key recommendation to the Global Fund for its role in health systems strengthening (HSS) is that it strongly communicates its ability to support HSS activities to recipients so that proposals submitted to the Global Fund can indicate this as a priority if other donors are not adequately supporting weak components of the health system such as supply chains, health information systems and mitigating the severe shortage of health workers. In addition assessments of the health system should be improved to enable more focused Global Fund inputs for health system strengthening.

Additional input from Mead Over suggests:

On the first question, the reader can consult Section D on page 21 of the working paper cited above, which is titled: *D. Expanding AIDS treatment may crowd out other health care*. However, the bottom line is “We don’t know yet.” The answers to the questions about whether donors should do more to strengthen health systems is unequivocally “yes”. This would include improving health worker educational systems. However the attempt to prevent health worker migration from AIDS affected countries (or their immigration into donor countries) is misguided and likely to have the unintended consequence of reducing both the quantity and quality of local health care workers. See Michael Clemens’ Working Paper on migration of health workers from African countries to donor countries.

PERFORMANCE OF GLOBAL FUNDS AND PARTNERSHIPS

5. In a 2007 report, the UK Department for International Development (DFID) concluded that “*the [Global] Fund is playing a valuable role within the international architecture mainly due to its ability to rapidly raise significant additional resources for the three diseases and produce impressive concrete results . . . However, individual country performance is varied, as proposals are dependent on the capacity within country to prepare them. There is also a concern about the Global Fund’s impact on health systems (which are generally under-resourced) and the sustainability of its operations, more generally*”.²³ What is your view on the performance of major donors like the Global Fund in providing treatment/prevention to patients in developing countries? Have these Funds and Partnerships produced positive results? Are the results and operations of these organisations sustainable? What is your assessment of their value for money?

Formal assessments of the impact of the Global Fund have not been conducted until recently (see below). However, comparative research and analysis from the HIV/AIDS Monitor suggest that the Global Fund is an important and much needed funding mechanism for AIDS given its ability to provide flexible funding for country identified priorities. Through ongoing research the HIV/AIDS Monitor has found that the Global Fund can strengthen its financing model, by (in addition to ensuring that its funding supports those areas of the response that other donors cannot fund-see above recommendation):

- *Re-examining strategies to build local capacity.* Global Fund ROs continue to face capacity constraints, suggesting that the Global Fund should re-examine how it identifies and/or addresses capacity constraints.

²² Médecins Sans Frontières, *Help Wanted: Confronting the health care worker crisis to expand access to HIV/AIDS treatment: MSF experience in southern Africa* (Johannesburg, MSF: 2007), p 2. Available online at http://www.doctorswithoutborders.org/publications/reports/2007/healthcare_worker_report_05-2007.pdf

²³ DFID, *GFATM Development Effectiveness Summary* (London: DFID, 2007), p 5. Available at <http://www.dfid.gov.uk/pubs/files/mdes/GFATM.pdf> (accessed 30 March 2008).

- *Simplifying procedures for good performers.* The Global Fund should streamline reporting requirements for ROs that have demonstrated an ability to effectively use earlier Global Fund grants. For example, these ROs could receive larger individual disbursements to cover at least twelve months of subsequent program activities. The Global Fund will soon adopt a streamlined procedure for good performers to access new funding (for up to six years) at the end of a current grant.
- *Publicly disclosing additional data.* The Global Fund should publicly disclose additional financial data that it already collects from ROs. In particular, the Global Fund should consider posting to its website the following information: first-year budgets and second-year budget estimates which are prepared at the outset of each grant; grant-specific documents known as “Sources and Uses of Funds”; and the Fiscal Year Progress reports submitted by each RO. By disclosing these data, the Global Fund will enhance its demonstrated ability to share information with multiple stakeholders and increase the effective use of its resources.

Additionally, the strength of the GFATM is its unique inclusion of civil society in the proposal development, program management and program evaluation for grant resources. This structure arguably gives the GFATM more legitimacy and makes its activities more transparent than is the case for the other donors. This is true regardless of the “effectiveness” of the GFATM *vis-à-vis* the other IGOs on more output oriented measures.

Furthermore, the GFATM and other multilaterals have a special advantage as channels for AIDS treatment funding. Donor countries which directly finance AIDS treatment for individual patients in poor countries are creating a dependency relationship between those patients and the donor. Since over the span of several years the patients who remain alive only because of this donor will find it increasingly difficult to oppose that donor in other areas (such as on UN votes), this engendered dependency relationship can be viewed as a kind of “post-modern colonialism”. In his paper, Mead Over argues that this new kind of colonialism, stemming from generous impulses, can nevertheless produce resentment among recipient countries just as traditional colonialism did. To counteract this trend, he suggests that the US should commit its AIDS treatment financing increasingly through the intermediary of the GFATM or other multilateral organizations.

6. How effective are these programmes in evaluating their results and their impact on health outcomes in beneficiary countries?

Donor-funded health programs have a mixed record of assessing their impacts on health and other dimensions of human welfare. In general, donor-funded programs—including many in the health sector—have been characterized by weak evaluation, often focusing on inputs (amount of money spent) and failing to measure results. This is the case for many reasons, including:

- (a) the knowledge generated through evaluation is a public good, and so no single agency or program has sufficient incentive to invest adequately;
- (b) agencies that fund or implement programs generally place priority on “doing” rather than “learning,” and may see in-depth evaluation as unnecessary research; and
- (c) there are bureaucratic disincentives to transparent evaluation if funding or prestige are placed at risk by revealing failures.

Health programs have generally undertaken better-than-average evaluation, however, because of the scientific tradition in the health sector, and the relative ease of measuring key outcome variables, such as child mortality (relative, for example, to development outcomes such as improved gender equality or stronger democracies).

Unfortunately, among global health efforts, HIV/AIDS programs have been among the least rigorously evaluated. The “emergency” and politically visible nature of the programs to scale-up anti-retroviral treatment has compromised opportunities for rigorous evaluation. For example, in the US PEPFAR program, decisions were made early on not to embed rigorous impact evaluation in the program design. Moreover, the relative scarcity of resources for prevention activities, as well as some significant methodological challenges (estimating “infections averted” in the absence of a context-specific model of HIV transmission) have resulted in relatively little evaluation of prevention efforts.

The GFATM is currently doing an “impact evaluation” which fails to articulate a coherent strategy for establishing a counterfactual and thus cannot actually aspire to “evaluate” any “impacts” at all. The World Bank funded a program called the Treatment Acceleration Project which was to have a “Learning Agenda”.

However, they failed to fully fund the Learning Agenda and are now pulling out of the Treatment Acceleration Project and its associated learning after only four years. One promising action is that some IGOs are supporting the new institution called the International Initiative for Impact Evaluation (3IE). See the following link for more information http://www.cgdev.org/section/initiatives/_active/evalgap

27 May 2008

Memorandum by Food and Agricultural Organisation of the United Nations

1. The Food and Agriculture Organization of the United Nations (FAO), together with the World Organisation for Animal Health (OIE), has taken a prominent role in coordinating the international response to the H5N1 highly pathogenic avian influenza (HPAI) crisis in animals. FAO's global programme aims to mitigate the risk of a human influenza pandemic by controlling infection with HPAI at its source in birds and to safeguard smallholders' livelihoods, food security and rural development in developing countries through the support to the poultry sector thanks to better control of HPAI and other major diseases. FAO works with a range of international, regional and national partners and has developed institutional structures to deal with the emergence and spread of transboundary animal diseases (TADs) of which HPAI is one. FAO works in close collaboration with the World Health Organization (WHO) to mitigate the risks of human infection when the TAD is zoonotic, as in the case of HPAI.

2. FAO's overall objective with respect to HPAI is *"to safeguard animal health and livelihoods from the threat of HPAI and mitigate the risk of a human pandemic through prevention and control of HPAI in the poultry sector at three interconnected levels: global, regional and national"*.

3. The desired outcomes of FAO's approach are threefold; a coordinated and efficient global response to HPAI; development of disease control strategies and options that are technically sound, economically sustainable, ecologically appropriate and socially acceptable, which are available and communicated to decision makers; and, regional and national capacities and capabilities are developed for effective prevention and control of HPAI in the animal population.

In response to the principle issues raised by the Committee:

4. *Question 1:* Infectious diseases remain a threat to human health, animal health and food security. In animal populations they can have severe social implications, including market shocks and disruption of orderly social structures, which may be out of all proportion to their direct effect on animal and human health. This is particularly so with zoonotic diseases. The last couple of decades have seen the emergence, or re-emergence, of a number of infectious diseases with potential global impact. Of the newly emerging diseases, about 75% have originated from non-human animal species. Failure to control TADs is often less an issue of lack of technical knowledge than a lack of effective animal health systems and particularly of strong Veterinary Services able to detect and respond to diseases, and significant weaknesses in communication strategies and planning. This is particularly so in Africa. In general the situation remains critical because currently recognized diseases threatening global spread are not being adequately controlled and, regarding HPAI, it can reasonably be expected that the virus will continue to circulate in the coming years. Furthermore, from the perspective of affected communities and the millions whose nutritional security and livelihoods are dependent on poultry, HPAI is an unprecedented crisis.

5. *Question 2:* For human infections with HPAI, the WHO official records show 351 reported human cases of which 219 were fatal (22 January 2008). Almost all have occurred in people who have close contact with infected birds.

6. *Question 3:* FAO's emergency prevention system (EMPRES) addresses TADs by focusing on early warning and early response, by enabling research and by coordination. Its disease intelligence warning arm is the Global Early Warning and Response System (GLEWS), which was a component of the FAO EMPRES programme and which has become, in July 2006, a joint FAO, OIE and WHO platform. GLEWS collects and analyses disease information derived from field officers, mission reports, FAO country Offices/teams, media, rumour tracking, etc, and distributes it to partner countries to facilitate their accurate risk assessments and disease preparedness plans. GLEWS is a growing system and, as international networks continue to be strengthened its value, will continue to increase. Furthermore, in 2007 FAO has established jointly with OIE and in strong partnership with WHO a Crisis Management Centre for Animal Health (CMC-AH) which can send a "fire-brigade" type team when new outbreaks occur in countries. In mid-2007, FAO established a Communication Unit within its Emergency Centre for Transboundary Animal Diseases (ECTAD), which is partnering with all other major agencies in analysing, developing, defining and implementing effective communication responses to the crisis.

7. *Question 4:* Global eradication of H5N1 HPAI in the immediate future is an unrealistic goal. It is clear from current experience with HPAI that countries which have well structured and resourced veterinary services are able to detect incursions of disease rapidly and to eliminate them. Therefore, while gaps in knowledge exist, it is possible with current knowledge to eliminate infection if the resources are available. A major component of the FAO/OIE strategy in combating the global threat of HPAI is to support national governments, within the framework of regional support and networking systems, to build capacity for surveillance, disease diagnosis, communication strategies, and response to disease incursion, and to have in place integrated national preparedness and response plans. While this is being done for HPAI, the structures and resources developed contribute to the control of all TADs. Given the inadequate state of the veterinary services in many of the countries that have requested international assistance, this is a huge undertaking that will require financial support and commitment for years to come. In some countries the first indication that HPAI is present in poultry was when human deaths occurred.

8. *Question 5:* Great progress has been made with global and regional coordination and support but the major constraint to controlling HPAI in birds is inadequate national veterinary capacity and capability in many infected and at risk countries. Additionally, much more focus and field-research needs to be undertaken to better understand transmission pathways in poultry production and marketing chains including the role of wild birds to identify barriers/enablers to change for improving interventions.

9. *Question 6:* In implementing its Global Programme, FAO has forged strong partnerships with OIE and WHO and works closely with the United Nations Children's Fund (UNICEF), which has an important role in avian influenza communication. FAO and other UN agencies work under the overall coordination of the office of the United Nations System Influenza Coordinator (UNSIC) in New York. Close working relationships are established with other international institutions such as the World Bank, the Asian Development Bank and the European Union, as well as strategic donors and regional structures such as the Association of Southeast Asian Nations (ASEAN) and the African Union's Interafrican Bureau of Animal Resources (AU-IBAR).

10. *Question 7:* Many factors contribute to the emergence of new diseases and international disease spread. Globalization and intensification of agricultural production systems and the international movement of animals, animal derived products and associated commodities have the potential to rapidly spread a disease that originates in one location across the globe. The major safeguard against this occurring is the formulation and implementation of sound biosecurity measures to control the movement of risk products. This has not yet been achieved uniformly and much of the spread of HPAI (and other TADs) can be attributed to trade in poultry and poultry products, particularly the informal trade. The role of wild birds still remains largely unknown. An additional aspect, that needs deeper analysis, is the role of incentives (financial as well as non-financial) that can catalyse rapid uptake of biosecurity measures among small and medium-sized poultry production enterprises, millions of which exist around the world.

11. *Questions 8, 9, 10* are not applicable.

12. *Question 11:* FAO's support to strengthening national surveillance systems for HPAI aims to provide early recognition of disease in poultry so that Public Health authorities can be alerted to the potential of human infections before they occur. Also the OIE/FAO Network of Expertise on Avian Influenza (OFFLU) interfaces with WHO and facilitates the exchange and molecular characterization of avian isolates of HPAI to monitor changes that might be consistent with mutations towards a pandemic virus. FAO has also strongly advocated with communication partners to prioritise interventions for the prevention of animal-to-animal transmission of HPAI and the early reporting of suspect events by communities. However, much more needs to be done in this domain, given that this is critical for stopping the spread of the disease at its source.

13. *Questions 12, 13* not applicable

14. *Question 14:* Exchange of current isolates of H5N1 HPAI is resisted by some developing countries because they fear losing out on fair access to any vaccines or new diagnostic tools that may be developed by commercial companies in developed countries. This is a critical issue that needs to be resolved and monitored to ensure good international access to information on any changes that are occurring in the virus towards pandemic potential.

15. *Question 15:* A major component of FAO's Global Programme for the prevention and control of HPAI is the development of technically sound control strategies and options and their communication to decision makers in partner countries. Activities conducted to strengthen national veterinary capacity include training and regional networking to achieve harmonization of approaches and sharing of experiences while still leaving room for adapting those sound policies and tools to local conditions and priorities.

16. *Question 16:* No comment

17. *Question 17:* The approach taken by FAO in supporting countries to develop HPAI preparedness and response plans is to ensure integration of the plans with all other government authorities who may be called on to play a role in response to a disease incursion. These plans are then tested in simulation exercises to evaluate adequacy of the planning and capability to respond. Surveillance and preparedness plans usually have a trigger event, such as mortality above a certain level in chickens, which initiates the response. There is scope to explore further how valuable a syndromic approach, based on a set of clinical signs, rather than a disease-specific approach, might be in providing early warning, which can then be investigated and further resolved. There is also evidence emerging that monitoring changes in market patterns and flows of commodities can be used to give early warning of possible disease events, whether or not they are deliberately initiated. More work is needed, both in respect of HPAI and in disease detection in general.

18. Communication strategies that raise public awareness, gain community engagement, motivate poultry producers to adopt the minimum set of biosecurity measures, and promote early reporting of disease events are critical if outbreaks, which may start in remote areas, are to be detected early enough to prevent spread.

19. *Question 18:* Over the past three decades there has been a steady stream of new infectious diseases emerging, as well as old diseases re-emerging or gaining new significance through greater prevalence or resistance to current treatments. About 75% of the new diseases are derived from animals. It can be reasonably expected that the rate of emergence of new diseases will continue in response to ecological changes impacting on human and domesticated animal populations, many of which will be caused or exacerbated by climate change. Of particular concern will be those infectious diseases transmitted by insect vectors. While much community focus is on human diseases, the impact of new diseases or diseases that move to new geographical locations (such as West Nile Virus in the USA) may be felt in domestic and wild animal populations also. Even those diseases that do not directly affect human populations may affect food security by their impact on food animal populations.

20. *Question 19:* The UK has pledged US\$10.17 million in support of FAO's global programme for prevention and control of HPAI. Of this amount US\$6.876 has been pledged to the Special Fund for Emergency and Rehabilitation Activities (SFERA). This latter pledge has added value in FAO's work because it provides flexible funding to meet priority needs rather than being earmarked to specific countries or regions defined by the donor. To date US\$5.579 million of the total pledged amount has been received by FAO. Funds have been utilized to: support global coordination activities; develop preparedness and response plans, training and veterinary capacity building in Ethiopia; to provide resources and expertise in Uganda; and to strengthen surveillance and diagnostic capacity, communication and public awareness, emergency preparedness plans and for socio-economic assessment in Kenya. The development and implementation of these projects is carried out with international and regional partners, and other donors (USA in the case of Ethiopia). Parts of some projects have been implemented by specialist institutions such as the Royal Veterinary College, London, for epidemiology training.

21. *Question 20:* The important role played by effective communication strategies and programmes cannot be over emphasized in keeping the public informed, aware and engaged in the detection and response to infectious diseases. This is particularly so with diseases of livestock such as HPAI, in which case an alert and engaged stock owner, who may be a villager with no more than 10 or 20 chickens, can play a critical role in early warning and response and instituting local biosecurity measures to protect their own health and to prevent spread of infection to other birds. Effective communication ahead of disease events is also valuable in mitigating market shocks and distortion of trading patterns that can follow disease identification. For example the impact on tourism as a result of the SARS outbreak was immense and reflected the public's fear of being exposed to infection by air travel.

22. There is global agreement among all partners that stopping the highly pathogenic avian influenza (HPAI) H5N1 virus "at source" (ie, among poultry) is critical in order to minimize the impact on agriculture and to prevent the emergence of a human pandemic. However, to date, the overwhelming majority of the communication interventions and discourse has been biased towards the issue of human rather than animal health. Much of this has been in the nature of an emergency response, led by outbreak and risk communication from a human health perspective, directed at the latter stages of the animal-to-human transmission, rather than the earlier stages of the poultry-to-poultry transmission. While these public health driven communication interventions may help prevent animal-to-human transmission of the virus, and perhaps human-to-human transmission in the future, they have done little to help prevent the spread of the virus through biomechanical transportation and animal-to-animal transmission. Factors that strongly influence public response have often not been clearly and consistently communicated. Emerging evidence from a wide array of studies suggest that, while most people in affected countries have heard and are aware of avian influenza, confusion still exists about its transmissibility, and means of prevention. News reporting has often tended to be sensational, confusing and inaccurate—fuelling rumours and loss of public trust and confidence in national authorities. This has generally

precipitated large-scale negative consumer reaction and poultry market shocks/disruptions during outbreaks. Existing communication capacities, and resource allocations for communication planning, especially for Ministries of Agriculture/Livestock, have been less than optimal, and thus, in the event of an outbreak, policy and decision-making within national governments still seem to be reactive.

23. Socio-economic information on such things as the impact of disease and control programmes on small holder livelihoods and markets is important in developing control strategies that are effective while avoiding negative impacts that will deter stock owners from reporting disease or will endanger food security for vulnerable members of society.

24. It has become clear that wildlife (primates, other mammals and birds) play an important role as reservoirs of infectious agents that, under suitable circumstances, spill over into human populations with devastating effects. At present the common approach has been to work back from finding a new human infection to try to discover from which animal species it has originated and the circumstances that may have led to its movement across species. A prospective approach could be taken to increase the study of infectious agents in wild life, focussing on targeted species that come into contact with humans, often as a source of food, and to ensure that tools are available to rapidly investigate any emerging human diseases that appear to have a wildlife reservoir. FAO is supporting major studies with partner organizations on migrating wild birds to clarify their potential role as international disseminators of H5N1 HPAI.

25. A comprehensive report on FAO's activities in prevention and control of HPAI is available at <http://www.fao.org/docs/eims/upload/236620/ah690e.pdf>.

February 2008

Memorandum by GlaxoSmithKline

INTRODUCTION

1. GlaxoSmithKline is committed to playing its full part in helping to address the healthcare challenges of the developing world by working in partnership to develop innovative, responsible and sustainable solutions.

2. GSK is proud of its long history in working in developing countries and our work is focused on four key areas²⁴: preferential pricing of our antiretrovirals, anti-malarials and vaccines; investing in research and development (R&D) that targets diseases disproportionately affecting the developing world; community investment activities and partnerships that foster effective healthcare; and working on innovative partnerships and solutions.

3. There are no easy solutions to the challenge of improving healthcare in developing countries. In many countries people do not have enough food, clean water, hospitals, clinics or healthcare professionals to care for them. Often the Governments of these countries simply do not have the resources needed to address the healthcare needs of their people. Significant additional funding from new national and international sources must be mobilised to make a real difference.

4. However, lack of resources can be no excuse for lack of action. HIV/AIDS, TB and Malaria are robbing communities and nations of their greatest asset—their people. That is why prevention and developing and distributing treatments is so critical. While it is primarily the responsibility of Governments and intergovernmental agencies, supplemented by the work of many NGOs, to deliver the holistic healthcare needed in these countries, the pharmaceutical industry can play a significant role in supporting their work.

5. The UK is a world leader in addressing these challenges. As a UK company GSK is always keen to explore ways of working with the UK Government on these issues. We urge the UK to continue to encourage the G8 and other developed nations to follow its lead. For example, others must show a similar focus and sense of urgency in delivering on the Gleneagles and UNGASS commitments, to achieve the Millennium Development Goals (MDGs).

6. This Call for Evidence noted that each organisation responding need only answer those questions in which it had a particular interest. Accordingly, GSK offers responses to questions 5, 6, 7, 11, 12 and 14.

7. GSK would like to thank the Committee for the opportunity to contribute to this important inquiry and we look forward to providing any additional information the Committee may require.

²⁴ For more information, please see <http://www.gsk.com/responsibility/cr-review-2006/access-to-medicines.htm>

Question 5. *What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted coordinated intergovernmental action?*

8. GSK believes that significant progress could be made in addressing these issues by:

- (1) Greater sustainable and predictable provision of financial resources
- (2) Greater action by developing countries to strengthen their own healthcare systems
- (3) Ensuring that the right environment exists to encourage and support R&D for the developing world
- (4) Addressing the issue of counterfeit medicines
- (5) Encouraging the removal of tariffs and taxes on medicines
- (6) Continuing to build a framework that encourages voluntary preferential pricing
- (7) Putting in place a global influenza pandemic preparedness plan to help developing countries

In terms of how these issues could be addressed, GSK suggests:

9. Greater sustainable and predictable provision of financial resources: The UK Government has played a leading role supporting multilateral funding mechanisms such as the *GAVI Alliance* and the *Global Fund to Fight HIV/AIDS, TB and Malaria* as well as playing a leading role in developing innovative financing mechanisms such as the International Finance Facility for Immunisation.

10. These mechanisms are making a significant difference but more needs to be done and the UK should encourage other high-income countries to play their full part in supporting these organisations. In addition ensuring adequate funding it is vital to look at ways of introducing greater predictably and sustainability of funding.

11. In terms of the International Finance Facility for Immunisation GSK remains committed to working with the UK and the World Bank to ensure that Advance Market Commitments (AMCs) are designed in a way that maximises their effectiveness. AMCs offer a powerful and cost-effective market-based financing mechanism to accelerate the development and availability of priority new vaccines against diseases that currently kill millions of people in developing countries. The mechanism complements existing prevention, treatment and research efforts by providing a financial commitment to subsidise the future purchase of vaccine. Early, guaranteed commitments encourage potential vaccine suppliers to invest in R&D and production capacity to serve developing countries, secure in the knowledge that there will be a viable market if they supply products that eligible countries want to buy. Such mechanisms, as well as others such as Advanced Purchase Agreements (APAs), if designed well, have huge potential in improving healthcare in developing countries.

12. In addition to existing and innovative funding mechanisms inevitably new resources will be required to tackle emerging threats, such as pandemic influenza. The WHO's Strategic Advisory Group of Experts on immunization (SAGE) recently recommended that WHO builds a stockpile of 150 million doses of H5N1 influenza vaccine. One third of these doses will be reserved to help contain an initial human outbreak, should H5N1 attain the ability to transmit from human to human, and the remainder would be reserved to help low and middle income countries fight a pandemic should it be caused by H5N1.

13. GSK fully supports efforts to help all countries, particularly the most vulnerable, prepare for an influenza pandemic. In June 2007 GSK announced that we intended to donate 50 million doses of H5N1 pre-pandemic influenza vaccine to the WHO's stockpile. In addition GSK announced that we would provide additional vaccine to WHO at a preferential price. The key issue now is ensuring that the stockpile has sustainable funding. The UK Government can play a leading role in providing new funding for, and increased commitment to, this and other global immunisation partnerships.

14. Greater action by developing countries to strengthen their own healthcare systems: The UK should continue to encourage, and financially assist, developing countries to prioritise health in their national budgets, strengthen their health systems and take a holistic approach to providing healthcare. This should embrace prevention—education and immunisation programmes—as well as the safe administration of quality treatment and be backed up with measures to address social factors such as stigma and discrimination and the migration of health workers. In supporting national health systems, the UK must seek a balance between the need for accountability and the desire for simplicity that comes from direct budgetary support. It is vital to monitor and evaluate and where appropriate take action.

15. Ensuring that the right environment exists to encourage and support R&D for the developing world: To help address diseases of the developing world, GSK is committed to investing in R&D and working in Public-Private Partnerships (PPPs) to help develop new medicines and vaccines for diseases of the developing world.

16. The PPPs that GSK is working with include Medicines for Malaria Venture (MMV), The Global Alliance for TB Drug Development (GATB), the Malaria Vaccine Initiative (MVI) and the International AIDS Vaccine Initiative (IAVI).

17. PPPs such as these are transforming the landscape of R&D into diseases of the developing world. Many of these PPPs are now showing real promise and there is a growing need for additional sustainable funding if we are to ensure that they deliver on their true potential ie that people in the developing world receive the new vaccines and medicines they produce. To ensure that promising vaccines and medicines make it through late stage development there is a need to strengthen the capacity of developing countries to carry out clinical trial activity. Developing this capacity will require all stakeholders to work together.

18. Addressing counterfeit medicines: The international community, and the G8 in particular, recognise that counterfeit medicines are a serious threat to public health in many developing countries. Sustained action is required to ensure that the threat from counterfeiting of medicines, in Africa, China and elsewhere continue to be recognised and that appropriate early warning alert mechanisms and regulatory procedures are in place and enforced. Not only do counterfeit medicines waste scarce resources, at their worse they kill.

19. Encouraging the removal of tariffs and taxes on medicines: In many developing countries affordability is significantly affected by high taxes and tariffs. GSK urges the UK Government to ensure that the EU supports proposals in international fora to eliminate tariffs imposed on medicines and medical devices. This will have a significant impact on reducing prices and hence affordability.

20. Continue to build a framework that encourages voluntary preferential pricing for therapies needed in developing countries: To enable companies to offer preferential prices to the poorest and most vulnerable countries, it is important that medicines reach the patients they are intended for and are not diverted by middlemen back into rich countries. Such illegal diversion of preferentially priced medicines must be condemned and appropriate measures put in place to prevent diversion along with penalties for those that carry out this illegal trade. Other developed world Governments should be encouraged to follow the EU's lead in introducing anti-diversion measures specifically aimed at ensuring preferentially priced products reach the people who so desperately need them and are not diverted to richer markets.

21. Additionally, Middle Income Countries must accept their responsibilities and not seek the lowest prices offered to the world's poorest countries and developed countries should not use the preferential prices offered to the developing world as benchmarks for their domestic drug prices.

22. Putting in place a global pandemic preparedness plan to help developing: Recognising that many developing countries may not have the necessary resources to protect themselves, a global pandemic preparedness plan is urgently needed. GSK is fully committed to working with WHO and others to address this issue.

23. Importantly, advances in technology and science have given us an unprecedented opportunity to prepare. Until recently one of the biggest challenges in confronting a pandemic has been that vaccines could only be produced after a pandemic had started. Identifying and isolating the virus and manufacturing lead times meant that the first vaccines would only become available some 4-6 months after a pandemic has been declared. In today's interconnected world, a pandemic virus could easily circumnavigate the globe within a matter of weeks. The first wave—which is usually the most deadly—could be over by the time the first pandemic specific vaccines become available.

24. This problem has led companies like GSK to develop what are often called pre-pandemic vaccines—vaccines which can be stockpiled in advance of a pandemic and which can be used as soon as, or even before, a pandemic has been declared. A number of rich countries are already stockpiling these vaccines.

25. GSK's pre-pandemic H5N1 vaccine uses novel proprietary adjuvant technology. Adjuvants are substances that boosts the body's natural immune response. Improvements in adjuvant technology mean that reduced amounts of antigen is needed for each dose of vaccine—so that potentially up to 12 times more vaccine can be produced in the event of a pandemic.

The ability to stockpile pre-pandemic H5N1 vaccine now, and the potential increases in pandemic production capacity mean that potentially all countries—including the poorest— have the tools to put in place a comprehensive pandemic preparedness plan if resources are mobilised.

26. GSK believes that the international community should:

- Ensure that enough pre-pandemic H5N1 vaccine is stockpiled to address developing countries' needs. As noted above GSK has announced its intention to donate 50 million doses but additional sustainable funding is also needed.

- Take steps to ensure that developing countries are able to secure access to the actual pandemic vaccine which will only become available after the pandemic strain has been identified and isolated. Many developed countries approach this problem by putting in place Advanced Purchase Agreements (APAs) to guarantee access to vaccine. GSK believes that APAs are one instrument which could be established to cover developing countries with the help of WHO and other supranational organisations.
- Ensure sustainable global manufacturing capacity for pandemic vaccine by sustainable increases in demand for seasonal vaccine. Pandemic vaccine will be made in the same plants as seasonal vaccines are currently made thus increasing seasonal production results in extra manufacturing capacity which could be switched to production of pandemic vaccine.

Question 6. *What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?*

27. As noted above GSK's approach to combating these four diseases is based on preferential pricing; investing in research and development (R&D); community investment activities and partnerships that foster effective healthcare; and, innovative partnerships and solutions.

28. Preferential pricing. GSK has offered sustainable preferential pricing for antiretrovirals (ARVs) since 1997 and for vaccines for over 20 years. Our AIDS medicines and anti-malarials are available at not-for-profit prices to public sector customers and not-for-profit organisations in 64 countries—including all the Least Developed Countries (LDCs) and all of sub-Saharan Africa (SSA). In addition, all private employers in SSA who provide care and treatment to their uninsured staff can purchase our ARVs at not-for-profit prices and all CCM-led programmes fully funded by the *Global Fund to Fight AIDS TB and Malaria* are also eligible as are projects run by the *US President's Emergency Plan for AIDS Relief (PEPFAR)*.

29. In total this means that our not-for-profit prices are now available in around 100 countries. Our prices are sustainable—we do not make a profit on them, but we do cover our costs. This means that we can sustain supply of these high-quality products for as long as they are needed.

30. GSK keeps its not-for-profit ARV prices under constant review. Our latest review in May 2006 resulted in price reductions of up to 30% to our abacavir containing ARVs (Ziagen and Trizivir), and also added two new ARVs—Kivexa and Telzir—to our not-for-profit offering.

31. While it is difficult to estimate the number of patients treated as a result of our preferential pricing agreements a report from the Accelerating Access Initiative (AAI)—a partnership of UNAIDS, the World Health Organization, UNICEF, the UN Population Fund, the World Bank, and seven research-based pharmaceutical companies (Abbott Laboratories, Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Gilead Sciences, Merck & Co., Inc. and F. Hoffmann–La Roche)—suggested that by June 2007, some 694,400 patients in developing countries were receiving at least one ARV treatment supplied by the seven pharmaceutical companies in the AAI. This includes 458,700 patients in Africa. Overall shipments and patient numbers are still low given the scale of the AIDS epidemic in Africa but there has been an over 45-fold increase in the number of people being treated with medicines supplied by the AAI companies in Africa since the establishment of the AAI in May 2000 which is encouraging.

32. In terms of our investment in research and development, as well as on-going research into HIV/AIDS (which is not just a disease of the developing world) GSK has a dedicated research centre in Tres Cantos, Spain where over 100 full-time research staff are committed solely to working on diseases of the developing world, primarily TB and Malaria. This dedicated resource operates on a no-profit, no-loss basis and much of the activity is done in conjunction with the product development Public-Private Partnerships (PPPs) who help to fund around half of the scientists.

33. In terms of community investment, GSK funds community-led initiatives in over 100 countries around the world. We have a wide range of partnerships, with a focus on health and education programmes for underserved communities. In the developing world, GSK's activities span four major developing world diseases (lymphatic filariasis, HIV/AIDS, malaria and diarrhoeal disease), a number of regional health initiatives, health education, product donations, and employee involvement. The examples below are indicative of our activities.

- HIV/AIDS—Since 1992, Positive Action has pioneered support for community organisations who are frequently the only source of HIV/AIDS education, treatment literacy and care for people living with HIV/AIDS in developing countries. During 2006 Positive Action supported 19 programmes in 17 countries. In 2005, GSK announced that it will provide \$1.8 million over the next three years for

a new Positive Action community programme with AMREF, an African-based NGO, to train healthcare professionals and improve access to HIV/AIDS services at 70 sites across Kenya.

- Malaria—Our African Malaria Partnership has supported education and behaviour change programmes in eight African countries, through partnerships with three non profit organisations. Since 2003 we have invested £0.9m targeting some 2 million people. In November 2005, GSK's African Malaria Partnership (AMP) announced a new £0.9m grant to the Malaria Consortium, an international non-profit organisation dedicated to improving malaria control. The three-year grant will support the Coalition Against Malaria a new advocacy programme that aims to raise awareness of malaria in Europe and throughout Africa to bring greater resources to bear against the disease. GSK won the Frost and Sullivan 2006 Global Excellence Award in Malaria Prevention and Treatment.

34. In terms of innovative partnerships GSK is constantly looking for creative ways and partnerships to help countries improve access to medicines. For example given the gravity of the HIV/AIDS crisis in sub-Saharan Africa, we granted our first licence in October 2001 to Aspen Pharmacare, sub-Saharan Africa's largest generics company, for the manufacture and sale of versions of Combivir, Epivir and Retrovir. The licence now covers both the public and private sectors across all of sub-Saharan Africa. In 2006 we granted our 8th voluntary licence for our antiretrovirals (ARVs) in Africa, where HIV/AIDS is having a devastating impact. This includes eight VLs in South Africa and two in Kenya. In 2006 our licencees supplied over 120 million tablets of their versions of Epivir and Combivir to Africa, more than we shipped ourselves.

35. The threat of an influenza pandemic poses a unique challenge. No other public health threat has the potential, if it happens, to affect every single person on the globe almost simultaneously. This challenge means that all stakeholders must work together to ensure that the world is prepared.

36. Since 2000, GSK has invested more than \$2 billion in increasing GSK's production capacity for influenza vaccines and anti-virals and in the development of more effective pandemic and seasonal influenza vaccines. In addition we have:

- Stated our intention to donate 50 million doses of pre-pandemic vaccine to the WHO stockpile.
- Stated that we would provide additional vaccine to WHO at a tiered price.
- Committed to supply H5N1 pre-pandemic flu vaccines, through individual country agreements, to developing countries who wish to secure direct supplies at tiered prices, reflecting a countries' gross national incomes (GNI) as defined by the World Bank.
- Committed to enter into advance purchase agreements with individual countries, or with supranational organisations, again using tiered pricing principles based on GNI to ensure that pandemic vaccine can be reserved for developing countries.
- Committed to explore, in the medium-term, partnership opportunities with developing countries for filling and finishing and in the longer-term opportunities for further transfer of technology.
- Signed a licensing agreement with Simcere Pharmaceutical Group of Nanjing, China, granting Simcere the right to manufacture and sell the anti-viral influenza treatment zanamivir in a number of countries including all Least Developed Countries. Zanamivir is the active ingredient in GSK's Relenza® (zanamivir for inhalation).

Question 7. What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient "joined-up" thinking in approaching the problem?

37. GSK believes that poverty is the biggest barrier to improving healthcare in general. The WHO recommends a minimum spend on health of £17 per person per year to provide the most basic health services. Yet the average spend in sub-Saharan Africa is just £5. The African Region of the WHO suffers more than 24% of the global burden of disease, but has only 3% of the world's health workers.

38. It is 10 years since GSK pioneered donation programmes and sustainable preferential pricing for antiretrovirals (ARVs) to prevent mother-to-child transmission of the HIV/AIDS virus. Since then we have learned many lessons. We have learned that stigma and discrimination are real barriers that limit access to treatment and that without the necessary healthcare infrastructure, access to treatment will always be denied to those who need it, no matter how low price medicines become.

39. Most importantly, we have learned that only an holistic approach embracing both prevention and treatment will work—one in which medicines play a supporting role in a comprehensive programme of prevention, health education, screening diagnosis and treatment, community care and support.

40. The global community must provide political will, a significant mobilisation of additional resources and a spirit of partnership if we are to see an improvement in healthcare and quality of life across the developing world. We will continue with our efforts, improving our initiatives by applying lessons learned and looking for opportunities to do more.

Question 11. What intergovernmental action is planned or in hand for early detection of the transmission of Avian Flu from birds to humans and of human-to-human transmission in potential source countries? Is this proving sufficiently effective to prevent an Influenza pandemic? What more could be done.

41. The WHO's Global Influenza Surveillance Network (GISN) plays a vital role in monitoring the evolution of viruses in potential source countries. The success of the GISN and the consequent benefits for public healthcare across the world has been based on all parties sharing and analysing influenza viruses for research and vaccine development both for seasonal and H5N1 vaccines. Prompt sharing of, and access to, virus isolates and related sequence data from GISN centres around the world with vaccine manufacturers is key in ensuring that all countries have access to the most effective and up-to-date vaccines.

42. However recent developments have lead to one country restricting access to viruses. While discussions are ongoing it is important to remember that production of influenza vaccine is already performed under tight time and capacity constraints. Any delay in availability of the viral strain to manufacturers could affect the timing of availability of vaccines. The GISN is at the centre of a network of the world's leading experts on influenza viruses and calls upon that expertise extensively. In doing so, the WHO GISN ensures the highest levels of safety and scrutiny in the handling of viruses. This would be difficult to replicate if the current arrangements were changed. Therefore it is vital that the international community maintains and improves the existing system of collaboration and does not inadvertently or otherwise destroy a system that has served global public health well for over 50 years.

43. Early detection is a key part in preparing for a pandemic. However, by itself it is not enough. Many Governments in the developed world are stockpiling pre-pandemic vaccines and putting in place Advanced Purchase Agreements (APAs) for pandemic vaccines to cover at least priority groups, such as healthcare workers, public safety workers, and essential service providers. However, the world's poorest countries currently lack resources to put in place robust and effective preparedness plans. The international community needs to help by putting in place an holistic, clear and coordinated preparedness strategy which combines education, non-medical and medical interventions, and other preventive mechanisms, as well as vaccination.

44. An approach based on sustainability, partnership, shared responsibilities and support for research and development can address this problem. Ensuring access to vaccines will require a new public-private partnership between WHO, developed countries, developing countries, industry and others. That partnership should seek to deliver the following:

- A stockpile of pre-pandemic H5N1 vaccine large enough to address the needs of developing countries
- Sustainable increased pandemic production capacity through sustainable increases in demand for seasonal vaccines
- Technical assistance to address potential bottlenecks especially in areas such as filling and finishing and the capacity in-country to run mass vaccination programmes
- Developing countries get access to pandemic vaccine. Many countries have entered into APAs for pandemic vaccines. These agreements are based on shared responsibilities and could be adapted and developed for WHO to operate a centralised agreement to cover developing countries
- An appropriate global regulatory framework for the rapid registration and licensure of pre-pandemic and pandemic vaccines
- An appropriate global framework for dealing with liability issues, given the unique nature of dealing with a pandemic.

45. Taken together, GSK believes that this holistic package of measures, along with the continued free and unrestricted access to viruses, provides a realistic, pragmatic and effective approach for helping the world's poorest countries.

Question 12. To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?

46. It is difficult to know if resistance is attributable to the rise in infection but it is clear that it resistance in general is a challenge in treating all four diseases as it is in managing many others.

47. With respect to HIV/AIDS increasing resistance to first line antiretroviral therapies, underlines the need for greater progress in prevention, plus continued R&D to develop new therapies. Incentives to invest the 100s of millions of pounds required to develop new medicines must be maintained.

48. For TB, multidrug-resistant TB (MDRTB) is a widespread and growing problem, especially in the former Soviet Union and China. An estimated 450,000 new MDRTB cases occur every year.

49. Combating Malaria has become harder, as drug-resistant forms of Malaria have developed and health infrastructures in malaria-endemic areas have deteriorated. Because of resistance, WHO recommends a combination of effective, low-cost interventions for malaria control and prevention, but these remain very much underutilized, primarily due to inadequate funding and poor health infrastructure in endemic countries.

50. What this shows is that there is a continuing need to discover and develop new medicines, vaccines, diagnostics and other health products to fight HIV/AIDS, TB and malaria. The pharmaceutical industry is at the forefront of the growing number of R&D projects aimed at this working in partnership with other public and private sector organisations to increase access, build capacity and bring newer and better medicines to patients. Detailed examples of some of these partnerships, which shows the broad range of public and private organisations the pharmaceutical industry works with, have been published by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) in a publication entitled "Partnerships to build healthier societies in the developing world—May 2007", a copy of which is attached to this submission.

51. Antibiotic resistance more generally has been recognised as an enormous threat to global public health. For example, WHO's 2004 Report Priority Medicines for Europe and the World highlighted the lack of new antibiotics pointing out that the current limited size of the market for antibiotics and the high investment costs and considerable time needed for R&D for new antibiotics has led many companies to stop investing in this area. The report says that this trend must be reversed by providing significant incentives to companies to invest and goes on to look at options such as creating a special regulatory regime for antibiotics and ensuring that pricing and reimbursement of antibiotics reflects the substantial benefits they can bring.

52. It is clear that appropriate incentives and innovative partnerships are needed to tackle the growing problem of antibiotic resistance. For our part GSK is committed to the discovery, development and commercialisation of new antibiotics. GSK has recently created an Infectious Diseases Centre for Excellence in Drug Discovery (ID CEDD) exclusively dedicated to discovering and developing novel treatments for bacterial and other types of infections.

53. Addressing the problem of antibiotic resistance needs an international coordinated effort between the public and private sectors. While there is no "one-size fits all" solution, GSK stands ready to work with all partners to ensure that action is taken to address this serious problem. Priority Medicines for Europe and the World concludes that "If no such action is forthcoming, we will have lived through a century (1950-2050) of antibiotics but our children and grandchildren will face a world without such therapy. This tragedy can be avoided but only with substantial coordinated investment . . .".

Question 14. Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?

54. Focus on patents in this debate is misleading and counter-productive. Patent protection stimulates and fundamentally underpins the continued research and development for new and better medicines for diseases including those which occur in the developing world. Without adequate intellectual property protection, the medicines that are needed in the developing world would not exist in the first place.

55. It is clear new medicines and vaccines to fight all four diseases are needed. We do not, for example, yet have a cure or a vaccine for AIDS. At the same time existing medicines are less and less effective as resistance to them grows.

56. Developing a new drug is time-consuming, risky, and expensive. The average cost of bringing a new pharmaceutical product to market has been estimated by Tufts University to be \$900 million. It is intellectual property protection that plays the critical role in stimulating such massive investment in R&D.

57. We want to play an active role in addressing the healthcare crisis in developing countries. We believe preferential pricing arrangements are the best way to do this because we are able to ensure delivery of a safe, quality product at an affordable price for as long as it is needed. This is where we focus our efforts. But in some

situations, partnerships and voluntary licences (VL) may also help to increase the supply of medicines. VLs enable local manufacturers to produce and sell generic versions of our products. We have granted eight VLs for our ARVs in Africa. This is a creative response to a unique situation. We discuss VLs with potential partners on a case-by-case basis, selecting the most appropriate licensees. We need to be sure that the manufacturer will be able to provide a long-term supply of good quality medicines and will implement safeguards to prevent the diversion of medicines to wealthier markets.

58. Too many people see local manufacturing, and tearing up intellectual property rules as a panacea. If this was the answer, India would deal with AIDS better than any country in the developing world. Until recently, India had no IP protection for pharmaceutical products, and has the most developed generics industry in the world, and yet access to ARVs for those who need them is arguably no better than in Africa.

59. Significantly, of the 325 medicines on the WHO's Essential Medicines List, over 95% are off patent—that is have no patent protection - and yet WHO state that a third of the world's population have no reliable access to these essential medicines. This is evidence that the lack of healthcare infrastructure and resources are the real problems, and where the focus should be, rather than on intellectual property. This means addressing mobilising resources, addressing stigma; removing import tariffs and taxes that raise prices and prioritising healthcare in national budgets. Driving out inefficiencies in the procurement, storage, prescribing and use of drugs is also important. The World Bank estimates that some African countries get the benefits of only \$12 worth of medicines for each \$100 spent on drugs by the public sector.

January 2008

Memorandum by Global Influenza Surveillance Network

3. There are the WHO systems: GOARN, the global influenza surveillance network and FluNet.

Many countries now have thermal scanners at points of entry. For example UAE will scan entrants and give febrile individuals a rapid diagnostic test (looking particularly for malaria). Infected individuals will be offered treatment. It is not clear what an infected individual's options will be for entry thereafter.

Proper consideration of the role of migration on the spread of infectious disease is needed. It is not sensible to let considerations of political correctness stop us from detecting and treating infected and infectious migrants. Both for their own good and for the good of the societies they join.

4. HIV/AIDS depends on how good drug distribution programmes are and how at-risk populations change their behaviour. The emergence of highly transmissible multi-drug resistant strains will also have a high impact.

Avian influenza (or any emergent influenza). The acquisition of the ability to transmit easily amongst humans is a process so poorly understood that it has to be treated as stochastic. It is not the case that H5N1 avian influenza is the only threat, a new pandemic strain might arise from a different genetic background that currently does not infect humans.

TB The increase in XDR TB needs to be followed very carefully to assess the global threat.

Malaria. Discussion of eradication is widespread. The problem is financial, not anything else. The Global Fund has dispersed 2.4 billion in the last five years with a reasonable match to malaria prevalence. In terms of financing what is needed to move towards eradication things are in a good position. If The Gates Foundation follows up their apparent interest in eradication with substantial funds it may become a possibility.

7. For malaria global warming is often cited as a risk factor for extensions in the range of spread. This is probably a red herring and drug resistance has been a much more important risk. Now that a new family of drugs (the artemisinins) is available prevalence is falling across Africa.

The thought that global warming would bring malaria back to N Europe pre-supposes a complete breakdown in the health infrastructure.

9. TB has always been hard to treat. The drugs have to be taken for a long time, including long after the patient feels well. Many countries use directly observed treatment strategies (dots) in which health workers visit patients every day to watch them take their medicine. This is costly in terms of man power, but can be very effective.

10. The adverse effects of DDT were from agricultural applications, not malaria control. For malaria control you would perform residual spraying to the inside of a hut. Janet Hemingway at the Liverpool School of Hygiene would know about this.

12. Different answers for different pathogens

HIV drug resistance is not yet the major reason for continued spread.

TB drug resistance is an important contributor to continued spread.

Malaria drug resistance has been the most important factor in the past. If drug resistance to the new family of drugs arises it will have enormous impact. MMV the medicine for malaria initiative considers this possibility and seeks out new drugs for the pipeline. Again we are in a better position than five to 10 years ago.

Avian influenza is not spreading amongst humans yet. However, I think it is extremely likely that an avian influenza that became capable of efficient human-to-human spread would very rapidly acquire drug resistance which would then render useless our proposed drug-based control strategies.

16. The 2005 IHRs allow WHO to “use” unofficial sources although it states that it will “verify with countries before taking any action”. This is an important step forward as it allows WHO to (at least partially) benefit from internet based sources of information. I assume you know about Promed www.promedmail.org. However the IHRs are largely about sharing information and expertise. It would be a mistake to rely on them to prevent the spread of infection. We would just know about it sooner and be able to help a source country with interventions. That could stop a pandemic for some infections but almost certainly won't for something like pandemic influenza.

18. We think there is a real threat from Dengue. Bacterial infections of childhood and from food are an important and growing threat to health. Our past vaccines have mostly remained effective for a long time. Newer vaccines may be much less durable (because of differences in the underlying biology of the pathogens they protect against). It would be prudent to be aware that vaccine resistance may become a public health problem in the future.

February 2008

Memorandum by the Health & Safety Executive

BACKGROUND

The Health and Safety Commission is responsible for health and safety regulation in Great Britain. The Health and Safety Executive (HSE) and local government are the enforcing authorities who work in support of the Commission.

HSE's mission is to protect people's health and safety by ensuring risks in the changing workplace are properly controlled.

HSE regulates health and safety in nuclear installations and mines, factories, farms, hospitals, laboratories and schools, offshore gas and oil installations, the safety of the gas grid and the movement of dangerous goods and substances, and many other aspects of the protection both of workers and the public.

RESPONSE TO ENQUIRIES

In responding to the inquiry, HSE's comments are restricted to risks to people at work and those who may be affected by those work activities rather than any public health role. The responses provided are where work related issues are pertinent to the question being posed and may affect the global spread of infectious diseases and in particular avian influenza, tuberculosis and HIV (less so malaria) and the intergovernmental response:

Q1) Increasing emergence or reemergence of infectious diseases may be influenced by the following work related matters:

- Worker/animal interface is pivotal in the spread of zoonotic diseases (eg avian influenza) and changing animal husbandry practices (eg scale, location) may increase the potential for exposure of humans (eg Q fever outbreak at meat processing plant).
- Movement of migratory workers from endemic to non-endemic areas—different strains & resistances from different geographical areas.
- Movement of contaminated materials (eg animals & their byproducts, bush meat).
- Increased frequency and distribution of work-related international travel.

Q2–5) No comment

Q6) HSE regulates organisations who may be deliberately working with pathogens; or who may be inadvertently exposed to pathogens as a result of their work activities—HSE's role is to check compliance with legislative requirements and consequently provide reassurance to Government and the public, that such organisms will not be released into the environment and community. In addition to its regulatory role, HSE is involved in cross-government initiatives (eg Pandemic Influenza Planning); provision of guidance (eg Protection against blood borne infections in the workplace; Protection of Poultry workers against avian influenza); research on protective measures against infection (eg evaluation of respiratory protection against influenza); and international guidelines on vaccine manufacture (eg WHO guidelines for H5N1 vaccine manufacture).

In order to deliver these initiatives, HSE works with other government departments and agencies (eg Department of Health, Department for Transport, Department for Environment, Food & Fisheries, Health Protection Agency, Environment Agency) and across international boundaries (World Health Organisation, European Biosafety Association); as well as with UK & international Scientific and Expert Advisory committees (eg Advisory Committee for Dangerous Pathogens).

Q7–9) No comment

Q10) No specific comment on Stockholm Convention, however, international legislation on the rationalisation and review of biocides and chemicals (ie Biocidal Products Directive; and the Registration, Evaluation, Authorisation and Restriction of Chemicals [REACH] Regulations) means that access to some disinfectants and the range of disinfectants available is likely to be reduced (eg Phenolic disinfectants for use against tuberculosis).

Q11) The UK government is preparing a unified cross-government response to the potential threat of an influenza pandemic, to which HSE is in agreement—this includes a Pandemic Preparedness Plan and associated guidance and contingency planning.

Q12) No comment

Q13) HSE is currently exploring with healthcare regulators and government departments in England, Scotland and Wales how its role as an independent health and safety regulator can contribute to reducing the incidence of healthcare associated infection (HCAI). This may involve HSE working in partnership with those other agencies in proactive inspection of infection prevention and control practice and in reactive investigation of HCAI incidents.

Q14–15) No comment

Q16) The International Health Regulations place requirements on countries to develop, strengthen and maintain core surveillance and response capacities to detect, assess, notify and report public health events to WHO and respond to public health risks and public health emergencies. In the work environment, the potential for laboratory incidents resulting in public health events is recognised (eg Re-emergence of 1977 H1N1 influenza virus worldwide is generally accepted as emerging from a laboratory; Release of SARS from laboratories in Singapore and China; Distribution of non-contemporary influenza H2N2 laboratory testing specimens internationally). The IHR will provide additional powers to limit movement of individuals who may have acquired an infection at work in the laboratory thereby reducing the possibility of such an event becoming a public health matter.

Q17) HSE works closely with the Home Office and the National Counter Terrorism and Security Office to provide training for police officers who visit laboratories to assess biosecurity and technical advice on the Schedule of biological agents which may be used by bioterrorists. HSE participates in HO-led incident response exercises related to deliberate releases and working groups/meetings to assess the development of “dual-use”²⁵ microorganisms.

Q18) The majority of new and emerging infectious diseases are zoonotic in origin. The human/animal interface is therefore of paramount importance in addressing the spread of such communicable diseases. Certain worker/animal interfaces may magnify this interaction through animal husbandry practices that are of increasing scale and greater distribution (eg avian influenza in poultry houses involving hundreds of thousands of animals; Q fever exposure of workers in high intensity abattoirs).

Q19) No comment

²⁵ Dual use refers to legitimate scientific research undertaken for societal benefit (eg technical advances in molecular biology) being potentially applied to malicious or harmful endeavours.

Q20) Polio eradication programme presents a scenario where the consequences of release of the virus from a laboratory are magnified, particularly when vaccination ceases. Consequently HSE has participated in WHO working groups to establish the proposed laboratory containment for working with polio post eradication and to establish an inventory and audit of sites holding polio virus or contaminated materials.

February 2008

Memorandum by the International Civil Aviation Organization (ICAO)

Question 1: *A recent report on Communicable Diseases by the UK Department of Health stated that “post-war optimism that their conquest was near has proved dramatically unfounded”. What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis?*

N/A

Question 2: *What reliable data exist regarding the numbers of people infected globally with the four diseases²⁶ on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?*

2.1 In 2005, the world's airlines exceeded the figure of two billion passengers carried on scheduled air services. Given predicted levels of growth, this figure is likely to more than double, to 4.5 billion passengers, by 2025.

2.2 It is not known how many airline travellers are suffering from the four communicable diseases of interest at the time of their air travel.

2.3 Although experience has shown that the on-board diagnosis of a traveller who is suffering from a communicable disease is uncommon in comparison to other on board medical events, reliable statistics are unavailable as there is currently no system in place for collecting and analysing data from different airlines.

2.4 To avoid delay, travellers may choose to withhold information concerning a communicable disease.

2.5 Influenza and TB are of particular significance to the aviation sector because they can potentially be transmitted from one person to another during casual contact during (and after) air travel. Malaria is also of interest mainly because of the need to disinsect the aircraft cabin when required by the government at destination. The need to use chemicals for disinsection purposes has been challenged recently.

Question 3: *What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? And what improvements might be made?*

N/A

Question 4: *Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years?*

N/A

Question 5: *What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?*

5.1 Mass screening of travellers for disease eg by temperature measurement or questionnaire at points of departure and entry is probably not very effective at detecting disease in travellers. However, it is not known to what extent such screening might have on deterring from travel potential travellers who are aware they have a communicable disease.

5.2 Although the diagnosis of a communicable disease in travellers is not their main role, airline operators have a part to play in detecting travellers who are obviously unwell and who may put other travellers at risk. They should collaborate with airport and public health authorities to develop a plan to deal with a case of suspected communicable disease should one be identified. The International Civil Aviation Organization

²⁶ HIV/AIDS, Tuberculosis, Malaria and Avian Influenza.

(ICAO), the International Air Transport Association (IATA) and Airports Council International (ACI) provide guidance on this topic, and others relating to the spread of communicable disease on their websites.

5.3 ICAO has collaborated with the WHO, IATA, ACI, the United States Centers for Disease Control and Prevention, the European Civil Aviation Conference (ECAC) and some other government agencies to provide guidelines concerning the spread of communicable disease by air that are specific to the aviation sector and which are in line with the International Health Regulations (2005). (see <http://www.icao.int/icao/en/med/guidelines.htm>)

5.4 ICAO also requires governments, as part of their compliance with the Convention on International Civil Aviation, to put in place a preparedness plan to manage, in the aviation sector, the risk from a public health emergency of international concern. This should be integrated with the general national preparedness plan.

5.5 The response of the aviation sector to the ICAO guidelines is patchy. In some countries, particularly in Asia where impact of the Severe Acute Respiratory Syndrome was most acute, preparedness is very good. In some developed countries outside Asia preparedness is also relatively well developed. In many other countries, especially those with few financial resources, preparedness planning is less well developed.

5.6 An important step forward, at least in the aviation sector, is improved integration of all involved stakeholders at a national, regional and global level.

Question 6: What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?

6.1 Article 14 of the Convention on International Civil Aviation obliges each Contracting State (government) to the convention to take effective measures to prevent the spread by means of air navigation of communicable diseases.

6.2 The ICAO Assembly has resolved that “the protection of the health of passengers and crews on international flights is an integral element of safe air travel and that conditions should be in place to ensure its preservation in a timely and cost-effective manner”.

6.3 As the focal point for aviation standard setting, ICAO is well placed to coordinate and collaborate with of health- and aviation-related organisations. It has a good and developing working relationship with WHO, and the IHR(2005) has many aspects related to points of entry and conveyance operators. ICAO also works closely with stakeholders in the aviation sector, particularly the trade associations of the International Air Transport Association and Airports Council International, that provide technical knowledge relating to aircraft and airport operations.

6.4 ICAO has only one staff member (a doctor) that has this topic as a major component of his work programme. His time is divided between safety related aspects of aviation eg medical standards for aircrew and air traffic controllers, and health related aspects, such as the management of diseases spread by air travel. There are significant resource constraints, related to both time and finance, that can be allocated to aviation health related topics.

6.5 The degree of synergy between the stakeholders mentioned above is important, has been effective and continues to develop in the aviation sector.

Question 7: What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient “joined-up” thinking in approaching the problem?

7.1 Horizontal communication, between the disparate and numerous stakeholders is essential, yet is not always easy for organizations used to communicating vertically. Resources to allocate to a “new” topic are scarce.

7.2 ICAO has found that, with respect to the aviation sector, national public health authorities may regard aviation as a relatively low priority when compared to their more pressing responsibilities involving population health care. On the other hand, aviation authorities do not see health as a pressing responsibility for themselves. The subject can therefore fall between two stools.

7.3 Public health authorities could involve the aviation sector to a greater extent in developing their plans for dealing with communicable disease, and vice versa.

Question 8: *Cases of Tuberculosis fell progressively in the UK until the mid-1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of Tuberculosis infections in Britain? And how could intergovernmental action help to reverse the trend?*

N/A

Question 9: *Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions—eg HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?*

N/A

Question 10: *To what extent do you believe that the 2004 Stockholm Convention limiting the use of DDT against Malaria-carrying mosquitoes has been a factor of increases in the spread of the disease? Has any risk analysis been carried out comparing the relative dangers to human health posed by DDT and Malaria?*

N/A

Question 11: *What intergovernmental action is planned or in hand for early detection of the transmission of Avian Flu from birds to humans and of human-to-human transmission in potential source countries? Is this proving sufficiently effective to prevent an Influenza pandemic? What more could be done?*

N/A

Question 12: *To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?*

N/A

Question 13: *In a number of countries, including the UK, there is a problem with hospital-acquired infections. What intergovernmental sharing of knowledge is taking place to help bring this problem under control?*

N/A

Question 14: *Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?*

N/A

Question 15: *What interchange exists between States in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?*

N/A

Question 16: *The International Health Regulations 2005 are intended to provide a global framework for the rapid identification and containment of public health emergencies. How effective do you consider this response system to be? Do improvements need to be made?*

16.1 The International Health Regulations (IHR) (2005) contains many references to requirements at ports of entry, including airports, and to conveyance operators, including aircraft. They came into force in June 2007, so it is not yet possible to evaluate their impact. However, they have generated interest from public health bodies with respect to the aviation sector and ICAO's initial impression is that they will have a highly beneficial effect on preparedness planning in the sector.

16.2 For 18 months, ICAO has been managing a project entitled “Cooperative Arrangement for Preventing the Spread of Communicable Disease by Air” (CAPSCA) in Asia, and this has recently been extended into Africa. Eventually, CAPSCA is planned to become a global initiative. It trains personnel and evaluates airports against the ICAO preparedness guidelines for a public health emergency. The IHR includes an element that requires airport assessment, to check compliance against the IHR for designated airports for States that request it. It is therefore possible that ICAO and WHO will cooperate in the area of airport evaluation in the future.

16.3 CAPSCA is currently funded by interested States and grant aid by the United Nations Central Fund for Influenza Action (CFIA). ICAO has encountered some reluctance from States to participate in, and fund, the CAPSCA project and so the CFIA grant has been very useful. A joint approach from WHO and ICAO is considered important to engage the local public health and the aviation authorities in preparedness planning.

16.4 There is currently a lack of available expertise to undertake training of local airport and airline staff, and to undertake airport evaluations. As the importance of such work becomes more apparent, and if funds are made available, this will hopefully become less of a problem.

Question 17: What intergovernmental planning has been undertaken to cope with the impact of an outbreak of infectious disease caused by deliberate release of micro-organisms into the environment? Is there adequate liaison between the various agencies involved, including intelligence, law enforcement and health care professionals? How could action by intergovernmental bodies help further?

17.1 ICAO participated in an international coordination exercise on bioterrorism in 2006, organized by the United States Department of State and the Swiss Federal Department of Foreign Affairs. It is willing to cooperate with international organizations on this topic in the future.

Question 18: Though our remit is focused specifically on known infectious diseases, we would be interested to know how you view the global threat from new or previously unrecognised ones and from the transmission of infections from animals to humans.

N/A

Question 19: What resources (subscriptions, staff, training, medicines etc) does the UK Government commit to intergovernmental bodies to help in the fight against the four diseases listed?

19.3 Along with 189 other Contracting States, the UK contributes to the funding of ICAO. A proportion is used to fund the activities that are relevant to this subject area. This is primarily the portion of funding for the salary, travel and subsistence of ICAO’s medical officer that is designated for this purpose.

Question 20: Do you wish to provide any other relevant information in addition to what you have said in answer to the above?

21 February 2008

Memorandum by the International Organization for Migration (IOM)

SUMMARY

The International Organization for Migration (IOM) provides health assessments (HA) for resettlement to other countries, including the United Kingdom (UK). Screening for tuberculosis (TB) is one of the most important elements of HA. IOM comments on three inquiry issues related to TB.

Comment on the Inquiry Issue 1

Human mobility impacts on the spread of diseases. Targeted health surveillance mechanisms and initiatives to overcome inequalities in accessing health services need to be put in place at various points of the migration cycle.

Comment on Inquiry Issue 2

Analysis of chest X-ray (CXR) findings and results of sputum tests among the refugees²⁷ resettling in the United States (US) from Thailand and the immigrants to the United Kingdom (UK) from the countries, where IOM is implementing the UK TB Detection Programme (UKTBDP) was conducted by IOM. The rates of CXR finding, suggestive of active TB, were significantly higher than the prevalence of all forms of TB reported by the World Health Organization (WHO) in the majority of examined cohorts. In the US-bound refugees the smear-positivity rate was ten times higher than the incidence of smear-positive TB cases reported for Thailand. Smear-positivity in the UK-bound migrants is lower than reported for the countries. The difference between smear-positivity rates in refugees and immigrants may reflect different prevalence of TB in different social strata. Active case detection reveals less advanced forms of TB than the passive case detection, which may partly explain lower positivity rate in some cohorts. These data suggest that the active case detection undertaken in the framework of the resettlement HA programmes may provide a better estimate of the magnitude of the problem in different cohorts and globally. In the setting of resettlement HA sputum smears alone are inadequate diagnostic tool. Analysis of sensitivity of sputum smears vs. cultures showed that sensitivity of sputum smears was 18.7%, which means that a significant number of cases of active TB, including multi-drug resistant TB (MDR-TB), are missed if the screening protocol does not include cultures.

Comment on Inquiry Issues 3, 4, 5

Surveillance systems need to be extended into migrant communities. There is a need for special policies and initiatives of integration that must take into consideration the risk for stigma that would hamper effective communicable disease control.

Comment on Inquiry Issue 6

IOM is uniquely positioned to contribute to the global fight against TB due to: presence in many countries, including countries with a high burden of TB, work with large caseloads of mobile populations, use of standard methodologies enabling unique epidemiological studies, contribution to cross-border control of TB through TB detection and treatment, availability of human resources with significant experience in TB and migration, growing laboratory services and use of modern tools of laboratory diagnosis.

Furthermore, IOM collaborates with the immigration and health authorities of the resettlement countries. IOM is a member of the Stop TB partnership and has an active role in the Global Laboratory Initiative. IOM works with other development partners, WHO, academia and various public and private institutions.

Comment on Inquiry Issue 8

In many low incidence countries with a long history of migration, the foreign-born population accounts for a roughly half of all new active TB cases. This high proportion of TB among foreign born persons therefore creates significant public health concerns and economic impact. IOM regards the UKTBDP as an important, albeit not the only, step that could potentially contribute to the reversal of the trend and suggests a number of measures to increase the effectiveness of the programme. The addition of sputum cultures to the screening protocol is expected to increase the TB detection rate and enable detection of drug-resistant forms. The public health impact of the programme is likely to increase if the programme is connected to the public health surveillance system in the UK. Migrants with CXR findings, suggestive of active TB, should be followed after arrival to the UK. The effective cross-border control of TB is impossible without the development of capacities of the health care systems in the countries of migrants' origin. IOM is strategically positioned to provide assistance with capacity-building of National TB Programmes.

Comment on Inquiry Issue 11

The Avian Influenza (AI) preparedness offers an example of the often neglected need for targeted programmes that reach migrants and mobile populations. In order to address this gap IOM has piloted initiatives in South-East Asia and Africa, supported by the Japanese Government, and well received by local Governments.

²⁷ According to the 1951 UN Convention, a refugee is a person who "owing to a well founded fear of being persecuted for reasons of race, religion, nationality, membership in a particular social group, or political opinion, is outside the country of his nationality, and is unable to or, owing to such fear, is unwilling to avail himself of the protection of that country".

INTERNATIONAL ORGANIZATION FOR MIGRATION—WHO WE ARE?

1. The International Organization for Migration (IOM) (www.iom.int) is the leading inter-governmental organization in the field of migration and works closely with governmental, intergovernmental and non-governmental partners. IOM works in the four broad areas of migration management:

- Migration and development
- Facilitating migration
- Regulating migration
- Forced migration

2. Migration health is one of the IOM activities that cuts across these areas of migration management. Other cross-cutting activities include the promotion of international migration law, policy debate and guidance, capacity building, public information and education, integration, protection of migrants' rights, the gender dimension of migration and environmental degradation and migration.

3. The United Kingdom (UK), as one of 122 Member States of IOM, utilizes the services provided by the Organization in various fields, including movement management, resettlement, cultural orientation, assisted voluntary return, capacity building, counter-trafficking, migration and development, and health.

HEALTH ASSESSMENTS

4. One of the largest services, provided by IOM's Migration Health Department (MHD) is health assessments (HA) for people settling in other countries. HA are conducted at the request of receiving countries, tailored to fulfill national immigration legislations and follow national guidelines/technical instructions. In 2006, IOM provided HA to more than 120,000 migrants in 46 countries (*Migration Health Annual Report, 2006*); in 2007—to more than 189,000 migrants, including about 90,000 migrants to the UK (*unpublished data*).

5. The objectives of HA programmes include:

- detection of conditions of public health importance: infectious tuberculosis (TB), other communicable diseases;
- detection of other conditions, requiring follow up and/or treatment after arrival, facilitation of integration of migrants;
- off-shore treatment of certain Sexually Transmitted Infections, TB, malaria, intestinal parasites;
- immunizations;
- counselling and health promotion;
- fitness-to-travel checks; and
- medical escort and evacuation.

HEALTH ASSESSMENT PROGRAMMES FOR THE UNITED KINGDOM

6. At the UK's request, IOM carries out two HA programmes:

- *HA of refugees within a framework of the Gateway Protection Programme*. The programme encompasses various aspects of health (communicable and non-communicable diseases, mental health, and fitness for travel). It is relatively small (less than 1,000 entrants per year).
- *The United Kingdom Pre-Departure Tuberculosis Detection Programme (UKTBDP)*. UKTBDP focuses on the TB screening of the applicants for UK visas for stays in the UK of more than six months. Currently the programme is implemented in eight countries of origin with a high TB burden as defined by the World Health Organization (WHO).

UNITED KINGDOM TUBERCULOSIS DETECTION PROGRAMME

7. UKTBDP started in October 2005 and was piloted in 2006 in five countries: Bangladesh, Cambodia, Sudan, Tanzania and Thailand. On 21 November 2006, the main phase of the programme involving nine other countries (China, Ethiopia, Ghana, Kenya, Nigeria, Pakistan, Philippines, South Africa and Zimbabwe) was announced in the UK Parliament. Within the first quarter of the year 2007, three of the nine countries (Ghana, Kenya and Pakistan) started the screening. The others were put on hold at the request of the UK.

8. The key objective of the programme is to address public health concerns about the spread of infectious TB in the UK by preventing the entry of people suffering from the disease until they have been successfully treated, and to facilitate the access to diagnosis and treatment of TB in the countries of migrants' origin. The programme is part of the UK Action Plan to reverse the rise in TB (*Stopping Tuberculosis in England: An action plan from the Chief Medical Officer, 2004*).

9. BENEFITS OF THE UKTBDP

- UK visa applicants suffering from infectious tuberculosis are diagnosed early and referred for treatment to local clinics adhering to international standards of treatment.
- Expected to reduce the risk for communities in the UK of contracting infectious TB from newly arrived migrants.
- Generates data on TB infection among travellers to the UK, enabling the UK Government to better understand the problem and respond with effective health policies.
- Countries of origin benefit from the sharing of best practices of TB testing and strengthening of laboratory capacity.

10. The TB screening protocols of all countries requesting HA prior to resettlement include chest X-ray and sputum tests: the majority of protocols require both sputum smears and sputum cultures, some require only sputum smears. The UKTBDP screening protocol includes chest X-ray for applicants of 11 years old or older, and laboratory diagnostics (sputum smears for Acid Fast Bacilli—AFB) for those whose X-ray is suggestive of TB. The applicants who either have normal chest X-ray or abnormal chest X-ray but negative sputum smears receive a certificate which allows them to continue with the visa application procedure. As of November 2007, the screening protocol in three countries (Bangladesh, Kenya and Thailand) includes sputum cultures for *Mycobacterium tuberculosis*.

11. This response to the Call for Evidence will mainly focus on the IOM's vision of some aspects of the global problem of tuberculosis from the point of view of the health service provider implementing HA of migrants globally. Some additional notes, though less supported by quantified evidence, will refer to the IOM assessment of trends with regards to communicable diseases and human mobility particularly in developing countries.

THE EVIDENCE

Inquiry Issue 1. *Progress made in reducing the spread of diseases vs. possible deterioration*

12. The equilibrium between infectious diseases control and spread remains an unstable and dynamic one, highly dependent on multiple human and microbial factors. Human mobility has traditionally been associated with the spread of diseases, and manifestly migration and mobility are nowadays on the increase globally. In many instances the same causes that sustain mobility (eg poverty, conflicts, human rights abuses, natural and man-made disasters with their corollary of disrupted health services) are also associated with risks and vulnerabilities for the growth and spread of communicable diseases. In this context, growing urbanization in crowded slum areas of various large cities of the world, and the existence of various site multipliers or 'hot spots' that sustain concentrated epidemics, represent potential risks for the insurgence and spread of communicable diseases: people with very different back-grounds, legal status, culture, knowledge, attitudes and behaviours vis-à-vis health share poor and insalubrious environments and have limited access to health care, yet they often remain determined to cross borders in seek of greener pastures, or engage in circular migration between urban and rural settings bringing with them their epidemiological profiles. Targeted health surveillance mechanisms and initiatives to overcome inequalities in accessing health services need to be put in place at origin, transit and destination in the migration cycle whatever the legal status of the migrant is.

Inquiry Issue 2. *What reliable data exist regarding the numbers of people infected globally?*

13. The main source of information about the global burden of TB is the WHO publications, in particularly, the annual report "Global Tuberculosis Control: Surveillance, Planning, Financing". Every year, WHO requests information from the National TB Programmes (NTPs) or relevant public health authorities in 212 countries or territories via a standard data collection form (*WHO REPORT 2007 Global Tuberculosis Control. Surveillance, Planning, Financing, p 10*). The reporting is predominantly based on passive case detection.

14. Active case detection undertaken by IOM in migrants in the course of pre-resettlement HA may allow more accurate in-depth analysis of the prevalence of TB cases in certain cohorts.

15. The following is the analysis of some TB indicators in two cohorts of migrants examined by IOM: the United States (US)-bound refugees in Thailand and the UK-bound immigrants in the countries where IOM implements the UKTBDP.

16. Two critical elements in the US and UK TB screening protocols are chest X-ray (CXR) and sputum AFB microscopy (AFB smears). In 2005 sputum cultures were added to the US protocol. We analyzed associations of smear-positivity with the CXR findings in the US cohort. We found that those with cavitary lesions, infiltrates, non-calcified pulmonary nodules and pleural effusions were more likely to have positive sputum smears (Table 1).²⁸ Similar data were reported earlier (*Chest* 1999; 115:1248-1253). Realizing that not all of these CXR lesions represent TB, we named them as CXR findings, suggestive of active TB. Considering that these findings, detected in migrants from high-burden countries should prompt immediate investigation for TB, we sought to assess the prevalence of such findings.

17. The rate of the CXR findings, suggestive of active TB, was higher than the prevalence of all forms of TB reported by WHO among the UK-bound migrants in five out of eight countries. In Bangladesh, Pakistan, Tanzania and Thailand this difference was several times higher,²⁹ though the rate of smear-positivity was lower in seven out of eight countries (Table 2). The prevalence of the CXR findings, suggestive of active TB, in the US cohort in Thailand was 25 times higher the prevalence of all forms of TB, reported by WHO, and the smear-positivity rate 10 times higher (Table 3). It is noteworthy that the US caseload represents one of the most destitute social stratum (refugees), while the UK caseload are mainly presented by the representatives of the middle and upper classes (students, fiancées and spouses of the UK citizens, and to a lesser extent working holiday makers), which can partly explain the difference in smear-positivity rates between these cohorts and lower than WHO-reported smear-positivity rate in the UK cohort. Of note though, is that in the UK cohort the highest smear-positivity rates were seen in the countries where IOM performs laboratory testing using its own laboratories (Bangladesh, Kenya and Thailand) as opposed to those countries, which use non-IOM laboratories.

18. Realizing the limited methodological validity of such a comparison, we believe that this data may indicate that the TB prevalence officially reported by the NTPs shows only the tip of the iceberg of the TB burden.

19. In the context of mandatory testing for migration purposes, the diagnostic yield of AFB-microscopy is lower than would be in a clinical setting due to several factors, including, but not limited to, lower level of cooperation (resulting in a production of inadequate sputum specimens), intake of anti-tuberculosis drugs, available in some countries over-the-counter, prior to testing and, possibly, lower bacterial load, which characterizes earlier stages of the disease detected through the active screening (*International Journal of Tuberculosis and Lung Diseases* 2001; 5(5):419-425). The addition of sputum cultures, which is a standard of diagnosis in the UK (*National Collaborating Centre for Chronic Conditions. Tuberculosis: clinical diagnosis and management of tuberculosis, and measures for its prevention and control. London: Royal College of Physicians, 2006*), but has not been included in the current UKTBDP screening protocol until recently, would increase the sensitivity of testing. In one of the studies, patients with smear-negative culture-positive tuberculosis appeared to be responsible for about 17% of TB transmission (*The Lancet* 1999; 353:444-449).

20. We analyzed the sensitivity of sputum smears among the US-bound refugees in Thailand (Table 4) and found that the sensitivity of AFB smears assessed against cultures was only 18.7%, the specificity was 99.3% and the positive predictive value was 53.7%.

21. The sensitivity of sputum microscopy in this study is lower than reported by other investigators (*Phil J Microbiol Infect Dis* 1987; 17:33-35; *Phil J Microbiol infect Dis* 1995; 24(2): 33-36), which may reflect a higher proportion of cases with lower bacterial load detected actively as compared to the passive case detection. On the other hand, these results show that sputum microscopy alone cannot be regarded as an adequate TB detection tool in the resettlement programmes (and possibly in other programmes, using targeted active case detection; this hypothesis, however, needs further confirmation). The importance of wider use of sputum cultures for TB diagnosis is further illustrated by the fact that in the IOM analysis of drug-resistance, out of 30 cases which showed resistance to at least one anti-tuberculosis drug, 22 were smear-negative. These cases, including five with multi-drug resistant TB (MDR-TB), would have been missed if sputum cultures had not been included in the screening protocol.

²⁸ The data are used with the permission from the Centers for Disease Control and Prevention, Atlanta, USA.

²⁹ The precise magnitude is not specified as the permission to use the data for this response has not been received from the UK government.

Inquiry Issue 3, 4, 5. *Surveillance systems, trends, gaps*

22. In the context of migration and health, surveillance systems need to be extended into migrant communities involving members of the community itself so as to overcome language, cultural, gender and other barriers. Such community actors need to be integrated into national health systems and programmes. Messages, programmes and initiatives often do not reach migrants communities, and particularly those that, because of their legal status, might be afraid to interact with institutions. Xenophobia, stigma and politically motivated attitudes towards migrants risk driving underground people that would otherwise need medical attention. This represents a potential multiplier factor for the growth and spread of communicable diseases. While human mobility is recognized as associated with health risks and vulnerabilities, no segregated data are widely available that provide evidence for specific policies and programmes development. The need for knowledge to sustain initiatives of integration and not exclusion, must take into consideration the risk for stigma that would hamper effective communicable disease control. Formulation of these policies requires involvement of various governmental and non-governmental actors in this field.

Inquiry Issue 6. What role does your organization play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organizations do you collaborate?

23. IOM is uniquely positioned to contribute to the global fight against TB. The salient features of the IOM's current and potential role in combating TB are as follows:

23.1 IOM is working in many countries with a high burden of TB.

23.2 IOM is dealing with a considerable caseload of mobile populations globally (Table 5).

23.3 IOM is performing TB detection in different countries and in different cohorts, using standard methodologies. This includes standard screening protocols, global standardization of all aspects of resettlement health assessment through the system of quality control and quality assurance, standardization of laboratory practices, centralized standardized data collection with the use of the institutional databases. All this positions IOM as a potentially important research partner, able to generate data which will contribute to the global understanding of the TB burden, monitoring its patterns and trends as well as be used for planning of targeted interventions:

- in the countries of migrants' origin;
- in the countries of migrants' destination; and
- globally.

However, at the present time, the research performed by IOM is mostly operational; its results are used for the planning of medical and resettlement activities. Scientific epidemiological research is not performed consistently due to the lack of specific funding and dedicated staff.

23.4 IOM contributes to cross-border control of TB through its early detection and treatment prior to resettlement. IOM has accumulated significant experience in the management of TB, including MDR-TB. In some countries IOM established its own Directly Observed Treatment (DOT) centres, in others the migrants are referred to the health care providers who adhere to the WHO standards of care. IOM DOT centres provide treatment for migrants with various forms of TB, including MDR-TB and TB-HIV co-infection. IOM has Green Light Committee approval for dispensing second line TB drugs to patients with MDR-TB.

23.5 IOM has highly qualified human resources with considerable exposure to diagnosis and management of TB, including physicians, public health specialists, laboratory specialists, health information specialists and researchers.

23.6 IOM is currently establishing TB culture laboratories and/or contributes to the strengthening of the existing laboratories for mycobacterial culture in several settings worldwide. These settings include Bangladesh, Kenya, Nepal, Pakistan, Thailand and Vietnam, with plans to expand TB culture services in other countries with standardized methodology, reporting and quality monitoring systems.

23.7 IOM has developed a laboratory diagnostic algorithm incorporating new diagnostic tools for the rapid detection of drug resistant strains of *M. tuberculosis* and the identification and differentiation of *M. tuberculosis* from non-tuberculous mycobacteria (NTM). These new molecular tools are expected to improve both TB diagnosis and case management. IOM and the Foundation for Innovative and New Diagnostics (FIND) have concluded a Memorandum of Understanding which will allow IOM to procure these assays at specially discounted rates.

24. IOM closely collaborates with the NTPs in the countries of origin and health authorities in the countries of destination. The examples include, but are not limited to, the Centers for Disease Control and Prevention, Atlanta, USA; Global Migration Unit, Department of Immigration and Citizenship, Australia; Medical Branch, Citizenship and Immigration, Canada, and others.

25. IOM is pleased to note a growing convergence of the approaches to the diagnosis and management of TB in migrants, however IOM believes that it would be useful if the resettlement countries continued their efforts in the direction of (1) harmonization of screening protocols; (2) harmonization of data collection and reporting; (3) research support and (4) information-sharing.

26. IOM is a member of the Stop TB Partnership and has an active role in the Global Laboratory Initiative in developing a strategic plan and roadmap to guide the massive scale-up of laboratory services as an essential first step in effectively addressing the diagnostic challenges of TB-HIV and MDR-TB within the Millennium Development Goals framework.

27. IOM promotes research, dialogue, policy review, technical cooperation and implementation of programmes that focus on the health of migrants and mobile populations. The Organization's competitive advantage is founded on its direct exposure through existing programmes to a variety of migrant categories, its multidisciplinary approach and its mainstreaming of health into the global role of the Organization in assisting Member States in meeting the challenge of managing migration. In this endeavour IOM works with other development partners, notably WHO to which is linked by a Memorandum of Understanding, with partner governments, academia and various public and private institutions. The IOM Migration Health Department intends to further develop this partnership and seeks continuous donor support to bridge the still existing gap between awareness and action in the domain of migrant health.

Inquiry Issue 8. Cases of Tuberculosis fell progressively in the UK until the mid-1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of Tuberculosis infection in Britain? And how could intergovernmental action help to reverse the trend?

28. Most migrants travel from countries where the incidence of active TB is greater than 40 per 100,000 population (high incidence) to countries where the incidence is less than 25 per 100,000 population (low incidence) (*British Thoracic Society Guidelines. Control and prevention of tuberculosis in the United Kingdom: Code of Practice 2000. Thorax 2000; 55: 887–901*). As a result, in many low incidence countries with a long history of migration such as the United States, United Kingdom and Australia, the foreign-born population account for a roughly half of all new active TB cases. This high proportion of TB among foreign born persons creates significant public health concern and economic impact on the annual health expenditure for TB in industrialized countries (*Eur Respir J 2005; 25: 1107–1116*). Screening for active tuberculosis and treatment is therefore an important component of pre-migration health assessments. It should be noted that HA programmes capture only a fraction of all mobile populations. Irregular migrants and those who are visiting their home countries and returning are not screened.

29. IOM regards the UKTBDP as an important, albeit not the only, step that could potentially contribute to the reversal of the trend.

30. However, in its present form the programme probably produces less public health benefits to both the UK public and the countries of origin than it could. The reasons for this are the following:

31. *Current screening protocol relies primarily on chest X-ray screening and AFB microscopy to detect and exclude only the most infectious cases. AFB microscopy alone is not as sensitive as mycobacterial culture in detecting active TB among immigrants.*

32. In 2004, LoBue *et al* conducted an evaluation of the screening of TB among immigrants to California. The study found infectious TB cases would arrive in the US despite pre-departure screening. The reasons for this are either due to suboptimal sputum collection and laboratory testing, or delays in the interval between their foreign and US examinations (*Chest 2004; 126: 1777–1782*). If ineffective screening methods are used which do not include mycobacterial culture infectious TB cases will continue to arrive into the resettlement countries. This is particularly problematic when migrants or refugees harbor multi-drug resistant TB. MDR TB was reported in several cases among Hmong refugees resettling from Thailand into the United States in 2004–05, before the culture was added to the screening algorithm. This prompted a review of the US pre-migration algorithm and mycobacterial culture was introduced as part of an enhanced screening scheme (*MMWR 2005; 54: 741–744*).

33. *The programme, to a certain extent, is disconnected from the public health surveillance system in the UK.*

34. As mentioned in the response to Inquiry Issue 2, IOM found a high prevalence of CXR findings that require follow up and testing for TB.
35. It is known that a certain proportion of individuals with the bacteriologically negative TB become smear and/or culture positive. It is also known that even symptomatic migrants delay seeking medical assistance after the entry into the country of destination (*American Journal of Respiratory and Critical Care Medicine* 1998 (157):1244–1248).
36. Follow up in the UK targeted at the entrants with significant X-ray abnormalities and negative sputum smears, especially those who are likely to be in contact with a community and whose whereabouts can be relatively easily traced (eg students), would constitute a more effective public health measure for the resettlement countries than the overseas screening programme alone.
37. *The programme needs to be better connected to the health care systems in the countries of origin.*
38. The UKTBDP integrates into the National TB Programmes (NTPs) in the countries of origin through strengthening diagnostic facilities, in particular TB laboratories, TB treatment facilities and training personnel. The majority of countries targeted by the programme, lack capacities in some or all components. One of the most serious concerns is the poor capacity and limited availability of TB laboratory services. In order to meet the UKTBDP's objectives IOM, in close cooperation with the Ministries of Health (MOHs), NTPs and professional agencies (WHO), is engaged in capacity development activities, which are focused on, but not limited to:
- upgrading of the existing laboratories;
 - establishment of new laboratories;
 - training of the national personnel; and
 - dissemination of the best practices.
39. Currently these activities are targeted to serve the populations which are ready to migrate and only indirectly and to a limited extent, benefit the rest of the population. Capacity building activities in the context of the UKTBDP are also limited by the scope of investigations required by the screening protocol. Yet there is a pressing need for the development of diagnostic modalities enabling detection of drug resistant forms of TB—cultures and drug susceptibility testing (DST), as well as newer techniques such as molecular diagnostics and rapid DNA testing for drug resistant tuberculosis.
40. TB specialists, debating controversies of the screening programmes, are unanimous in the opinion that “the most effective (not to mention more just) long-term solution is to increase our efforts to control TB in developing countries” (*American Journal of Respiratory and Critical Care Medicine*; 2001 (164): 915).
41. IOM has human resources and expertise to develop capacities of MOHs and NTPs, which could significantly contribute to the overall strengthening of national and regional health systems. IOM has a history of successful capacity building activities for the TB laboratories in South East Asia, Africa and Eastern Europe, where IOM provided equipment, set up facilities for TB cultures and DST, trained laboratory personnel and established a system of quality control.
42. Combining the screening component with a capacity building component would be beneficial for both countries of origin and resettlement countries. The infrastructure built through the capacity development component would enhance the effectiveness of the TB screening for migration purposes. In turn, the screening programme is likely to provide an insight into the health care system and its strengths, weaknesses, needs, identify optimal strategies and bring the international experience to guide capacity building activities. The report of the UK *All Party Parliamentary Group on Global Tuberculosis* recommends supporting global partnership and to “continue to provide predictable finance to WHO, the Stop TB Partnership and other international organizations involved in global TB control”.
43. IOM, with its network of operational units providing services to the most needy and often hard-to-reach populations, working hand in hand with the governments, NGOs, national and international organizations and professional bodies is strategically positioned for such a partnership, channeling the resources and provision of technical expertise to the countries with the high TB burden.
44. Continuation of the capacity building efforts on a larger scale would hit several targets:
- Improve access to TB diagnosis and treatment for the population of countries with the high TB burden;
 - Facilitate development of diagnostic tools for detection of drug resistance;
 - Contribute to development of human resources;

- Improve acceptance of the resettlement programmes by the governments in the countries of migrants' origin and host communities.

Inquiry Issue 11. *Avian Flu*

45. The Avian Influenza (AI) preparedness offers an example of the often neglected need for targeted programmes that reach migrants and mobile populations. In various countries campaigns and plans have neglected the reality of today's multiethnic, multicultural communities. Few countries had included into their plans specific actions, both in terms of prevention, response and support to livelihood for migrants and mobile populations in the context of AI epidemics. With the support of the Japanese Government and in coordination with UN partners, IOM has piloted initiatives in South-East Asia and Africa well received by local Governments. IOM seeks continuous support in this sector and more globally for policies and programmes that promote the health of migrants and consequently their contribution to the growth and development of their host community and origin as well.

IOM appreciates the opportunity to answer this important Inquiry and hopes that its contribution will be useful.

February 2008

Annex

Table 1

ODDS OF BEING SMEAR POSITIVE DEPENDING ON THE CXR FINDINGS IN THE US-BOUND REFUGEES, THAILAND, 2006–07 DATA

Number of observations = 11,967

<i>CXR</i>	<i>Odds Ratio</i>	<i>Std Err</i>	<i>z</i>	<i>P > z</i>	<i>[95% Conf Interval]</i>
Infiltrate	38.26599	13.36807	10.43	0.000	19.29519–75.88864
Cavity	7.706189	4.068185	3.87	0.000	2.738297–21.68696
Effusion	3.887104	2.164701	2.44	0.015	1.304962–11.57856
Nodule(s)	3.182966	1.914342	1.93	0.054	0.979244–10.34601
Other	0.382220	0.129551	–2.84	0.005	0.196700–0.742717

Table 2

RATE OF CXR FINDINGS, SUGGESTIVE OF ACTIVE TB, AND SMEAR-POSITIVITY IN THE UK-BOUND MIGRANTS (2005–07), AND TB INDICATORS, REPORTED BY WHO (2007)

The table can be released as soon as the permission to use the data has been received from the UK government.

Table 3

PREVALENCE OF CXR FINDINGS, SUGGESTIVE OF ACTIVE TB, IN THE US-BOUND MIGRANTS IN THAILAND (2006–07) AND PREVALENCE OF ALL FORMS OF TB, REPORTED BY WHO

<i>Country</i>	<i>IOM</i>		<i>WHO (Global Tuberculosis Control, 2007)</i>		
	<i>CXR, suggestive of active TB (%)</i>	<i>Smear-positive (%)</i>	<i>Incidence, all forms (%)</i>	<i>Prevalence, all forms (%)</i>	<i>Incidence, smear-positive (%)</i>
	n = 11,967				
Thailand	4.96	0.65	0.14	0.20	0.06

Table 4**RESULTS OF THE SPUTUM MICROSCOPY AND CULTURE IN
THE US-BOUND REFUGEES, THAILAND**

Culture	AFB smear		<i>Total</i>
	<i>Positive</i>	<i>Negative</i>	
Growth	101	440	541
No Growth	87	12,737	12,824
Total	188	13,177	13,365

Table 6**IOM HEALTH ASSESSMENTS PER LOCATION OF ORIGIN, MIGRANT/REFUGEE STATUS AND DESTINATION, 2006**

<i>Region of Origin</i>	<i>Country of Destination</i>														<i>Grand Total</i>
	<i>USA</i>		<i>Canada</i>		<i>Australia</i>		<i>New Zealand</i>		<i>United Kingdom</i>		<i>Other</i>		<i>Total</i>		
	<i>Migrants</i>	<i>Refugees</i>	<i>Migrants</i>	<i>Refugees</i>	<i>Migrants</i>	<i>Refugees</i>	<i>Migrants</i>	<i>Refugees</i>	<i>Migrants</i>	<i>Refugees</i>	<i>Migrants</i>	<i>Refugees</i>	<i>Migrants</i>	<i>Refugees</i>	
Russia	4,337	5,572	1,988	685	1,006	0	250	0	0	0	41	0	7,622	6,257	13,879
Ukraine	5,544	896	2,345	5	301	0	86	0	0	0	0	0	8,278	901	9,179
Kazakhstan	102	176	739	364	166	0	25	0	0	0	1	0	1,033	540	1,573
Uzbekistan	27	189	0	101	0	0	0	0	0	0	0	0	27	290	317
Moldova	222	763	88	0	25	0	4	0	0	0	0	0	339	763	1,102
Belarus	57	242	430	0	61	0	17	0	0	0	0	0	565	242	807
Tajikistan	0	135	0	93	0	0	0	0	0	0	0	0	0	228	228
Kyrgystan	0	45	0	70	0	2	0	0	0	0	0	0	0	117	117
Republic of Malta	0	30	0	0	0	0	0	0	0	0	0	0	0	30	30
East Europe and Central Asia	10,289	8,048	5,590	1,318	1,559	2	384	0	0	0	42	0	17,864	9,368	27,232
Kenya	180	11,576	151	1,399	1,255	1,644	108	0	0	250	0	0	1,694	14,869	16,563
Ghana	65	878	0	0	0	509	0	0	0	0	0	0	65	1,387	1,452
Tanzania	0	868	0	152	0	1,206	0	0	1,943	0	0	0	1,943	2,226	4,169
Uganda	0	118	0	362	0	617	0	0	0	0	0	111	0	1,208	1,208
Guinea	0	777	0	0	0	0	0	0	0	0	0	0	0	777	777
Ethiopia	0	1,071	0	165	0	206	0	3	0	0	0	0	0	1,445	1,445
Gabon	0	23	0	0	0	0	0	0	0	0	0	0	0	23	23
Sierra Leone	0	72	0	0	0	0	0	0	0	0	0	0	0	72	72
Cote D'Ivoire	0	1	0	0	0	0	0	0	0	0	0	0	0	1	1
Zimbabwe	0	145	0	0	0	0	0	0	0	0	0	0	0	145	145
Zambia	0	116	0	0	0	0	0	0	0	376	0	0	0	492	492
Sudan	0	0	0	0	0	0	0	0	816	0	0	0	816	0	816
Rwanda	0	16	0	26	0	25	0	0	0	0	0	0	0	67	67
Somaliland	0	0	0	114	0	6	0	0	0	0	0	0	0	120	120
Somalia	0	0	0	4	0	0	0	0	0	0	0	0	0	4	4
Burundi	0	685	0	0	0	0	0	0	0	0	0	0	0	685	685
Jordan	0	0	0	0	0	0	0	9	0	0	0	14	0	23	23
Democratic Republic of Congo	0	0	0	108	0	0	0	0	0	0	0	0	0	108	108
Iraq	0	0	0	0	13	65	0	18	0	0	0	0	13	83	96
Eritrea	0	0	0	0	0	63	0	1	0	0	0	0	0	64	64
Malawi	0	0	0	0	0	0	0	0	0	0	0	151	0	151	151
Namibia	0	95	0	0	0	0	0	0	0	0	0	0	0	95	95
Republic of Congo	0	0	0	0	0	109	0	0	0	0	0	0	0	109	109
Africa	245	16,441	151	2,330	1,268	4,450	108	31	2,759	626	0	276	4,531	24,154	28,685
Vietnam	4,963	1,364	3,022	0	2,751	0	147	0	0	0	0	0	10,883	1,364	12,247
Bangladesh	0	0	0	23	0	0	0	0	19,714	0	0	0	19,714	23	19,737
Thailand	0	8,007	0	900	1	1,662	0	620	8,743	90	159	0	8,744	11,438	20,182
Cambodia	1,016	87	638	37	1,237	0	644	3	67	0	76	0	3,678	127	3,805
Indonesia	0	916	262	2	107	0	2	1	0	0	0	0	371	919	1,290
Afghanistan	0	0	0	0	0	0	0	18	0	0	0	0	0	18	18
Pakistan***	0	0	0	0	0	0	58	0	0	0	0	0	58	0	58

<i>Region of Origin</i>	<i>Country of Destination</i>														<i>Grand Total</i>
	<i>USA</i>		<i>Canada</i>		<i>Australia</i>		<i>New Zealand</i>		<i>United Kingdom</i>		<i>Other</i>		<i>Total</i>		
	<i>Migrants</i>	<i>Refugees</i>	<i>Migrants</i>	<i>Refugees</i>	<i>Migrants</i>	<i>Refugees</i>	<i>Migrants</i>	<i>Refugees</i>	<i>Migrants</i>	<i>Refugees</i>	<i>Migrants</i>	<i>Refugees</i>	<i>Migrants</i>	<i>Refugees</i>	
Asia and Oceania	5,979	10,374	3,922	962	4,096	1,662	851	642	28,524	90	76	159	43,448	13,889	57,337
Romania	0	0	3,694	0	171	0	83	0	0	0	0	0	3,948	0	3,948
Bulgaria	0	0	1,113	0	0	0	0	0	0	0	0	0	1,113	0	1,113
Serbia and Montenegro	329	2	312	0	517	8	35	0	0	0	151	0	1,344	10	1,354
FYROM****	885	1	77	0	209	0	13	0	0	0	0	0	1,184	1	1,185
Kosovo (Serbia and Montenegro)	706	0	263	0	29	0	6	0	0	0	0	0	1,004	0	1,004
Bosnia and Herzegovina	0	4	161	59	343	68	4	0	0	0	0	0	508	131	639
Croatia	0	0	21	0	264	0	14	0	0	0	0	0	299	0	299
South-East Europe	1,920	7	5,641	59	1,533	76	155	0	0	0	151	0	9,400	142	9,542
Worldwide	18,433	34,870	15,304	4,669	8,456	6,190	1,498	673	31,283	716	269	435	75,243	47,553	122,796

* Migrants moved on a voluntary basis; ** Refugees moved on an involuntary basis

*** Because of the small number of assessments in South Asia and Oceania, these regions have been included under South-East Asia in the remainder of the document

**** Former Yugoslavia Republic of Macedonia

Memorandum by the International Pharmaceutical Federation (FIP)

8Q: Cases of TB fell progressively in the UK until the mid 1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of tuberculosis infections in Britain? And how could intergovernmental action help to reverse this trend?

The vast majority of TB cases in the UK are notified as residents in London and the vast majority of these are individuals not born in the UK. However, to draw from this the conclusion that the rise of TB prevalence is due solely to immigrants from high TB prevalence countries introducing TB into an otherwise low incidence country would be inaccurate. Notification statistics demonstrate that non-UK born individuals that develop TB do so generally after they have been in the UK for some years. Although this is not always the case, it would be worth considering other factors, such as social deprivation and access to health care. Why are TB rates highest in the most deprived boroughs? What is wrong with the health and/or social systems in the UK that individuals develop TB in the UK after many years without disease in their countries of origin? Particular attention should also be paid towards “hard to reach” or high risk groups that might encourage the nosocomial spread of TB. Groups include illegal immigrants—who would not necessarily register for health care—street sex workers, intravenous and crack cocaine drug users, and homeless individuals whose lives are likely to be chaotic with TB treatment representing a low priority. Provision of directly observed treatment (DOT) in the community, such as in General Practitioners or community pharmacies, may improve access to care.

Greater attention should also be paid towards screening systems, particularly the Port of Arrival screening offered to “high risk” immigrants for later follow-up. The various services available are largely inefficient or of unknown/unquantified efficiency. A comparison of systems may help to identify the best model (alone or integrated screening) of screening strategy. In addition, other forms of screening should be explored. For example, the ubiquity of general practitioners and community pharmacies provides a unique opportunity for identifying and treating individuals infected with TB that might not normally access healthcare.

Q9: Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions—eg HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?

TB treatment is highly efficacious and cost-effective. Taken correctly almost all TB patients would achieve a cure. There are many reasons why cure rates of 98% are not achieved and the reasons depend on the setting, for example, high versus low income countries and high versus low HIV prevalence. However, the length of treatment must play a part with the minimum duration of six-months treatment of TB and three-months treatment (recommended in the UK) for latent infection. Symptoms are likely to disappear after two weeks treatment of pulmonary TB, and extrapulmonary TB may be asymptomatic. Therefore, to continue with over five months additional treatment demands much of the patient both in terms of will power and the understanding of disease. In reducing the duration of treatment, for example, by introducing more efficacious drug treatments or including other antituberculous drugs into existing regimens to improve efficacy, may help to circumvent this problem or at least reduce the impact of non-adherence. Alternatively, greater emphasis on patient counselling and using better engagement strategies, putting patients at the centre of their care in the absence of much therapeutic choice, may help.

Sharing of experience between different countries, including between high and low prevalence settings to identify common themes and strategies, would help in the common goal of reducing the global prevalence of TB. For example, if TB rates in the UK relate to TB rates in high TB burden countries through immigration then it makes sense to develop seamless strategies that span geographical boundaries. It should be possible for a patient to begin treatment in one country and finish treatment in another without interruption in treatment. In the absence of any new technological breakthroughs in TB it is worth also focusing on what can be best made out of existing technologies. Are pharmaceutical formulations adequate for those who struggle to adhere to treatment or children, for example? Are these accessible? Are second-line treatments readily available and/or affordable where needed? Does the ubiquity of first-line TB drugs, especially in developing countries, hampering the eradication of TB, and, if so, what measures can be put in place to prevent this from continuing?

February 2008

Memorandum by the Malaria Centre, London School of Hygiene & Tropical Medicine (LSHTM)

These comments are restricted to points about malaria specifically and in answer to the specific questions posed by the Committee; the LSHTM is responding more generally to the Committee across the 4 diseases and this acts as a malaria-specific annexe to that response.

1. *A recent report on Communicable Diseases by the UK Department of Health stated that “post-war optimism that their conquest was near has proved dramatically unfounded”. What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis?*

1. Experience has shown that where nothing else changes the overall burden of malaria decreases as economic status improves. This process is now taking place for malaria in many, but by no means all, parts of Asia. However, in Africa malaria remains a major burden and whilst there is early evidence it may be decreasing in some areas it remains very common. Deaths from malaria increased in some areas over the last decade- this was probably linked to increasing drug resistance.

2. *What reliable data exist regarding the numbers of people infected globally with the four diseases³⁰ on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?*

2. Generally accepted WHO estimates are 300–500 clinical cases of malaria and more than 1 million malaria related deaths per year, 80–90% of these being in tropical Africa, although there are many important areas of the world where the transmission rates are not much better than an educated guess. In highly endemic areas of tropical Africa there are many more than 500 million infections acquired per year, but many of these are more or less symptomless infections of older people who have acquired a considerable degree of immunity in response to repeated infections in childhood. Recently there has been much more funding for malaria control from the Global Fund for AIDS, TB and Malaria (GFATM) and other donors and in the last 12 months the GFATM has provided 46 million long lasting insecticidal nets to several African countries. Furthermore, indoor spraying with residual insecticides is being revived and modern more effective (and more expensive) anti-malaria drugs are being made available.

In the UK and other developed countries malaria transmission was eliminated in the first 60 years of the 20th century. However *Anopheles* mosquitoes (of a different sub-genus from those in Africa) still exist in developed countries and potentially can pick up malaria parasites; very occasional transmission has been reported in Italy from imported infections. In the UK there are about 1,750 malaria cases a year, but all are imported in people who have recently travelled in the tropics and acquired their infections there.

4. *Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years?*

4. If current levels of funding from donors are sustained or increased for insecticidal nets, indoor residual spraying, anti-malaria drugs and support for health services, further reductions in the burden of malaria can be expected. However, there are no grounds for complacency; previous reductions have been followed by rebound when control measures were relaxed. Recent progress could be reversed if spreading occurs of recently detected genes for resistance to pyrethroid insecticides or Artemisinin based anti-malaria drugs. Existing efforts to develop replacement compounds need to be re-inforced. The continuing reduction of falciparum malaria in Asia will probably continue as areas industrialise. Malaria has reinvaded areas (such as in Central Asia) where complex emergencies have had an impact on control measures.

5. *What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?*

5. Until recently the principle blockage was inadequate resources to deploy tools known to be effective at preventing and treating malaria. This is still a problem, but currently a declining one; the Bill and Melinda Gates Foundation, WHO and the Roll Back Malaria partnership have all committed to the elimination of malaria—a challenging goal. Other major doors, such as the Clinton Foundation, which have not worked previously on malaria are now entering the field and there are many new smaller, NGOs being established to

³⁰ HIV/AIDS, Tuberculosis, Malaria and Avian Influenza.

support malaria control (eg. UK Coalition on Malaria, European Coalition on Malaria etc). It is essential that a realistic roadmap for the elimination of malaria is devised and that all major groups can support.

The major current blockage in much of Africa are the very weak health systems and services. Most of those who have malaria do not reach the formal healthcare sector, those that do are often misdiagnosed or treated with inadequate drugs. Current bednet distribution systems only reach a fraction of those who need them in many highly endemic countries. Effective tools to prevent and treat malaria are therefore not getting to those who need them even where the resources to provide them are there. Reversing this will require significant and long-term investment in health systems, which are seldom donor priorities.

6. *What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?*

6. The LSHTM Malaria Centre has over 70 scientists for disciplines ranging from basic science through clinical research to social science and economics whose main interests are malaria who work in a multidisciplinary way. This is probably the largest scientific malaria grouping worldwide. In addition to research LSHTM staff provide technical advice on malaria to DFID, DH, WHO and NGOs as well as technical agencies in endemic countries. LSHTM also has an important training role providing masters and doctoral level training for many developing country scientists and control programme managers who are playing a critical role in malaria control in their own countries.

7. *What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient “joined-up” thinking in approaching the problem?*

7. (a) *Global warming*: if an *Anopheles* mosquito picks up malaria parasites by biting an infected person, the development of the parasites to the stage at which they can be passed on during another bite is highly temperature dependent. African *Anopheles* populations are larger where temperatures are higher, provided that there is enough rain to produce clean surface water in which their larvae can survive. In African mountains *Anopheles* populations and malaria incidence decrease progressively from high levels in the warm lowlands to almost zero at 1,700 metres where it is much cooler. If there is substantial global warming it is reasonable to expect the upper altitude limit for malaria transmission to rise. However, the Intergovernmental Panel on Climate Change (IPCC) has recently stated that there is no convincing evidence that such a change has occurred yet.

The impact in Europe is however likely to be limited or nil provided effective health systems remain in place. After eradication of malaria transmission in Italy in 1962, *Anopheles* populations continue to exist but since that time there have been only about five cases of malaria which are not readily explained as imported cases in travellers who have been in the tropics. Italian summers are hotter now than the most extreme predictions for climate change in the UK. This indicates that, with an effective and equitable West European health service, almost all imported malaria cases are promptly and effectively treated before a local *Anopheles* mosquito could be infected if it bit the person concerned. The HPA Malaria Reference Laboratory (part of the Malaria Centre) provides surveillance for the UK.

(b) *Poverty*: Poverty and malaria constitute a vicious circle. It has been estimated that up to 15% of some African countries GDP is lost to malaria, and whilst the data on which this is based should be treated with caution it certainly takes a major economic toll on development. At an individual level malaria increases poverty by many routes, including: (i) in the wet (growing) season, when farmers have most work to do, they are often incapacitated by malaria, the incidence of which peaks in the wet season when *Anopheles* breed in largest numbers and (ii) children are often kept away from school by malaria attacks.

The poorest suffer most of the effects of malaria, being more likely to acquire the disease, and more likely to die from it if they get it. They tend to live closest to mosquito breeding sites and be least protected by malaria control programmes. They are least able to buy effective protection (such as insecticide treated bednets), or to buy effective antimalarials which are only provided free in some countries. Currently most countries rely

on user fees for healthcare. Indirect costs of seeking healthcare are also a major barrier, and the poorest often get most of their care from shops where advice is often poor. Free bednet distribution only occurs in a minority of settings.

(c) *Population movement*: The current mass movement of rural Africans into urban slums will have many adverse effects, but it may actually reduce malaria incidence as the polluted surface water in urban slums is only suitable for the breeding of *Culex* mosquitoes, not *Anopheles* which are the only vectors of human malaria.

(d) *International travel*: Increased inter-continental travel will increase the number of people from countries which now have no malaria transmission, such as the UK, who need to be warned to take anti-mosquito and drug prophylactic precautions while in the tropics. International travel makes the spread of drug resistant malaria, once it starts, rapid and inevitable, and will complicate efforts to eliminate malaria in some geographical regions whilst it continues in others.

10. *To what extent do you believe that the 2004 Stockholm Convention limiting the use of DDT against Malaria-carrying mosquitoes has been a factor of increases in the spread of the disease? Has any risk analysis been carried out comparing the relative dangers to human health posed by DDT and Malaria?*

10. In the preamble to the Stockholm Convention on Persistent Organic Pollutants, there is mention of the desirability of replacing DDT house spraying against malaria mosquitoes by equally effective and affordable alternatives, if and when these become available. However, there is a detailed amendment in the Convention which specifically authorises continued indoor use DDT against disease vectors using W.H.O. approved methods. The amendment accepts that outdoor use of DDT against agricultural pests should be banned because of the evidence that DDT break down products can enter the outdoor food chain and cause harm to attractive wildlife such as peregrine falcons. In the final round of negotiations about the Convention in 2000, the amendment was introduced by the South African delegation and the wording was subject to detailed negotiation by contact groups. When finally brought to the plenary negotiating session, the amendment was accepted *nem.con.* by the 150 United Nations delegations present.

The South Africans were motivated to introduce this amendment because their own anti-malaria spraying programme was facing a serious problem. After 50 years of successful use of DDT from 1945 to 1995 they had yielded to environmentalist pressure and switched from DDT to pyrethroid spraying. Within four years, one of the two important malaria transmitting species in southern Africa, *Anopheles funestus*, was found to have evolved resistance to pyrethroids, but not DDT, and incidence of malaria cases had increased by four fold. Fortified by the existence in the Convention of the amendment which they had introduced, the South Africans switched back to DDT spraying in 2001. The next year they switched to Artemisinin Combination Therapy as first line anti-malaria drug. By 2004 incidence of malaria had declined by 91% compared to the peak year in 2001 (Maharaj *et al.*, 2005). With South African assistance parts of Zambia and Mozambique have successfully taken up indoor spraying with DDT against malaria mosquitoes.

There have been numerous published reviews of the evidence about possible adverse effects of DDT on human health. Most show no convincing evidence of such adverse effects, but there is evidence of an association between level of DDT break down products in sera of American women in the 1950s-60s and probability of them having pre-term births (Longnecker *et al.*, 2001). However detailed data were collected by Giglioli (1972) on maternal and infant survival and the birth rate in Guyana in the 1930s (before availability of DDT), the 1940s (during its intensive indoor use against malaria mosquitoes) and in the 1950s (after malaria eradication had been temporarily achieved). The data show remarkable and progressive improvements in maternal and infant survival and live birth rate over those three decades which indicates that, if it is true that DDT causes an increase in premature births, the beneficial effect of DDT used to eradicate malaria far outweighs any adverse effects.

Where there is resistance in malaria mosquitoes to pyrethroids but not DDT, as was found in South Africa, there is clearly a strong argument to continue to, or to switch back to, spraying DDT. However, where (as is often the case) there is no resistance of this type, the argument for using DDT is that the cost per house sprayed per year is somewhat less than it would be for using a pyrethroid. This cost difference is now not very large. Some donors are concerned about use of DDT and are willing to donate a larger sum to allow a pyrethroid to be used to protect the same number of houses. It is surely better that they do so rather than delay start of a spraying project while wrangles continue about which insecticide to use.

REFERENCES

Giglioli (1972) *Bull WHO* **46**: 181–202. Longnecker (2001) *Lancet* **358**: 110–114. Maharaj *et al* (2005) *S Af Med J* **95**: 871–4.

12. *To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?*

12. There is clear evidence that part of the recent deterioration in the global malaria situation, especially in Africa, was due to the emergence of resistance to chloroquine and sulphadoxine pyrimethamine (SP). Unfortunately, the malaria community was slow to pick up on the advantages of combination therapy in the prevention of the emergence of resistance. This lesson has now been painfully learnt and it is likely that in future antimalarials will, as in the case of tuberculosis and HIV, almost always be deployed as combination therapy. This should delay the emergence of drug resistance but will not prevent it. Thus, it is essential that research continues to develop new classes of antimalarials even at a time when there does not seem to be an urgent need, as is the case at the moment when high levels of success are being achieved with artemisinin combination therapy (ACTs). It is important that groups such as the Medicines for Malaria Venture, which are developing new drugs continue to receive support.

14. *Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?*

14. For malaria there is a small but real time-lag and increase in costs associated with the fact that drugs have to be registered separately in each country. A pan-African, or regional (eg SADEC) recognition of drug licensing would be helpful.

On an IP related issue, the penetration of fake (useless) antimalarials into the market is a very worrying development which may lead to many avoidable deaths. These are very sophisticated fakes generally imported into the end-country, and this requires rapid international action by governments. In parts of Laos 80% of all antimalarials sold are fake. However, in Thailand the problem has been largely avoided to date by making the sale of antimalarials illegal and providing them free of charge through a widespread network of government health centres, backed up by quality control of supplies.

15. *What interchange exists between States in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?*

15. For malaria the main issue is detecting the spread of drug resistance and insecticide resistance. Various resistance detection networks have been set up to do this, often with starter funding from donors (including DFID) but securing funding for these to continue has proved very difficult. Research funders say this is the proper job of government, and governments do not see this as a priority. As a result almost all have collapsed. Resistance monitoring therefore depends on ad-hoc groups of research groups—which means that large parts of Africa and Asia have no data on drug or insecticide resistance at all, and public health planning occurs only when resistance has reached crisis levels.

16. *The International Health Regulations 2005 are intended to provide a global framework for the rapid identification and containment of public health emergencies. How effective do you consider this response system to be? Do improvements need to be made?*

16. It is unlikely the IHR, either old or new, will be relevant to malaria.

16 January 2008

Memorandum by the Malaria Consortium

Whilst the Malaria Consortium works on a range of communicable diseases, including malaria, tuberculosis, childhood infections and neglected tropical diseases, we have focussed on malaria in this submission.

1. We believe that the assessment that post-war optimism regarding the control of infectious diseases was unfounded is correct. However, the situation cannot be called a crisis but rather reflects the “natural” development and the ability of the biological agents to adapt to medicines and control measures by developing resistance and finding new epidemiological niches. The rapid progress of

reduction of infectious diseases after World War Two, as a result of new antibiotics and the socio-economic changes through industrialisation, misled the public health community to believe that this progress could go on and drive many infections to extinction. Although one such success was achieved with small pox, this remains the only one. Other diseases have made progress towards elimination such as polio and guinea worm but efforts drag on, demonstrating the enormous inputs needed at the final stages of such endeavours to “mop-up” the last foci of the disease. At the same time diseases such as HIV/AIDS, ebola and SARS have demonstrated the potential of viruses in the biotope to jump the animal/human barrier, creating new infectious threats and/or epidemics. Two issues, which threaten progress in elimination of communicable diseases are resistance and increasing mobility of human populations. Resistance to drugs and insecticides has set back progress. For instance, resistance of the malaria parasite *Plasmodium falciparum* to chloroquine was associated with increased child mortality in Africa in the 1990s. Large and small scale population migrations make containment of communicable diseases more challenging. While the situation today is not a crisis, it should remind us that infectious diseases will always be part of human life and that we cannot relax the attempts to develop new and better weapons to counter this threat, especially given the genetic potential of the infectious agents to mutate and adjust to new environments and counter-attacks. The rate of progress in reducing spread of communicable diseases is slower than acceptable. We do now have excellent and proven tools to combat diseases, but lack of investment has meant that, until very recently, there was little impetus to apply them on a meaningful scale.

2. Among the four infections the committee is primarily concerned with, malaria is probably the one with the least reliable figures on disease burden and incidence of infection and disease. This is not a flaw of the monitoring and surveillance system but rather a function of the complexity of the interaction between the human host and the infectious agent, the malaria parasites. Depending on the level and history of exposure (transmission) humans develop a partial immunity to the parasite that will generally prevent death from the disease and greatly reduce and mitigate clinical episodes of malaria without suppressing infection and (asymptomatic) parasite presence in the blood. In areas with high levels of transmission almost continuous presence of some parasites and often multiple simultaneous infections are the norm rather than the exception among children and adolescents. This makes it almost impossible to monitor incidence of infection or get reliable counts of clinical episodes attributable to malaria. Similarly, many deaths through malaria—which occur in highly endemic areas mainly among very young children—are not attended to at a hospital and hence not registered making accurate counts of the death toll from malaria very difficult. That being said, there have been increased efforts in recent years to apply complex epidemiological and mathematical techniques to get a reasonable estimate of the number of deaths which all seem to agree in the order of magnitude of deaths and clinical episodes. Based on these figures (including the most recent UNICEF Malaria in Children Report 2007) the number of deaths has not been dramatically increasing in recent years and is now showing a trend to decline owing to the efforts of intensified malaria control particularly in Sub-Saharan Africa in recent years. Data from particular countries such as Eritrea and Zanzibar clearly demonstrate these declines in malaria prevalence, morbidity and mortality. It can be expected that such success stories will be coming from an increasing number of countries in the coming years. In Southeast Asia malaria has shown a sharp decrease in recent decades, which relates to a combination of better control programmes, changes in the environment. The effect of economic development is likely to be important, but more difficult to assess.
3. Not applicable.
4. Given the significantly increased funds available for malaria control in general and particularly in Sub-Saharan Africa, one can expect a dramatic decline of malaria incidence, prevalence, morbidity and mortality. However, while it should be possible to eliminate the infection in areas of the world where transmission is moderate or low, most experts agree that with our current tools and interventions a sustainable interruption of transmission in the high transmission areas of Africa is not possible. This means that control efforts have to be maintained at high level and the continuous efforts to find new drugs for treatment and new insecticides for prevention must continue, as the parasites will eventually develop resistance to the currently effective weapons. Elimination of tropical malaria (*Plasmodium falciparum*) from Africa will, however, require additional interventions currently not available, namely safe medicines that are able to kill gametocytes (the forms taken up by the mosquito vectors) and additional leverage to reduce transmission such as a transmission blocking vaccine. Malaria eradication, is an important vision for the future but one we should only practically engage in once we are certain to have the necessary means to achieve it.

5. With funds available at the time the major blockage for rapid implementation—particularly in Sub-Saharan Africa—is the limited capacity of countries to absorb these funds and implement prevention measures at high quality at scale and to make treatment available to all who need it while at the same time increasing the capacity for adequate diagnosis of malaria. This is largely a result of insufficient prioritisation of funding into national health systems as a whole with much health funding disease specific and poorly co-ordinated. In addition the unpredictability of funding from inter-governmental sources seriously hampers long-term planning.
6. Malaria Consortium engages in the control of malaria as well as other communicable diseases such as tuberculosis, pneumonia, diarrhoea and some so called neglected tropical diseases such as lymphatic filariasis, and visceral leishmaniasis (Kala Azar). We support national malaria control programmes in the design and implementation of intervention strategies such as distribution of long-lasting insecticidal nets through various mechanisms, applying indoor residual spraying, rolling out new treatment and diagnostics policies in the government, non-for-profit and private health services including approaches to community based treatment and diagnosis. We also directly implement some of these interventions and test new tools in vector control for their field effectiveness. Other areas of our work are operational research and monitoring and evaluation of inputs, outputs, processes, outcomes and impact. These include the development of new tools and research on implementation, and also design and establishment of routine monitoring and surveillance systems and national and sub-national household surveys to assess coverage and impact. Finally, we have played a significant role in development of international policy for several years, and are increasingly engaging in advocacy. Our configuration consists of a small UK-based head office with a large regional office in Uganda and several country and subnational offices in Africa and one in Asia. Our team is multi-disciplinary and based on high level technical specialist expertise combined with operational delivery capacity. Our decision to place most of our resources, where the communicable diseases programmes are operating has been extremely effective in linking up-to-date awareness of the practical country level issues with clear awareness of global policy and strategy context. As our organisation has no core funding, it depends on executing projects for various donors including GFATM, DFID, Irishaid, USAID/PMI and the Bill & Melinda Gates Foundation. We are not adequately resourced for playing a more advisory role at regional and international level, but have tried to contribute as much as we can. Our close involvement in the coordination efforts of the Roll-Back Malaria Partnership through its sub-regional networks and various working groups ensures maximum synergy with others in the field. We collaborate with ministries of health and a wide range of international organisations.
7. Poverty probably is the most important non-health related driving factor in malaria or rather the factor preventing rapid progress. Global warming only plays a marginal role in some highlands and at the fringes of malaria transmission at present. However, environmental factors, particularly man-made sources of malaria transmission are also significant (agriculture, construction sites) and much could be achieved by involving these areas more in control efforts. At times environmental changes have also worked in support of malaria control, eg deforestation in Southeast Asia which has reduced the habitats of the malaria vectors. Lack of general country development particularly transport infrastructure is an additional important non-health barrier to rapid progress making implementation and monitoring of high quality programmes—key for achieving ambitious control or elimination targets—highly problematic. Greater investments in the education sector at all levels, primary to tertiary, will be crucial to overcome the barrier of inadequate capacity to control communicable diseases.
8. Not applicable.
9. Not applicable.
10. The 2004 Stockholm convention against persistent organic pollutants including DDT has—in our assessment—not in the least contributed to spread of malaria (which has not occurred at a significant level) nor the increasing number of cases (which had been mainly due to drug resistance). This is because most countries in Sub-Saharan Africa have never applied indoor residual spraying at national scale and, therefore, lacking the systems and capacity, spraying DDT was until recently not an option. In addition, in most of these countries other insecticides such as pyrethroids are sufficiently effective meaning that DDT is not the only solution.
11. Not applicable.
12. Not applicable.
13. Not applicable.

14. While patents do play a role with respect to medicines against malaria and insecticides against the vectors they are not limiting control efforts in the same way as is the case with HIV/AIDS. The problem lies more in the rate at which companies producing medicines are prequalified to supply to the major funding sources.
15. Outbreaks of malaria are currently a problem only within some counties (highlands, refugee situations, other population migrations) but not between countries or continents. This is due to the more complex transmission modalities of malaria compared to bacteria or viruses. Outbreaks will only become a more than local concern when malaria elimination has succeeded in large areas currently endemic.
16. Not applicable.
17. Not applicable.
18. Not applicable.
19. Not applicable.
20. We should be willing to provide more detailed information if called upon by the committee.

The responses presented have been contributed by several staff within our organisation, and are an organisational submission.

21 January 2008

Memorandum by the Medical Research Council

1.1 In spite of the post-war revolution in antimicrobials and vaccines, infectious diseases have remained at the forefront of global morbidity and mortality. The old infections of malaria and TB have not been controlled; the new disease of HIV has had a terrifying impact; viruses such as influenza continue to adapt and re-emerge in forms that exploit changes in human society. International travel facilitates global spread of pathogens, and microbes have evolved resistance at a rate that often outstrips the development activities of the pharmaceutical industry. On the positive side, the perception that poverty related diseases would be eliminated as a consequence of economic development has been replaced by appreciation of a two-way process in which disease control is itself a driver for development, leading to an increase in awareness and funding for disease control efforts.

1.2 (Malaria) There is still no effective vaccine, and only recently has there been renewed research interest in the development of new drugs. Following the failure of eradication campaigns based largely on anti-mosquito measures in the 1960s, interest in the disease waned. It is only recently that approaches such as insecticide-treated bed nets and combination drug therapy are being deployed.

1.3 (AIDS) Over the past 10 years there has been remarkable progress in developing drugs for AIDS patients and significant progress in distributing them in resource-poor countries. However these treatments are not curative and the development of vaccines and microbicides capable of preventing HIV-1 spread has been disappointingly slow. HIV/AIDS will therefore continue acting as a major brake on global development for the foreseeable future.

2.1 (TB) The WHO and the Global Partnership to Stop TB maintain realistic data on the number of cases of active disease. The number of individuals who have been infected far exceeds those that develop disease; estimates of the number of infections are very approximate. The incidence of TB increases dramatically in individuals who are coinfecting with HIV. This has had a major impact on TB in sub-Saharan Africa.

2.2 (Malaria) There have been reasonable estimates of the number of clinical cases of malaria in Africa each year but the number of individuals who are infected but without clinical signs is much higher.

2.3 (AIDS) Yearly estimates of the number of people infected with HIV-1 and deaths from AIDS are published every year by UNAIDS/WHO. The 2007 figures show an apparent decrease in the numbers. However this reflects changes in the methodology of estimation rather than any real decrease. Determining real time trends in HIV-1 incidence remains enormously difficult; thus gauging the success of intervention measures for preventing HIV spread remains a formidable task.

2.4 (Flu) The WHO Global Influenza programme coordinates the validation of human cases of H5N1 and provides up-to-date reports of recent cases. The panzootic in birds continues (expanded during 2005 to encompass Europe and Africa as well as Asia); occasional human cases continue to be identified in new locations emphasizing the continued pandemic threat.

3. (Flu) WHO coordinates the Global Influenza Surveillance Network (as well as other infectious disease networks) that comprises 121 national influenza centres in 93 countries. Current enhancement of the network includes establishment of regional reference laboratories in areas previously poorly represented and additional WHO Collaborating Centres.

4.1 (TB) The Global Plan to Stop TB aims for a 50% reduction in TB worldwide, in line with the Millennium Development Goals. This will not be achieved in Africa (due to HIV-TB) or in Eastern Europe (due to drug-resistant TB). It is anticipated that economic development in Asia will reduce TB over the next decade.

4.2 (Malaria) The Gates Foundation has recently announced a commitment to the eradication of malaria in the longer term. Whilst current methodology can achieve substantial reduction in malaria provided that it is delivered to areas of need, there is also an urgent need for new antimalarials and/or the development of an effective vaccine to ensure that such success can be maintained.

4.3 (AIDS) In 2006 the UN member states agreed to work towards the goal of “universal access to comprehensive prevention programmes, treatment care and support” of HIV/AIDS by 2010. Provided the promises made are kept, and the goals in scaling up health sector interventions are met, there is every prospect of a significant improvement in global HIV/AIDS mortality figures.

4.4 (Flu) H5N1 is endemic in birds in a number of countries and it seems likely that sporadic human infections will continue to emerge. However there is a finite probability that a pandemic will develop.

5.1 (TB) Diagnosis of TB relies mainly on a test introduced in the 1880s; the only vaccine for TB (BCG) was introduced in the 1920s and is ineffective against the major form of the disease; no new drugs have been developed for TB since the 1960s. There is a critical need for basic research directed toward the development of improved tools for TB control.

5.2 (Malaria) There is also a critical need for improved tools for malaria control, to prevent transmission from mosquito to man, drugs to treat clinical infections and an effective vaccine to prevent death and disease. Improved diagnostics are also required particularly to identify active infection and thereby facilitate appropriate drug use.

5.3 (AIDS) Any complete solution to the problem of HIV/AIDS will involve either a treatment that cures individuals from HIV-1 infection (eg drug therapy) or a simple method to prevent virus transmission (eg vaccination). None exists as yet.

5.4 (Flu) Better coordinated action to reduce infection in poultry is required. Economic concerns need to be addressed.

6.1 The main role of the MRC's National Institute for Medical Research is in carrying out fundamental research to understand the complex biology of these formidable pathogens and to feed the translational pipeline that leads to new tools for disease control. If we are to avoid repeating the post-war failures in disease control, we have to develop a better fundamental understanding of the process of infection and the causation of disease in a multidisciplinary effort that includes microbiology together with immunology and population biology. This is being achieved in the research environment of NIMR, with appropriate links to clinical and pharmaceutical partners.

6.2 (Flu) MRC has a 60 year old commitment to WHO to support the World Influenza Centre at NIMR, which as a WHO Collaborating Centre, has a key role in monitoring the evolution of human influenza (and advising on vaccine composition) and detection and identification of novel, potentially pandemic human influenza infections.

7.1 (TB) International travel and immigration are important influences on spread of TB. There is a need for enhanced international surveillance; particularly to monitor the spread of untreatable multidrug-resistant and extensively drug-resistant strains.

7.2 (Malaria) Climatic changes such as rainfall and changes in land use such as deforestation or drainage can affect mosquito breeding and therefore the potential for the transmission of malaria. Poverty and social disintegration, caused by wars or civil strife can very quickly affect the effectiveness of control programmes.

7.3 (AIDS and Flu) Poverty remains an important consideration.

8. (TB) A total of 8497 TB cases were reported in the UK in 2006, with an incidence of 14.6 per 100,000 of the population as compared to 11.6 in 2000. The incidence was 44.8 per 100,000 in London, and 72% of all cases occurred in individuals born outside of the UK. While a large proportion of cases result from transmission outside of the UK, periodic TB outbreaks in schools and local communities highlight the risk of local spread. Eliminating TB from the UK will depend on effective global control.

9. (TB) There are four limitations facing TB control efforts: (a) inefficient diagnosis means that active cases are infectious for long periods before receiving treatment, (b) treatment requires daily delivery of a combination of drugs over a period of six months or more; resulting in problems of drug delivery and patient compliance, (c) selection and transmission of untreatable drug-resistant strains as a result of inefficient treatment, and (d) dramatically enhanced progression to active disease in individuals coinfecting with HIV. There is no single mechanism to address all the issues. We need to develop better diagnostics, novel drugs that act more quickly, and new effective vaccines. Development of these tools is limited by a lack of understanding of the fundamental underlying biology of the disease from the causative microorganism to the host response.

10. (Malaria) There is no doubt that spraying with residual insecticides such as DDT can have a substantial effect on malaria transmission. The cessation of its use, together with the absence of alternative control measures, has had a significant effect on the spread of the disease.

11. (Flu) The World Health Assembly 2005 imposed on member states the obligation to detect and report cases of H5N1. WHO is helping to coordinate the increased capability of member states to do this, for example by establishing Regional H5 Influenza Centres and promoting training etc, financed especially by the US and World Bank. Progress is gradual; it is unlikely to prevent a pandemic, but should allow better implementation of pandemic plans, ameliorating its impact. Better responses to calls for sharing of benefits would achieve more effective international cooperation.

12.1 (TB) Currently, the incidence of drug-resistant TB is high in Eastern Europe (perhaps 10–20% of total cases). In most parts of the world, drug-resistant strains account for less than 10% of total cases. Spread of multidrug-resistant and extensively drug-resistant strains presents a major future threat to TB control. Development of tools to identify highly-transmissible resistant strains needs more research.

12.2 (Malaria) Resistance to chloroquine, once an effective and cheap drug of choice for malaria, and to other drugs such as Fansidar®, has had very substantial effect on the impact of malaria. Cheap and effective new drugs and combinations are urgently required since in the near future we are going to be largely reliant on expensive artemisinin-based combination therapies (ACTs), to which resistance will undoubtedly develop.

12.3 (AIDS) The importance of drug resistant HIV transmission is unclear and requires further investigation

12.4 (Flu) Not currently an important factor in the case of avian flu. Of enormous potential importance if transmission of drug-resistant virus to humans occurs.

13. No response.

14.1 (TB) Research funding from the Bill & Melinda Gates Foundation has a positive influence in insisting on “global access” for all new medicines.

14.2 (Malaria) Not an important consideration.

14.3 (AIDS) Clearly there are tensions between the IP/profit concerns of the pharmaceutical industry and the health needs of economically disadvantaged nations and these have impacted the flow of medicines. These tensions will continue in the future unless extended agreements can be negotiated.

14.4 (Flu) IP represents a major issue in the provision and use of genetically engineered H5N1 candidate vaccine viruses that has had serious repercussions on international co-operation. It is being strenuously addressed at the intergovernmental level.

15.1 (TB and malaria) There are good interactions between research laboratories in the EU and the US. Interactions with laboratories in endemic countries vary in quality. There is a particular need for robust surveillance systems to monitor transmission of drug-resistant TB between eastern and western Europe.

15.2 (Flu) Much has and is being done in relation to influenza and pandemic planning. WHO has taken an important lead in many areas.

16. (Flu) These regulations seem to have omitted an essential requirement: the provision of assistance to developing countries in developing the capacities to fulfil their obligations.

17. No response.

18.1 Cross-species transmission of an animal virus into humans occurs on a regular basis. Fortunately person-to-person virus transmission is rarely sustained. However the example of HIV-1 tells us what can happen if an animal virus becomes established in the human population. There is no inherent difference between an animal and a human virus; funding bodies and governmental departments should be discouraged from creating artificial distinctions in research responses in this area.

18.2 (TB) Bovine TB is strictly regulated by test-and-slaughter policies in most developed countries, but there is little or no regulation in most developing countries. The economic and health benefits associated with reduced productivity of livestock and transmission to humans are largely unknown.

19.1 (Flu) The WHO-designated laboratory at NIMR and other influenza laboratories in the UK provide substantial support to WHO in the provision of expertise, training and reagents to promote international co-operation against flu.

20. While public health measures and translational research are clearly urgent priorities for infection control, development of effective new measures will depend on achieving a better understanding of the complex biology that underlies infection, immunity and progression to disease. There is still a major need for research in this area.

17 January 2008

Memorandum by Merlin

ABOUT MERLIN

1. Merlin is the only UK specialist agency, which responds worldwide with vital healthcare and medical relief for vulnerable people caught up in natural disasters, conflict, disease and health system collapse. Merlin's aim is to ensure that vulnerable people who are excluded from exercising their right to health have equitable access to appropriate and effective healthcare.

2. This aim is inspired and underpinned by the World Health Organisation (WHO) declaration³¹ that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without discrimination of race, religion, political belief, economic or social condition". In support of this aim, Merlin works in partnership with global, national and local health agencies and communities to strengthen health systems and build community resilience to better prevent, mitigate and respond to health outcomes.

THE ISSUES

3. The following represents a consolidated response to some of the key issues raised by the Inquiry.

PRINCIPAL BLOCKAGES

4. From Merlin's perspective the challenges faced, in achieving progress towards prevention and control of the three major diseases (TB, Malaria and HIV) in particular, and by that measure the Millennium Development Goals (MDGs), are determined in large part by the capacity of national health systems. Although cost effective solutions are available for the prevention and treatment of these diseases, for example insecticide treated nets for the prevention of malaria and the provision of anti-retroviral therapy for HIV, the inability of many health systems to plan, support and deliver essential health services will nonetheless result in poor health outcomes.

5. Merlin's experiences within the context of fragile states support that view that at present many health systems simply do not have the resource capacity to support the scale up of the solutions needed to address the continued high burden of communicable disease. Central to this poor resource capacity, is the lack of investment in human resources for health (and in particular health staff who are skilled in communicable disease surveillance, prevention and control), and the need for increased and predictable donor financing to address the investment shortfalls of recent years.

Human Resources for Health

6. From Merlin's perspective, early investment in strengthening human resources will be critical to securing future progress against the MDGs and promote health system development. Evidence shows that the quantity and quality of health workers is positively associated with essential health interventions including immunisation and primary health care (WHO,2006). Further the 2006 World Health Report (ibid), confirms that countries experiencing the greatest difficulties in achieving the MDGs face absolute shortfalls in their health workforces.

7. A review of human resources for health in two of Merlin's key programmes in Liberia and Kenya in 2007 highlights the critical role that human resources play in a functioning health system—particularly in difficult or fragile environments where the workforce may have been exposed to extreme pressures such as conflict and long-term underinvestment in the health sector. Key issues identified at the country level by Merlin programmes include:

³¹ As reflected in the WHO constitution (1946), Alma Ata Declaration (1976) and World Health Assembly (1998).

- the lack of qualified human resources especially in remote areas (urban concentration and rural deficits);
- poor remuneration of staff contributing to their movement/migration to better paid options often outside the area or country;
- low levels of general education (especially of woman in some countries) which restricts the numbers which can be trained up to join the health workforce;
- the lack of frameworks in place for supervision and on-the-job training and quality management; and
- the lack of investment in staff training and development by government and international donors.

8. These findings are borne out by the WHO report which calls on its Member States to show national leadership in three strategic areas: by improving the poor performance and working conditions of health workers; through the provision of better information to inform strategic planning and better education; and, through strengthening core institutions, policy frameworks and leadership and management development. However, despite the WHO's leadership in this area, further effort is required to translate policy approaches to action on the ground.

Financing Health Systems

9. The significant burden of disease in developing countries from HIV, TB and malaria places enormous pressures on already weakened and under financed health systems (World Bank, 2006)—the incidence of TB in Sub-Sahara Africa is the highest in the World and 90% of all Malaria deaths in 2003 were also in this region (WHO, 2003). If investment in human resource capacity is to be sustainable, developing countries will require increased, predictable and longer term financing by the international donor community and a commitment to promoting longer term support for health systems by Intergovernmental organisations. In Eastern DRC, Merlin has been supporting the health system for more than 10 years, during conflict and a series of ensuing humanitarian crisis. The absence of long term, predictable financing severely constrains International NGOs ability to support the Ministry of Health in strategic planning and provide services to those most in need.

10. Merlin would like to see new proposals put forward for funding mechanisms that are longer term, encourage risk and support innovation. Intergovernmental organisations have a significant role to play in facilitating greater awareness of the challenges faced by health systems and in promoting longer term financing instruments. Mechanisms such as those proposed by the Good Humanitarian Donorship (GHD) initiative aimed increasing the flexibility and predictability of funding are positive steps in this direction.

11. While long term financing for national health systems remains a key concern, the growing plethora of global health initiatives channelling vast sums into disease and intervention specific health programmes sits in stark contrast. There is significant on-going debate about the value of such initiatives, but what is recognised is that with more than 90 global health initiatives at present, including GAVI and the Global Fund for HIV, Malaria and TB, efforts are needed at global level to rationalise this number and mitigate the impact vertical programming on health systems.

12. Merlin's experiences of the Global Fund to date have been mixed. In DRC, a Global Fund programme in Maniema Province, Eastern DRC has required setting up parallel primary health care structures. Administration, supervision, and logistics capacities as well as clinical care run alongside pre-existing services missing the opportunity to support the development of capacity within the pre-existing system. In addition there have been issues with the unpredictability of the funding to support ARVs leaving both recipients as well as Merlin staff in an uncertain and difficult position and preventing new entrants to the programme being admitted. In contrast, in Nyanza Province Kenya, Merlin is working under the auspices of the Global Fund, in partnership with the Ministry of Health, to build the capacity of health facilities to provide effective diagnosis and treatment of malaria. The programme is directed at supporting the Ministry of Health to deliver services in accordance with Kenyan national policy.

13. This lack of support for national led systems is frequently highlighted as a failure of some health initiatives. In addition, the proliferation of Initiatives places considerable strain on the management capacities of developing countries and can act as a drain on precious (human) resources; diverting priorities away from where they are needed most to "disease specific" interventions. At present global initiatives are not accountable to national health systems and the considerable level of funding not sustainable in the long term by developing countries national budgets. Although significant steps in terms of reducing the burden of disease are being taken by the Global Fund and others arguably this must go hand in hand with support for national health systems. IGOs, and in particular WHO must seek to advocate for stronger resonance between the interventions of global health initiatives and the strategic plans of national health systems. A first step has been

taken; in September 2007, UN agencies and the WHO supported the launch the International Health Partnership, aimed at improving the way that developing countries and international donors work together to support national health plans. IGOs should seek to promote these links wherever possible.

AVIAN INFLUENZA

14. The WHO has designed a Global Influenza Preparedness Plan to facilitate planning, preparedness and response. However, while there is a plethora of guidelines and initiatives in place at Intergovernmental level, Merlin is concerned about how this might translate at national level, particularly in difficult environments and fragile states, where national planning is weak and there is great variability in terms of national planning and capacity to respond.

THE IMPACT OF TUBERCULOSIS

Tuberculosis is a major health concern in Kenya; recent data from Merlin's programmes in the Western Highlands and Lake Victoria region indicate that Kenya has amongst the highest TB prevalence in the World at 884/100,000. Half of those with TB are also HIV positive. In Merlin's experience in Kenya, the rising incidence of TB can be attributed to: the high prevalence of HIV and AIDS; the poor economic situation of people living with HIV and AIDS; low case detection rates due to poor diagnostic capacity as a result of a poor training, an absence of quality control procedures and equipment; and, poor access to diagnostic facilities for patients. In terms of access to essential drugs within the health system, while this can be a challenge, the difficulty from Merlin's experience lies in the capacity to effectively diagnose TB owing to shortages in essential diagnostic reagents due to problems in the distribution system especially from national to facility level.

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 World Bank (2006) Health Financing Revisited.
January 2008

Letter from Nuffield Council on Bioethics

I have pleasure in attaching a response from the Nuffield Council on Bioethics to the inquiry on controlling the spread of communicable diseases,

We focus in the response on relevant findings from the Council's recent report: *Public Health: Ethical issues*, which, among other things, considered infectious disease as one of its case studies. Our observations concern two main areas. First, the infrastructure and capacity required for the sharing of pandemic-relevant information with surveillance systems managed by WHO. Secondly, intellectual property and access issues arising in the context of the recent controversy about Indonesia's refusal to share influenza virus isolates with the WHO-sponsored surveillance programme, as discussed at the World Health Assembly in May 2007.

I hope that this is a helpful contribution to the Inquiry. Please let us know if we can be of further assistance.

18 January 2008

Memorandum by the Nuffield Council on Bioethics

1. In November 2007, the Nuffield Council on Bioethics published a report on *Public health: ethical issues*. The report uses a number of case studies to illustrate a discussion about ethical issues in public health, one of which was that of infectious disease.
2. In this response we draw your attention to a summary of the principal findings from our report that are relevant to your inquiry. Page and paragraph numbers are provided, which refer to the respective sections in the full report, a copy of which is included with this response.

Question 3: *What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? And what improvements might be made?*

3. In the report, we highlight two examples of international disease surveillance systems that have been problematic in some way. The first relates to the handling of the SARS outbreak; the second to recent controversy about Indonesia's refusal to share influenza virus isolates with the WHO-sponsored pandemic surveillance systems.

4. In the case of SARS, "China was criticized by WHO and countries internationally for delays in reporting cases and an initial lack of cooperation with WHO" (p 71). This development was one of the major precipitants to changes in the *International Health Regulations*, which were published in 2005 (p 71). While these may reduce the likelihood of such a scenario arising again, we nevertheless drew the following conclusion:

"Countries have an ethical obligation to reduce the risk of ill health that people might impose on each other across borders. Therefore countries should notify other relevant countries and bodies about outbreaks of serious diseases at the earliest stage, following the relevant procedures laid out by WHO" (Para 4.50).

5. Aside from any political considerations that may affect the transmission of relevant information, countries differ widely in their capacity to monitor the outbreaks of any infectious diseases. Applying the ethical framework which we set out as the "stewardship model" (p 25) to the global context, we concluded that there was a need for greater investment in surveillance capacity in poorer countries (identified also by both WHO and the UK's Foresight Programme). We recommended that:

"Countries such as the UK should seek to enhance the capacities of developing countries to conduct effective surveillance of infectious diseases. The UK health departments, in liaison with the Department for International Development, should work to take this forward with international partners such as WHO, the European Centre for Disease Prevention and Control (ECDC) and the Centers for Disease Prevention and Control (CDC) in the USA" (para 4.50).

6. In the case of pandemic influenza surveillance, we note that "a controversy in early 2007 highlighted the fragility of global pandemic preparedness, when the Indonesian Government decided to suspend the sharing of clinical specimens of human avian influenza viruses with the surveillance system managed by WHO" (Para 4.51). We go on to explain that this situation was "a cause for serious concern because of the risk that it would severely hinder international surveillance and preparedness activities" (para 4.52). Despite several special meetings and a dedicated WHO Resolution at the World Health Assembly in May 2007, the situation as we understand it was that cooperation had still not resumed in January 2008. This example is further relevant to question 14, and we copy our recommendations concerning ways of making progress in the controversy below.

Question 14: *Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?*

7. The situation in Indonesia over pandemic preparedness arose in part because of considerations relating to intellectual property, and the country's concern that it would not be able to access the benefits such as vaccines. Further background to this situation can be found in the report at paragraphs 4.52–4.55. We concluded as follows:

"WHO is in a unique position to enable centralised and transparent determination that a novel virus has emerged, to evaluate pandemic-related evidence, and to develop response strategies, as acknowledged in the *International Health Regulations 2005*. This capacity must be sustained". (para 4.54)

"WHO should not merely facilitate access to virus isolates for commercial companies, leaving the question of availability of vaccines to market forces. It should use its authority to impress on pharmaceutical companies their social responsibilities. Patents and other forms of intellectual property rights can be useful ways of rewarding research investment and stimulating innovation and progress, but they can also come into conflict with the interests of the wider public, as the Council has reported elsewhere. While we cannot address here all the complexities raised by the sharing of virus isolates for the purpose of monitoring and developing vaccines, virus isolates should not be treated like any ordinary commodity, as adequate access and use is of the greatest importance for public health, both on a national and global level. Therefore, we urge WHO to explore, in liaison with governments and relevant industries, the notion of viewing virus isolates as a form of 'public good', and to take a flexible approach to patenting and intellectual property protection". (para 4.55)

Question 19: *What resources does the UK Government commit to intergovernmental bodies to help in the fight against the four diseases listed?*

8. While we are not best placed to comment on the resources currently committed by the Government, we draw attention to a relevant conclusion concerning capacity building which can be found above, below paragraph 5 of this response.

Letter from One to One Childrens Fund

We welcome and are pleased to respond to the Committee's Inquiry, "Acting through Intergovernmental Organisations to control the spread of diseases".

Since the early 2000s, One to One Children's Fund has helped thousands of children suffering from trauma, or living with HIV/AIDS or amid political conflict to gain resilience, health and hope. We work with local partners to create models of psycho-social and medical care and education that have been replicated by governments and communities in Africa, Kosovo and India as well as the Middle East.

This submission focuses on our engagement with HIV/AIDS treatment in Africa outlining how we have worked with local practitioners to develop and support innovative models of best practice, such as the Paediatric AIDS Treatment for Africa (PATA). We urge policymakers in Britain and internationally to consider how they can co-ordinate better to deliver greater focus and resource to enable extension of this and other successful blueprints for the treatment of HIV/AIDS in children. The One to One Children's Fund programme has been acknowledged as a key stage in the development of a national rollout plan for children in South Africa.

In 2002, One to One Children's Fund began working in partnership with Kidzpositive and its co-founder Dr Paul Roux, paediatric consultant at the Groote Schuur Hospital in Cape Town. We funded a pioneering programme of anti-retroviral (ARV) research and treatment for infected children from the townships of the Western Cape. Over 90% of the recipients responded dramatically to the medication, being able to leave hospital and demonstrate that indigent families from poorer communities could adhere to a complex drug regimen in the home. As the Premier of the Western Cape observed in 2004

"One to One has assisted us in developing a child treatment model that will be used across the province and which has potential to be used across South Africa. By developing a holistic approach to treatment that includes aspects like income generating projects and education of families, this model has been very successful in keeping patients on the strict treatment program".

(Marthinus van Schalkwyk)

In Africa there are now over 2.3 million children infected with HIV, but currently fewer than 5% have access to lifesaving medical treatment. The vast majority of children lag far behind adults in gaining access to the rollout of anti-retroviral treatment. It's hard to comprehend, but a child dies from an AIDS related illness every minute of every day. One to One Children's Fund strives to enhance quality of health care, holistic treatment and comprehensive support for HIV/AIDS children, their families and for communities throughout Africa. While progress is being made in provision of care and treatment for children affected and infected with HIV, current coverage levels, particularly in Sub-Saharan Africa remain unacceptably low.

PATA, a One to One Children's Fund initiative that now links some 50 child HIV clinic teams from more than 20 African countries to develop professional capacity to cope with the epidemic in a ripple across Africa. It is dedicated to expanding access to care for children affected and infected with HIV and their families throughout the African continent. PATA's is also supported by Kidzpositive, UNICEF, the Clinton HIV/AIDS initiative, Sidaction.

PATA values and promotes models of care that address both the medical and psychosocial needs of the child and that offer high quality, integrated, patient-centred, and affordable services. The organization works collaboratively with healthcare teams, serving as a resource to support achievement of their stated goals. PATA facilitates the development of local capacity for high quality HIV care through promotion of learning through team work, sharing of experiences, and spreading of good practice. The foundation of PATA lies with the PATA teams: multidisciplinary *Treatment Teams* of nurses, pharmacists, counsellors and doctors, who work together at clinics across Sub-Saharan Africa to form a community of compassionate and committed individuals who provide treatment and care to children infected with HIV and their families. Nearly one third of children receiving ARVs are cared for in PATA affiliated clinics.

PATA believes in the principle of developing sustainable interventions that are linked to, rather than in parallel with the work of government and other partners. PATA works to extend the horizons of care for each of its affiliated clinics by encouraging Treatment Teams to network with each other through annual meetings, a newsletter and the PATA website. This enables PATA teams to share learning and experience and ultimately develop their own visions for health care improvement. PATA also supports Treatment Teams to reach out

to neighbouring clinics and other partners to improve quality of care and extend the “PATA effect” through leadership and mentoring.

The fundamental purpose of PATA is to assist Treatment Teams to improve the quality of health care they deliver to their patients. PATA works to build health care capacity in local communities through support for training, mentoring, increased access to tools, resources and information, and support for local initiatives supporting infected and affected children. PATA seeks to achieve this through fundraising from private and institutional donors, partnering with individuals and international agencies and building relationships with other field-based organizations.

It also aims to increase access to essential health care services for HIV-infected/affected children through provision of support for increased geographical coverage of clinics for HIV-infected and affected children as well as assistance in reaching clinics from remote sites through provision of transportation subsidies. Furthermore, it is focused on strengthening aspects associated with psychosocial care and support for children living with HIV including assistance with disclosure, addressing stigma and discrimination, management of side effects, and improving adherence to ART.

PATA’s annual conference is held to coincide with World Aids Day and is a key catalyst in the organisation’s drive to increase the spread of expertise by systematically identifying (through evaluation) and disseminating examples of replicable good practice. The report of the 2007 is currently being published and we will send a copy to the Committee as soon as it is available. A representative from UNICEF who attended the 2006 event observed:

“PATA is pretty much the best FORUM I have ever attended and I have been attending them for years”. (Robert Gass, UNICEF)

Crucially, the organisation evaluates the impacts of its interventions, including impact of performance improvement activities at PATA clinics on overall child health outcomes including overall child mortality, and impact of targeted support for HIV care and support on the delivery of broader health care. Further information in this regard can be submitted, should the committee request.

Other key initiatives which are being rolled out via PATA Clinics are:

- (1) Expert patient projects where HIV positive people are trained to support, counsel and advise newly diagnosed patients, including children. In the process people with HIV/AIDS are destigmatised. They also perform vital functions in clinics, freeing up health care professionals’ time, eg taking temperature, weighing and data recording, counting pills etc.
- (2) Focus on adolescents, looking at ways to educate and stop the spread of HIV in this particularly susceptible group.
- (3) Focus on TB –prevention and treatment. The opportunistic nature of the disease means that it is inextricably linked with HIV/AIDS. PATA’s 2007 conference had masterclasses focusing on adolescents and TB.

One To One also funds initiatives in South Africa linking HIV/AIDS initiatives with football, “KickAids”. Young people are attracted to testing events via football. These one-day events provide healthy, team participation in the most popular sport in Africa and use the opportunity to educate about HIV, counsel for testing and then do simple, accurate tests. Results are made known, kids are counselled to either remain HIV-free or are offered medication and counselling to deal with their HIV + status. A major cross- Africa roll-out of this initiative is planned for 2010 to coincide with the World Cup in Cape Town, South Africa.

Our vision is for all HIV-infected and affected children in Africa to have access by 2015 to comprehensive, high quality health services including ART. We believe that this can best be achieved by supporting committed health care providers to enhance, expand and extend their work to impact others through a ripple effect in the community (the “PATA effect”). We would welcome discussions with the Committee and key policymakers in the UK and internationally to help us make this a reality, maximizing value from considered, targeted and evaluated resource allocation.

21 January 2008

Memorandum by Research Councils UK

Research Councils UK is a strategic partnership set up to champion the research supported by the seven UK Research Councils. RCUK was established in 2002 to enable the Councils to work together more effectively to enhance the overall impact and effectiveness of their research, training and innovation activities, contributing to the delivery of the Government’s objectives for science and innovation. Further details are available at www.rcuk.ac.uk

This evidence is submitted by RCUK on behalf of the five Research Councils listed below and represents their independent views. It does not include or necessarily reflect the views of the Science and Innovation Group in the Department for Innovation, Universities and Skills. In addition to contributing to the main text, four of the Councils have provided additional specific information about their research in separate Annexes, as detailed below:

Biotechnology and Biological Sciences Research Council (BBSRC)	Annex 3
Economic and Social Research Council (ESRC)	Annex 4
Medical Research Council (MRC)	Annex 5
Natural Environment Research Council (NERC)	
Science and Technology Facilities Council (STFC)	Annex 6

Annex 1 explains the abbreviations used in the text, and Annex 2 provides examples of Research Council contributions to the work of Intergovernmental Organisations.

INTRODUCTION

1. The Research Councils welcome the opportunity to respond to the House of Lords Committee's Call for evidence.

2. In this introduction, we aim to set relevant activities of the UK Research Councils in the broader context of the role of science and international community in addressing the challenges of health and disease globally. The scope of many questions asked in the Call is broad, reflecting the interconnectedness of science, organisation and policy, and of research and downstream development and implementation to improve health. Within the limitations of Call specification, we are not able to address all questions comprehensively, for instance in relation to Questions 2 and 6.

3. The protection of populations from infectious diseases is of concern to international organisations, particularly UN organisations such as the WHO, not least because of the rapidity of spread from one country to another (as instanced by SARS) and the potential scale of human mortality (eg 1918 pandemic influenza) and socioeconomic impact of endemic disease (eg HIV/AIDS, malaria, high worm burdens). Furthermore, the social and economic impact of infectious disease in Low Income Countries (LICs) poses threats to global security.³² (Annex 1 provides a glossary of abbreviations).

Global Health Research

4. The Research Councils' investment in research relevant to health of the world's poorest people and disadvantaged populations ("global health") is significant, both in terms of scale and sustained commitment. The outcomes of our research, often executed with or subsequently built on by partner organisations, has had a significant impact on international health policies, particularly through the World Health Organisation (Some examples are provided in Annex 2).

5. Funding research in and involving LMICs is not only consistent with the principle of international solidarity (as espoused in the UN Millennium Goals and by the Africa Commission), but also benefits the UK. In particular, the UK can learn from the clinical experience where infections are more prevalent than in the UK and—through partnerships with the governments, organisations and communities of those countries—conduct research not possible in the UK. The host countries benefit from the translation of the knowledge gained into new and improved policy, practice and products, investment in health and research infrastructure, and the development of human capital. Intergovernmental organisations, such as the World Health Organisation (WHO), play an important role in promoting implementation of research findings.

6. From a broader perspective, research itself is an international activity that is actively promoted by the Research Councils. The Committee should be aware that several international research organisations that do not fall directly within the scope of the Call enable essential basic science, for instance the European Bioinformatics Institute (a component of the European Molecular Biology Laboratory).

³² *Health is Global: Proposals for a Government-wide Strategy* Department of Health, 2007 www.dh.gov.uk/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_072697

The Global Burden of Infectious Disease

“Infectious diseases in humans now threaten us all—and with our assistance, can cross the globe in hours. Worldwide, they account for over a fifth of human deaths and a quarter of morbidity. They disproportionately affect the poor—in some African countries, they have contributed to reducing life expectancy to around 40 years”.

Foresight.³³

7. The global burden of infectious disease is unevenly distributed. Data for 2002 indicated that 75% of all deaths due to infectious disease occurred in southeast Asia and sub-Saharan Africa.³⁴ Emerging economies typically experience a shift as new wealth brings changes in diet and lifestyle. These changes then become reflected in a steep rise in non-communicable diseases, such as cardiovascular disease, cancer and diabetes. Working with national governments, and organisations such as the US Centres for Disease Control and Prevention (CDC) and its EU equivalent (ECDC), the WHO has leading normative role in monitoring and reporting these trends and promoting appropriate public health responses.

An Historical Perspective

8. The 20th century saw many campaigns to control or eradicate particular “the great” endemic infectious diseases, in particular:

- small pox (a success);
- malaria (many regional successes in control where the epidemiology of the disease, transmission characteristics and sustained country resources were compatible with success; in sub Saharan Africa the approaches were not compatible with any sustained impact);
- polio (eradication prevented by pockets of entrenched population rejection of immunisation and subsequent spread);
- onchocerciasis (successful control in large parts of west Africa); and
- the elimination in China of filariasis by sustained chemotherapy in some 350 million people.

9. That these campaigns were “vertical” (specific to one disease) often reflects the unique biology of each of the pathogens (involving, for many, intermediate vectors such as the mosquito). Consequently, each control programme demanded a specialism in surveillance and control technologies and skills. Many were launched at a time when the military had a prominent role in tropical infection control and when colonial infrastructures were in place. Success or failure depended on many factors—biological, social, economic and organisational. Common to the history of the great campaigns is their scale, systematic and disciplined organisation, cost and challenges of sustainability. Each also had to be tailored to the specifics of the disease epidemiology, the biology of pathogen, human and vector, and behavioural, social and environmental influences—ie a strong basic and translational research base.

10. Today too, one strategy cannot fit all. So, HIV, MRSA, TB and influenza prevention each require an infection-specific set of behavioural responses by people as individuals, as well as differentiated interventions at organisational and societal levels. Inevitably, the current state of knowledge and the tools available for control differ from one infectious disease to another.

Categories of Infectious Disease

11. In considering the effectiveness of the international response to infections, the following three categories of infectious disease, based on endemicity and availability of effective strategies for population protection, may be of use to the Committee:

- **Endemic diseases for which effective, cost-effective interventions are available:** Diseases caused by worms exact a significant burden on people’s ability to work and resist other infections. They include filariasis, onchocerciasis, Guinea worm, schistosomiasis and intestinal worms that cause anaemia. Low cost or donated drugs that are effective in reducing new cases (incidence) and in improving health. For each parasite, research has shown low cost drugs to be effective in reducing new cases (incidence) and in improving health. For instance, river blindness (onchocerciasis) is no longer a public health problem for some 60 million people in 10 West Africa countries, as a result of community distribution of donated ivermectin (Mectizan, Merck & Co. Inc), effected through the

³³ Foresight. *Infectious Diseases: Preparing for the Future. Executive Summary*. Office of Science and Technology. 2005. http://kim.foresight.gov.uk/Previous_Projects/Detection_and_Identification_of_Infectious_Diseases/Reports_and_Publications/Final_Reports/Index.html

³⁴ Global Health Council. Infectious diseases. www.globalhealth.org/view_top.php3?id=228

African Programme for Onchocerciasis Control (APOC) across 19 countries. However, other such opportunities (eg for community control filariasis, viral hepatitis and respiratory and diarrhoeal disease) remain unrealised: neglected, according to some commentators, by the international community's concentration on the big three (HIV, TB and malaria)—excluding the majority of the world's poorest from cost-effective programmes that would have a rapid impact on people's lives.

- **Endemic disease for which affordable, effective interventions are not (or incompletely) available:** HIV, malaria and TB are endemic in much of the developing world and in Africa in particular. Each is difficult to prevent or treat, and has sophisticated biological mechanisms for persisting in its human host, serving also as a continuing reservoir of new infection. For malaria, there are some 13 candidate drugs in clinical trials. Combination therapies and insecticide-treated bednets may now be turning the tide in malaria control. But they will need implementation on a vast scale: even then transmission is unlikely to be completely halted. 16 malaria vaccine candidates are in clinical trials, one of which is expected to reach Phase 3 clinical trials shortly.³⁵ For HIV, a vaccine is more distant goal, requiring long term investment in basic and translational research. Current antiretroviral therapies (ART) are based on combination therapies that keep the virus in check but people remain infected and may experience ill health as they age with HIV. The development of technologies languishes for neglected diseases characterised by a relatively low prevalence (eg African trypanosomiasis, sleeping sickness).
- **Emergent potentially epidemic infections for which interventions may not be effective or available:** Newly emergent viruses with exotic names often excite considerable attention, although their global burden is usually infinitesimal. Vigilance and coordinated, rapid response are essential because viruses against which human populations have had no prior exposure, and consequently no acquired immunity, have caused epidemics in the past (eg 1918 pandemic influenza). Adaptation to man of viruses whose natural hosts are birds or other animals, and to easy transmission from one person to another, is difficult to predict. In the case of avian flu, such viruses seem likely to emerge from South Asia where high human population density, close contact with food animals, poor husbandry and high humidity occur on a large scale. Current technologies cannot yet deliver an effective pandemic flu vaccine to populations in advance of an outbreak. Moreover, the arsenal of effective drugs is small.

Intergovernmental Organisations and Research

12. International (including intergovernmental) organisations have a **crucial roles in research** that are additional to coordinating international health controls. Their roles include the following:

- Promoting alignment of translational research strategies to internationally agreed public health priorities.
- Informing international health policy development on the basis of research evidence.
- Standardisation in research (eg IAVI's role in reagents, research protocols, and measures of effect in HIV research).
- Catalysing collaboration between the best research teams internationally, including collaborative access to research infrastructure (eg well equipped, skilled laboratories "at the front") and resources (eg well defined study cohorts in populations of relative high prevalence, samples and data).
- Stimulating the development of research (and control) capacity in endemic (often low income) countries. Examples include programmes of the European and Developing Countries Clinical Trials Partnership (EDCTP) and the UNICEF/UNDP/World Bank/WHO Special Programme for Research & Development in Tropical Diseases (TDR).

13. A range of organisations are active internationally. They can be characterised as follows:

- **International governmental organisations (IGOs):** Foremost in health is the WHO. Other United Nations organisations that have acquired health mandates include UNICEF, The World Bank, UNDP UNAIDS, the World Food Programme and UNFPA. A similar set of organisations are active in the control of animal disease including the OIE (and there are important issues about the

³⁵ Moran M et al. *The Malaria Product Pipeline: Planning for the Future*. The George Institute for International Health, September 2007.

connectivity between the two sectors), especially as three-quarters of human pathogens are derived from animals. There are perennial concerns about competition or duplication within the UN family and need to coordinate veterinary and human public health agendas in the zoonoses.

- **National governmental organisations with an international mandate:** These include the UK Department for International Development (with which MRC, ESRC and The Wellcome Trust all have partnership programmes), and the USA Centres for Disease Control (the UK's Health Protection Agency does not have an equivalent international mandate).
- **International non-governmental organisations and foundations:** Foremost among the NGOs funding and influencing research are the large private foundations, the Bill and Melinda Gates Foundation (Gates Foundation) and, in biomedical research, The Wellcome Trust. Many international (and national) NGOs whose primary remit is the delivery of healthcare also play a crucial role in engaging communities (and countries) in health and social research, eg in clinical trials and studies of health behaviours.
- **Public private partnerships:** Over a 100 PPPs are contributing to the development of new drugs and vaccines for infectious disease. These can be separated broadly into (a) product development partnerships such as the MMV or DNDI and (b) Alliances and partnerships committed to delivery of interventions for particular diseases or conditions. These partnerships have emerged for a variety of reasons, including limited confidence in WHO to deliver on its mandate and the need to involve NGOs as implementers.
- **International financing mechanisms:** The Global Fund for AIDS, TB and Malaria (Global Fund), the US President's Emergency Plan for AIDS Relief (PEPFAR) and the President's Initiative in Malaria (PMI) are directing significant new funding into infectious disease control. There is concern in the research community over the power of these organisations (and the Gates Foundation) to drive the disease control and research agenda (their funds dwarf those of the WHO). Criticisms include: too great a focus on vertical programmes and "the big three" diseases; too great an optimism based on a narrow set of strategies and technologies, for which evidence of public health impact is often inadequate; too little consideration of distortion of recipient country policies and health systems.

14. The relationship between the Research Councils and international governmental and non-governmental organisations is as follows:

- A RC role in representing the UK, eg the MRC role in the EDCTP, IARC (a WHO organisation) and the EMBL, among others.
- RC-funded scientists (at UK universities and RC institutes in the UK and overseas) act as technical advisors, eg to WHO and Gates Foundation—informing research strategy and evaluating research proposals and progress.
- RC-funded scientists and staff lead and coordinate research programmes that these organisations coordinate and/or fund
- The funding of major Research Facilities eg Diamond by the Wellcome Trust.

15. A combination of technical advice and research, eg the role of the MRC National Institute of Medical Research WHO Influenza Centre in identifying new flu strains and informing WHO policy on the strains to be included annually in seasonal flu vaccine.

16. It is important to recognise that international governmental organisations, typically those of the UN and European Union, are only part of the picture, there are many other actors such as academia and the Non Governmental Organisations, many of which work together with IGOs through specific partnerships (eg StopTB).

RESPONSES TO SPECIFIC QUESTIONS

17. In the remainder of the RCUK submission, our response follows the Committee questions, which are reproduced in italics.

1. *A recent report on Communicable Diseases by the UK Department of Health³⁶ stated that "post-war optimism that their conquest was near has proved dramatically unfounded". What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis?*

"While there is great uncertainty about the future, we should expect many of today's major human and animal infectious diseases to broadly continue in importance—indeed, it could be decades before

³⁶ Department of Health. *Getting Ahead of the Curve*, January 2002.

some, like HIV, will peak. However, we should also expect diverse diseases to continue to emerge or re-emerge. Infectious diseases will continue to jump between wild and domesticated animal species and humans".³⁷

Foresight.

18. *Getting Ahead of the Curve*³⁸ rightly highlights the challenges of controlling endemic infectious disease and outbreaks caused by newly emerged, re-emerged or newly resistant infectious agents. Knowledge about the epidemiology, the biology, social and environmental determinants of transmission, infection and disease; the tools for diagnosis, prevention and treatment; the systems for innovation and implementation; and the research evidence of what works—are all essential to realistic disease prevention and control targets and strategies.

19. In relation to the UK, the optimism seems unfounded, not only in relation to the health and economic consequences of important human infectious diseases (MRSA, STDs) but also the even bigger economic losses related to infectious diseases of animals with (eg BSE) and without (eg foot and mouth) spread to humans.

20. The progress globally in the last 20 years in reducing morbidity and mortality from many infectious diseases is demonstrated by the dramatic reductions in infant and child mortality, especially post-neonatal mortality, which in these age groups was mainly of infectious causes. Vertical control programmes have achieved significant progress in several tropical diseases particularly in Asia and the Americas. Sub-Saharan Africa has seen success in vertical onchocerciasis and trachomatitis control, but still lags behind on key Millennium Development Goal (MDG) targets. However, vertical programmes can challenge already fragile health systems (eg salaries of polio surveillance officers being > 10-fold that of doctors in other parts of the health sector in sub-Saharan Africa).

21. On the positive side, the perception that poverty related diseases would be eliminated as a consequence of economic development has been replaced by appreciation of a two-way process in which disease control is itself a driver for development, leading to an increase in awareness and funding for disease control efforts.

22. There are still opportunities to implement affordable, simple, and effective interventions, such as deworming in LMIC settings, that could bring significant benefits not only to health but, for instance, success in education. That they are not is considered by some commentators to be a failure of policy and political will. They argue that by harnessing funding streams to the big three, other more achievable health gains are being neglected. Not surprisingly, others highlight the entrenched challenges and burdens attributable to HIV, malaria and TB in particular, and the need for concerted, sustained and focused funding and action.

23. Challenges to the global community include the scale and speed of individual travel and population movement, greater exposures to zoonotic infections, complex social, economic and environmental changes (eg lifestyle, land and water use, livestock practices, urbanisation, trade and economic conditions, climate and the distribution of vectors of disease) and fragile health systems. For many populations, the threat from exotic infection and the burden of endemic infectious disease can be expected to become worse—possibly much worse. From the perspective of 2008, sub-Saharan Africa looks to be particularly, though not uniquely, vulnerable.

2. *What reliable data exist regarding the numbers of people infected globally with the four diseases³⁹ on which the Committee is focusing particular attention? What trends are discernible in both the numbers infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?*

24. The WHO puts a huge effort into developing reliable estimates of mortality, morbidity, health burden etc. The scale of mortality is 1.7 million deaths annually due to TB; 1 million due to malaria and 2 million due to HIV. These estimates are based on models that draw on relatively few studies, which themselves may have had limitations. The estimate of avian flu deaths (some 200+) is also a likely underestimate, due to weak surveillance and reporting systems.

25. UNAIDS recently revised downwards its estimate of the prevalence of AIDS to 33.2 million,⁴⁰ partly as a result of improved methods for in-country data collection and analysis and reflecting revisions of estimates in India. While the prevalence may be levelling off, new infections and longer survival mean that the number of people living with AIDS is still increasing. Two-thirds of people with HIV live in sub-Saharan Africa. Experts are concerned that in this region in particular, the patchy roll-out of antiretroviral therapy (ART) in weak health systems, together with the debilitating effects of co-infection (with TB and with other sexually transmitted diseases, STDs), will create circumstances that favour the emergence of drug-resistant strains of

³⁷ Foresight. Op cit.

³⁸ Department of Health. *Getting Ahead of the Curve*, January 2002.

³⁹ HIV/AIDS, Tuberculosis, Malaria and Avian Influenza.

⁴⁰ UNAIDS: *AIDS epidemic update*. December 2007.

virus. Possible adverse effects of ART availability on preventative behaviours, such as condom use, are another major concern.

26. In the case of malaria, mis-diagnosis of clinical cases averages some 60% and can be as high as 90%. The main reasons are symptom overlap with bacteraemias and pneumonias and mis-classification of causes of death (any child dying with a history of fever in the malaria season likely to be labelled a malaria death). These are significant challenges to data reliability. The lack of autopsies and accurate post-mortem pathology means that the accuracy is unlikely to improve and WHO will continue to rely on models to extrapolate from the limited surveillance data.

27. Nevertheless, there are encouraging signs that malaria is decreasing in some parts of Africa, possibly through some increased access of poor people to effective treatments (including the new combination therapies) and insecticide-treated bednets (ITNs). However, these measures leave behind a non-immune population of susceptible individuals, so sustained surveillance, application of preventative measures and the availability of effective and affordable drugs is essential.

28. The Bill & Melinda Gates Foundation has recently committed itself to eradicating malaria in the longer term. Some experts are sceptical that this is achievable. They consider there remains an urgent need for more accurate and earlier diagnosis, new antimalarials and the development of an effective vaccine to ensure that such success can be maintained.

29. TB data are weak because, like malaria, accurate diagnosis is challenging. Particularly worrying are multi- and extensively drug resistance (MDR and XDR, respectively) strains, and strains not recognised by routine diagnosis and surveillance. Globally, the number of people infected with TB is likely to rise owing to resistant strains and co-infection with HIV. Furthermore, the only vaccine for TB (ie BCG) is ineffective against the major form of the disease; no new drugs have been developed for TB since the 1960s.

30. As at 11 January 2008, the WHO reported the cumulative number of laboratory-confirmed human cases of avian influenza A/H5N1 as 349, including 216 deaths. It is likely that these data underestimate the actual number of cases because reporting systems are weak in many of the countries concerned (see our response to Question 3). The panzootic in birds continues (expanded during 2005 to encompass Europe and Africa as well as Asia); occasional human cases continue to be identified in new locations emphasizing the continued pandemic threat.

31. Experience has shown that the overall burden of infectious diseases decreases as economic status improves. This process is now taking place in the newly developing economies in Asia where non-infectious diseases are overtaking infections as the main cause of ill health. However, in sub-Saharan Africa infectious diseases still account for a high proportion of deaths and serious illnesses, especially among children.

32. As indicated elsewhere in our response, the underlying causes of infection and changes in prevalence and threat are infection-specific and often complex. There is an extensive research literature that it would be inappropriate to try and review here.

3. *What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? And what improvements might be made?*

33. Surveillance networks abound but are fragmented, mostly formed along political rather than geographic lines. For instance, WHO regions reflect political expediency (with India and Pakistan, north and South Korea, and Israel and Palestine in separate regions). The European Centre for Disease Prevention & Control (ECDC) comprises only EU countries, excluding big non-EU countries such as Turkey through which infections may pass. In the WHO/Afro Region, meetings are held along language lines not geography. Sudan is included in the Eastern Mediterranean Region and not the Afro Region. Despite efforts, eg of the WHO Health Metrics Network, laws, procedures and practices for health data sharing remain inconsistent between countries.

34. Commentators consider the numerous surveillance and control activities of WHO, CDC, ECDC, and national public health authorities to be fragmented and patchy, with gaps in coordination and continuity. Vertical disease-specific programmes are perceived as operating independently of each other, even within the same organisation. There are concerns about duplication of effort and lack of sustainability. Although focusing on pandemic threats, the 2005 International Health Regulations (IHR) could provide a basis on which to build comprehensive surveillance, including the legal framework for countries to improve and share surveillance data.

35. There is need to develop and sustain laboratory capacity in developing countries across the spectrum of infectious disease surveillance. Past donor initiatives have lacked continuity. While building capacity, the accountability required of vertical programmes has in some cases actively hindered broader microbiological

capacity development. There is a challenge for IGOs—and WHO in particular—to facilitate, foster and fund systems that develop and sustain epidemiological and laboratory capacity, so that surveillance and response can be effective—and cost-effective—across a range of infections.

36. Surveillance and modelling of social, environmental (including climate) and biological changes (including in animal host and vector populations) likely to be associated with new or increased transmission could be coordinated to improve timely preparation and response measures.

37. The extensive 2005 Foresight⁴¹ project on the detection, identification and monitoring of infectious disease identified the importance of the following in surveillance: simple, affordable, non-invasive near-subject testing; high throughput detection systems (eg for screening at airports); and novel information systems rapidly to capture, analyse and interpret diverse, high-volume data. Implementation of such technologies will depend on internationally agreed policies and standards.

4. *Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years?*

38. Sub-Saharan Africa in particular has a significant challenge to reach the health-related MDGs.⁴² Experts comment that even where the tools are available, political commitment is often lacking and health systems fragile. To provide quantitative predictions is difficult for the reasons given in our response to Question 3.

39. The research community is more optimistic about malaria control than about TB, and TB than HIV. This reflects the availability and implementation of effective tools for reducing transmission of infection and for treating those people already infected, as discussed earlier in this submission. Over the past ten years there has been remarkable progress in developing drugs for AIDS patients and significant progress in distributing them in resource-poor countries. However these treatments are not curative and the development of vaccines and microbicides capable of preventing HIV-1 spread has been disappointingly slow. HIV/AIDS will therefore continue acting as a major brake on global development for the foreseeable future.

40. Even were the MDG targets of placing more people on ART achieved (eg “3x5” HIV treatment target, with around 1.2 million people on ART in Africa in 2006), this alone would not achieve a reduction in HIV transmission.

41. Drug resistance has persistently bedevilled malaria and TB control. Combination therapies, eg in HIV and malaria, may reduce the likelihood and rate of spread of resistant strains, but rigorous monitoring is required to contain emergent strains. That in turn requires strengthening of in-country laboratory capacity.

42. Resistance is emerging in *Anopheles* mosquitoes to the pyrethroids that are the active insecticides in ITNs. The efficacy of bednets cannot be expected to be retained for much more than a decade without the need to a new insecticide. Most public health pesticides were first developed for agriculture. Research on new insecticides effectively ceased as the agrochemical industry turned to genetically engineering crops that are intrinsically resistant to pests.

43. Surveillance and control of infections other than the big three must be sustained, eg in measles, which could rebound and again cause more deaths than malaria.

44. The Lords’ Committee will be aware of expert opinion that an influenza pandemic is inevitable but unpredictable—given gaps in fundamental understanding of the natural distribution of flu viruses in bird populations, the adaptation of avian (and other potentially other) flu viruses to rapid human-to-human transmission and the causes of human death and survival when infected.

5. *What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?*

45. The list of barriers to progress cited by the research community is long:

- A critical technical issue is the accuracy and timeliness of diagnosis. Late diagnosis often equates to “too late for treatment” (and this applies equally to non-communicable disease). Untreated infections can also fuel ongoing transmission.
- Treatment and prevention strategies rely on a small number of tools, many with limited or waning effectiveness (BCG vaccine, and drugs) and important gaps (eg absence of vaccines for malaria and HIV).

⁴¹ Foresight. Op cit.

⁴² UN Millennium Development Goals: www.un.org/millenniumgoals/

- Failures of international and national policy makers to commit to action where knowledge and tools are available. Similarly, the understandable focus on LICs may divert action and funding from MICs, where transmission control may both be more tractable and provide models and skills transferable to LICs.
- Failures within and among international organisations, including IGOs, to coordinate and sustain surveillance and control activities. This applies to animal diseases (eg avian flu in poultry) as well as to human infections.
- Credibility of international organisations that set unrealistic targets, eg the Roll Back Malaria Abuja targets for net coverage, 3x5 for HIV treatment (See paragraph 40).
- Inadequate knowledge of the (often complex) biology of infection, disease and transmission; the contribution of behaviour/lifestyle; and of more distal environmental factors necessary for the design of effective surveillance and control strategies. As the Call recognises, objectives can be overly optimistic, not least because policies are inadequately based on robust evidence.
- Weak health, higher education and innovation systems for translating knowledge and technologies into policy and practice.
- Finite capacity of LMICs to absorb advice, not least because those “who need to know” are overwhelmed by (a) operational obligations, (b) the number, complexity and sometimes rivalry of donors, and (c) a plethora of policies and guidance.
- The relatively low commercial rewards for developing new products for low income populations.
- Cultural and political resistance to effective prevention strategies, such as condoms (by some donors) and vaccines (by some populations) and, in developed markets, the potential for litigation.
- Inconsistent laws, policies and practices (and uncertainties about interpretation) eg in datasharing and the distribution of intellectual property rewards.
- Weak health education at community levels, particularly of women.
- Conflict and insecurity.
- Weak governance in many LICs both at a national and institutional levels. Distortion of priorities resulting from an imbalance of power and resources.

6. *What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?*

BBSRC

46. BBSRC funds research on animal diseases, of which work on zoonoses has relevance to this Inquiry. This includes studies of the pathogenesis of viral, bacterial, parasitic and fungal infections of animals, including host/organism interactions at the cellular and molecular levels. The Council encourages the development of novel approaches to the control of new and emerging diseases as well as alternatives to existing chemotherapeutics. BBSRC also funds research on arthropod vectors of animal pathogens that might provide models for understanding the incidence and spread of malaria or other vector-borne human diseases. However, BBSRC does not fund research focused on specific human diseases and disease processes, which fall within the remit of the Medical Research Council.

47. Of particular relevance to the present inquiry, in 2007, BBSRC funded four awards, totalling £4.5 million, under its Combating Avian Influenza Initiative. Further details of this initiative are provided in Annex 3.

48. Additionally, in 2006–07, BBSRC spent the following estimated sums on research relating to malaria (£1,338k, including work on mosquitoes), avian influenza (£842k), HIV/AIDS (£186k) and human (non-bovine) tuberculosis (£930k).

ESRC

49. The ESRC funds research on population dynamics and social factors in relation to health and has two key research schemes relevant to this enquiry:

- a responsive-mode scheme in partnership with DFID; and
- a collaboration with the Hewlett Foundation to examine the relationship between population and poverty with a focus on a range of reproductive health issues.

50. ESRC has funded several HIV and TB relevant projects through the two schemes (there are no projects specifically on malaria). ESRC funding on these diseases is mainly made in response to proposals from academia. Responding to public health needs for interdisciplinary research in on influenza, ESRC recently coordinated the development and funding of the project, Behavioural Responses to Pandemic Influenza (PI) in the UK. Further details of the ESRC portfolio are at Annex 4.

MRC

51. The MRC expenditure on global infections research in 2006–07 was £30.4 million. By disease, the investment was as follows:

- Infections £30.4 million, of which: £10.9 million on HIV/AIDS; £7.8 million Malaria; £7.1 million Bacterial infections including TB; and £4.6 million other infections (including helminth, bacterial, protozoa, non-HIV viruses).

The distribution of that expenditure was as follows:

- £11 million—intramurally in Africa through the MRC Gambia Laboratories (working on malaria, TB, HIV and other virus infections) and the MRC/UVRI Uganda Research Unit on AIDS.
- £8 million—intramural programmes at NIMR and UK-based MRC Units (including the MRC Human Immunology Unit).
- £12 million through grants and fellowships in UK Universities, including support for the MRC Tropical Epidemiology Group at the London School of Hygiene and Tropical Medicine (LSHTM).

52. In addition, Council has made the special contributions of £1.2 million in 2006–07 as co-funding of trials and capacity building with the EDCTP (see below) and £2 million in 2005–06 to strengthen clinical trials capacity at the Tanzanian National Institute for Medical Research in Mwanza, underpinning LSHTM programmes funded by the MRC. Examples of MRC programmes are at Annex 5.

53. The MRC benefits from several strategic partnerships in global health research, including the following:

- *Department for International Development (DfID)*: DfID funding to MRC of £4 million per annum underpins basic and translational research immediately relevant to DfID's health strategy. In addition, £9.25 million of MRC funding for three large trials HIV studies is matched by £45 million of DfID funding.
- *European and Developing Countries Clinical Trials Partnership (EDCTP)*: The EDCTP is a partnership between 16 European countries and 46 sub-Saharan African countries with funding from the EU and the European partners. In developing new clinical tools against AIDS, malaria and tuberculosis the EDCTP coordinates and funds Phase II and III clinical trials in Africa and associated research capacity development.
- *The UK Funders Forum for Global Health Research* brings together the MRC, The Wellcome Trust, ESRC and DfID. The Forum identifies opportunities for closer coordination and joint working.
- *The UK Collaborative for Development Sciences (UKCDS)* see paragraph 60.

NERC

54. The Centre for Ecology and Hydrology (CEH), one of the Research Centres wholly owned by NERC, has conducted extensive research into the molecular biology of human pathogens and their modes of action. It is now focussing more on the environmental distribution and transport of certain pathogens, the ecology of selected invertebrate vectors and the distribution and role of pathogens in the population biology of natural (non-human, non-livestock) hosts in the environment.

55. It is worth noting the significant effect that some diseases can have on wildlife populations and ecosystem function—with implications for humans. An obvious example is the impact of squirrel pox on the balance between red and grey squirrel populations. The potential for climate change to cause habitat loss and crop and tree damage through effects on the spread of pathogens is particularly concerning.

56. The recently-announced “Living With Environmental Change” (LWEC) interdisciplinary policy partnership programme, being led by NERC, will help to improve our understanding of climate change and the prediction of local and regional change, which should help to provide the basis for improved prediction of the spread of vectors and pathogens. NERC's Environment and Human Health programme and the Ecosystems Services for Poverty Alleviation (ESPA) programme will both contribute to LWEC.

57. NERC-CEH is keen to work with researchers funded by other relevant Research Councils such as BBSRC and MRC where possible in the area of emerging diseases, and cross-Council programmes such as LWEC provide one opportunity.

7. *What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient “joined-up” thinking in approaching the problem?*

58. Several of non-health issues are identified elsewhere in our response, in particular under Question 5.

59. Taking a developing country perspective, a range of other infectious diseases are significant causes of morbidity and mortality in the developing world. Many are water borne and food-borne infections. It is important to tackle their underlying socioeconomic and environmental causes. This again argues for a health systems approach embedded in a strong public health policies that aims for multiple disease containment and prevention.

60. The newly established UK Collaborative for Development Sciences (UKCDS) brings together several RCs (BBSRC, ESRC, MRC, and NERC), DfID and other government departments. It is currently examining opportunities for cooperation and synergy in climate change and research capacity development. Prompted both by this initiative and the NERC's Environment and Human Health programme, the RCs and The Wellcome Trust are exploring needs and opportunities in relation to zoonoses and the ecology on infectious disease. The Research Councils are working with policy partners on the LWEC Programme (Paragraph 56).

61. Poverty and population migration are common to many communicable diseases. Consequently, interventions to reduce poverty, such as increasing access of women to primary education, might be expected to reduce transmission and disease incidence. However, experimental interventions have not always demonstrated the desired effect. This experience points to the complexity of causes and the need for a deeper understanding of causative and modifying influences.

62. Social reactions such as stigmatisation can influence a community's reaction to people with conditions such as HIV, other STIs and TB. They also affect the response of people at risk and patients to prevention and health care services. Research to understand the roots of such belief systems makes an important contribution to the design of culturally appropriate interventions.

63. Many commentators agree that disease prevention requires multidisciplinary, multisector, systems approaches in addition to specific biomedical technologies. The UK has academic strengths in the evaluation of health services and public health interventions, environment and health research, social, health economics and health policy research applicable to understanding health systems.

64. It is clear that at an international level, much remains to be done to achieve effective “joining-up” for one infection, let alone across diseases and systems. Logically, the WHO should be best placed to create a roadmap for global control of malaria, or influenza, that can be subscribed to by the major players. UK preparations for responding to pandemic influenza may provide a test bed for coordination at a national level.

8. *Cases of Tuberculosis fell progressively in the UK until the mid-1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of Tuberculosis infections in Britain? And how could intergovernmental action help to reverse the trend?*

65. The UK HPA reports that TB rates in the United Kingdom are higher now than at any other time since 1987, and are also higher than those in most other western European countries. Fortunately, UK rates of both resistant and MDR strains of TB have remained stable for the past few years and MDR rates are lower than other countries in Western Europe.⁴³

66. 8,497 TB cases were reported in the UK in 2006, with an incidence of 14.6 per 100,000 of the population as compared to 11.6 in 2000. The incidence was 44.8 per 100,000 in London, and 72% of all cases occurred in individuals born outside of the UK. TB outbreaks in schools and local communities highlight the risk of local spread. Within the indigenous UK population, many cases are in HIV co-infected people.

⁴³ HPA. *Tuberculosis in the UK. Annual report on tuberculosis surveillance and control in the UK.* Health Protection Agency, November 2007.

67. The organisation of screening for TB before leaving the country of origin, or immediately upon arrival, would assist in diagnosing and treating infected immigrants. (Similar screening for HIV could also prove valuable now that drugs are available for treatment. However, many donors including the Global Fund advocate strongly against requiring disclosure of HIV status when crossing borders).

68. ESRC research highlights the methodological challenges of working with recent migrants to the UK (who are often of no fixed abode) and low income groups (who are often unwilling to participate in surveys). This experience highlights the value for RC-researchers of working closely with the NHS (to access health information) and the Home Office (migrant information). The newly funded UK Household Longitudinal Survey (UKHLS) will commence in early 2009. Its large sample size and specific attention to recruiting from minority groups will contribute to understanding the distribution of migrant populations in the UK.

9. Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the numbers of reported cases worldwide seem to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions—eg HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?

69. TB diagnosis is difficult, complicated, labour-intensive and expensive for patients and health systems, especially where co-infection with HIV is common. Moreover, inefficient diagnosis means that active cases are infectious for long periods before treatment starts.

70. The duration of TB treatment is long and labour-intensive, and achieving compliance is real challenge in resource-limited, high prevalence settings. Shorter treatment is needed as well as an effective vaccine.

71. Twenty-three high-incidence countries account for approximately 80% of all new TB cases. In many of these, TB incidence continues to rise. Not only is the incidence of TB increasing globally, but so is that of MDR and XDR resistance TB.

72. Co-infection of TB and HIV is particularly widespread in southern Africa, with estimates that 50% of new adult cases of TB are also HIV-positive. In some TB hospital settings, over 80% are co-infected. Co-infection enhances the progress of infection to active disease. Commentators point to the importance of a health systems approach in tackling the complexities of co-infection, particularly in resource poor and crisis settings.

73. The World Health Organisation has played a leading role in developing the current strategy of Directly Observed Treatment—Short course (DOTS) to improve adherence and response to treatment and to prevent the development of resistance. WHO led the development of the global Stop TB strategy and is a leading partner in the Stop TB Partnership, which aims to eliminate TB. The Global Fund and World Bank are among the other international partners. There is concern about selection and transmission of untreatable drug-resistant strains as a result of inefficient treatment.

74. There is no single mechanism to address all the issues. Better faster diagnostics are essential to replace the current sputum microscopy so inefficient in resource poor settings. So too are novel drugs that act more quickly, and an effective vaccine. Development of these tools is limited by a lack of understanding of the fundamental underlying biology of the processes of infection, susceptibility, immunity and disease progression.

10. To what extent do you believe that the 2004 Stockholm Convention limiting the use of DDT against Malaria-carrying mosquitoes has been a factor of increases in the spread of the disease? Has any risk analysis been carried out comparing the relative dangers to human health posed by DDT and Malaria?

75. Comparing the risks to people of DDT as used in malaria control campaigns and of uncontrolled malaria, DDT is relatively safe—although special measures are need to mitigate occupational risks. There is no doubt that spraying with residual insecticides such as DDT had a substantial effect on malaria transmission although there were concerns about the development of DDT resistance. The cessation of its use, together with the absence of alternative control measures, has had a significant deleterious effect on the spread of the disease.

76. While DDT use against malaria had very clear human benefits, these were set against the long term environmental risks, which were substantial and were given priority over the public benefits.⁴⁴

⁴⁴ *Silent Spring*, by Rachel Carr had a great influence on public opinion.

11. *What intergovernmental action is planned or in hand for early detection of the transmission of Avian Flu from birds to humans and of human-to-human transmission in potential source countries? Is this proving sufficiently effective to prevent an Influenza pandemic? What more could be done?*

77. The World Health Assembly 2005 imposed on member states the obligation to detect and report cases of H5N1. WHO is helping to coordinate the increased capability of member states to do this, for example by establishing Regional H5 Influenza Centres and promoting training etc, financed especially by the US and World Bank. Progress is gradual; it is unlikely to prevent a pandemic, but should allow better implementation of pandemic plans, ameliorating its impact.

78. The WHO has published guidelines, informed by UK experts amongst others, on diagnosis, treatment, surveillance, infection control and vaccines.

79. The WHO advises vaccine manufacturer's on the composition of seasonal influenza vaccine, based on the advice contributed by, among others, the WHO Influenza Collaborating Centre established at the MRC National Institute for Medical Research 60 years ago. The Centre monitors changes in influenza virus isolates that have significance for human health and protection as those changes occur. Led by Dr Alan Hay, the Centre works closely with the HPA and with the three other WHO Collaborating Centres (USA, Japan and Australia) and the global network of National Influenza Centres. The 50-year old system of virus sharing that has worked on goodwill was challenged during 2007 by Indonesia, which has the majority of the world's confirmed human cases of H5N1 and is seeking guaranteed access to affordable vaccines created from Indonesian virus isolates. WHO is working with pharmaceutical companies and governments to put together a package to help developing countries respond to a pandemic.

12. *To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?*

80. The history of malaria control offers many lessons. Emergence of parasite resistance to chloroquine and sulphadoxine pyrimethamine has contributed significantly to the failure to control malaria, especially in Africa. Some experts consider recent deployment of artemisinin combination therapy (ACT) for malaria—together with mosquito control (eg ITNs)—appears to be turning the tide. Others are less optimistic, not least because they are concerned that the availability of ACT is limited. Moreover, counterfeit ACT is readily available. Combination therapies for HIV, TB and malaria can be expected to delay the emergence of drug resistance but not prevent it. Consequently the search for new classes of drug must continue. There is also a need for swifter translation of knowledge of drug susceptibility and resistance into effective policies and implementation on the ground.

81. International organisations have an important role in identifying and promulgating best prophylaxis and treatment policies and practice; validating and implementing standardised resistance testing; and in stimulating, coordinating and funding the development of new classes of drug. We are not in a position to comment on the effectiveness of international coordination.

82. Within the UK, the MRC manages a £16+ million initiative on translational infections research. The initiative was launched and coordinated by the UK Clinical Research Collaboration. MRC, the Department of Health and the Wellcome Trust have each committed £5 million to a joint programme of research, with BBSRC and the devolved administrations contributing the remainder. In addition, opportunities for collaboration with Canadian Institutes for Health on novel antimicrobials are under consideration. The UKCRC programme builds on—and also address gaps in—the funders' individual initiatives in healthcare associated infections and antimicrobial resistance. However the scope of the initiative is broader than these two topics alone.

13. *In a number of countries, including the UK, there is a problem with hospital-acquired infections. What intergovernmental sharing of knowledge is taking place to help bring this problem under control?*

83. Please see the answer to the previous question. In relation to infection control, this question opens up a set of issues particular to healthcare settings, whereas the control of HIV, TB, malaria and pandemic flu is based largely in the community and at a population level. The RCs are not best placed to address the particular question about IGO sharing of knowledge.

14. *Are there any difficulties with regard to patents or intellectual property which are impeding the flow of medicines or other control methods to those infected? Is intergovernmental action needed to improve the situation?*

84. The research community has an interest in the Trade Related Intellectual Property Rights Agreement, under which developing countries can gain affordable access to generic versions of licensed drugs, while protecting innovation and new product development. The supply of affordable quality drugs is also important for clinical trials funded by MRC and partner organisations such as the EDCTP.

85. IP represents a major issue in the provision and use of genetically engineered H5N1 candidate vaccine viruses that has had serious repercussions on international co-operation. It is being strenuously addressed at the intergovernmental level. (See paragraph 79).

15. *What interchange exists between States in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?*

86. WHO has a leading role in standardising practice and training, mostly through short-courses and workshops (involving RC scientists and laboratories). However, a move to long-term in-country capacity building is needed. This could start with improving basic nurse and physician training, then long-term epidemiology and laboratory career development programmes. Several UK institutions are involved with distance learning to complement in-country training and there are undoubtedly opportunities to do more.

87. The MRC through the Gambia laboratories and Unit in Uganda contributes to building capacity in clinical practice as well as research. Recent developments include the capacity development initiatives of The Wellcome Trust and the EDCTP.

16. *The International Health Regulations 2005 are intended to provide a global framework for the rapid identification and containment of public health emergencies. How effective do you consider this response system to be? Do improvements need to be made?*

88. In relation to influenza, these regulations seem to have omitted an essential requirement: the provision of assistance to developing countries in developing the capacities to fulfil their international obligations.

17. *What intergovernmental planning has been undertaken to cope with the impact of an outbreak of infectious disease caused by deliberate release of micro-organisms into the environment? Is there adequate liaison between the various agencies involved, including intelligence, law enforcement and health care professionals? How could action by intergovernmental bodies help further?*

89. The links between human health and global security concerns has been recognised as an issue requiring further research in the context of the new Cross-Council Global Threats to Security programme.

18. *Though our remit is focused specifically on known infectious diseases, we would be interested to know how you view the global threat from new or previously unrecognised ones and from the transmission of infections from animals to humans*

90. Many infectious organisms of wild and domesticated animals are unable to infect humans, or if they do they rapidly disappear without causing disease. Evolution of strains of these organisms able to infect man, cause disease and be transmitted to other humans is inevitable but unpredictable. Mutations are most likely to occur in viruses than other micro-organisms, because of their relatively high reproductive rate. But the acquisition by bacteria of DNA from other bacteria can give rise to strains with new or augmented virulence and drug resistance.

91. Zoonotic transmission of new pathogens to man requires susceptible humans to be in association with infected livestock or wild animals—or vectors such as man-biting insects. Certain lifestyles (hunting and certain farming practices) and population movements (civil conflict, famine) can all mediate the emergence and maintenance of zoonoses. Environmental change including that consequent on climate change will inevitably change patterns of human-animal contact.

92. West Nile encephalitis, monkey pox, Ebola viruses, Chikungunya virus, SARS, HIV and human H5N1 flu are examples of zoonotic diseases (although human H5N1 has to date not acquired the property of easy human-to-human transmission). New zoonoses can be expected. Zoonoses that can evade early detection and

in which disease has an unremarkable onset pose a greater threat than the dramatic, sudden killers. Most zoonoses lead to small, localised outbreaks in groups at risk, but the possibility of more general epidemics cannot be excluded.

93. Bovine TB is strictly regulated by test-and-slaughter policies in most developed countries, but there is little or no regulation in most developing countries. The economic and health benefits associated with reduced productivity of livestock and transmission to humans are largely unknown.

94. New zoonotics are inevitable. But their source, scale, timing and visibility are unpredictable. A high degree of international cooperation is required to identify and control emerging zoonoses at an early stage. This is an important responsibility of the WHO, the World Organisation for Animal Health and the Office International des Epizooties (OIE) in partnership with national animal and human health surveillance systems. As noted elsewhere in this response, such systems are barely functional in many LICs and need to be given higher priority by governments.

95. NERC, MRC, BBSRC and The Wellcome Trust are currently considering whether there are opportunities to promote effective new collaboration across their research communities on the ecology of infectious disease and zoonoses in particular.

19. *What resources (subscriptions, staff, training, medicines etc) does the UK Government commit to intergovernmental bodies to help in the fight against the four diseases listed?*

96. The WHO-designated laboratory at NIMR and other influenza laboratories in the UK provide substantial support to WHO in the provision of expertise, training and reagents to promote international co-operation against flu.

20. *Do you wish to provide any other relevant information in addition to what you have said in answer to the above?*

97. Note that the UK part of the circulation list below is somewhat restricted to England. It may be helpful to contact the Royal Society of Edinburgh (which has done a study on pandemic influenza) and experts on infectious disease within Glasgow/Edinburgh Universities. It might also be helpful to consult experts award-holders listed at Annexes 3 to 6.

RCUK

21 January 2008

Annex 1

GLOSSARY OF ABBREVIATIONS

ACTS	Artemisinin combination therapy
BBSRC	Biotechnology & Biological Sciences Research Council
CDC	US Centres for Disease Control and Prevention
DfID	UK Department for International Development
DNDI	Drugs for Neglected Diseases Initiative
DOTS	Directly observed treatment (as in TB)
ECDC	European Centre for Disease Prevention & Control
EDCTP	European and Developing Countries Clinical Trials Partnership
EBI	European Bioinformatics Institute (an out-station of the EMBL)
EMBL	European Molecular Biology Laboratory
ESPA	Ecosystems Services for Poverty Alleviation
ESRC	Economic & Social Research Council
FDA	US Food and Drug Administration
Global Fund	Global Fund for AIDS, TB and Malaria
HPA	Health Protection Agency (England)
IARC	WHO International Agency for Research on Cancer
IAVI	International AIDS Vaccine Initiative
ITN	Insecticide treated bed net
LIC	Low income countries
LMIC	Low and middle income countries
LSHTM	London School of Hygiene & Tropical Medicine

LWEC	Living with Environmental Change
MDR	Multidrug resistant, as in TB
MIC	Medium income countries
MDG	UN Millennium Development Goals
MRSA	Methicillin Resistant Staphylococcus aureus
MMV	Medicines for Malaria Initiative
NERC	Natural Environment Research Council
NERC-CEH	NERC Centre for Ecology and Hydrology
NIMR	MRC National Institute for Medical Research
NGO	Non governmental organisation
OIE	Office International des Epizooties
PEPFAR	US President's Emergency Plan for AIDS Relief
PMI	US President's Initiative in Malaria
RC	Research Council
RCUK	Research Councils UK
SARS	Severe acute respiratory syndrome
STD	Sexually transmitted disease
STFC	Science & Technology Facilities Council
TDR	UNICEF/UNDP/World Bank/WHO Special Programme for Research & Development in Tropical Diseases
UKCDS	UK Collaborative on Development Sciences
UKCRC	UK Clinical Research Collaboration
UNAIDS	United Nations AIDS programme
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
UNPFA	United Nations Population Fund
WHO	World Health Organisation
XDR	Extensively drug resistant

Annex 2

EXAMPLES OF RESEARCH COUNCIL CONTRIBUTIONS TO THE WORK OF INTERGOVERNMENTAL ORGANISATIONS

This Annex lists a few of the Research Council achievements that are contributing to improving and saving lives in the developing world.

Insecticide treated bednets save children's lives (MDGs 4 & 6)

MRC demonstrated in The Gambia in 1986 that sleeping under bednets treated with safe pyrethroid insecticides reduced people's exposure to malaria infected mosquito bites. A further MRC study demonstrated a 63% drop in deaths from all causes in children under five years when using such nets. These and other studies led to the establishment of national bed net programmes and the World Health Organisation (WHO) Malaria Intervention for Child Survival Programme. One of the most effective practical interventions against malaria, insecticide treated nets are now saving lives across the world.

Vaccination against respiratory disease can work in Africa (MDG 4)

Haemophilus influenzae type b has almost been eradicated in the developed world. However a lack of reliable vaccine supplies means it persists in Africa where it is one of the most common causes of fatal meningitis and bacterial pneumonia in children. Following trials carried out by the London School of Hygiene and Tropical Medicine and the MRC Gambia Laboratories, in partnership with the Gambian government, the country's vaccination rate has reached 80 per cent and the disease has been almost eliminated among children. On the basis of the Gambia studies (and others in China and Uruguay), the WHO Global Programme for Vaccines and Immunization recommended that "Hib vaccine should be included in routine infant immunization programs".

Eliminating blinding trachoma worldwide

Across the world some 150 million people suffer from active *Chlamydia trachomatis* infection, the leading preventable cause of blindness. In 1993, an MRC Clinician Scientist published a trial showing that a single dose of oral azithromycin was at least as effective as the then WHO-recommended treatment—supervised application of tetracycline ointment twice daily for six weeks. This MRC trial influenced Pfizer, the manufacturer of azithromycin, to start a donation programme for trachoma control (135 million doses pledged to date). With this safe, effective, single-dose treatment incorporated in WHO-recommended guidelines, the World Health Assembly resolved in 1999 to eliminate blinding trachoma completely by 2020.

US approval of an anti-HIV drug specifically formulated for paediatric use

Treatment of HIV/AIDS in children is a great challenge in LICs. One of the reason that paediatric formulations are difficult to give and are expensive. Data from an EDCTP-funded study, involving the MRC Clinical Trials Unit, contributed to the US Food & Drug Administration (FDA) granting tentative approval for the registration of a fixed-dose anti-HIV drug specifically formulated for children. That the three component drugs are combined in one tablet, and the tablets can be stored, distributed, and administered easily to children is a significant advance in resource-limited settings.

Following tentative FDA approval, this antiretroviral drug will be included in the WHO Prequalification Programme and will become available for distribution under the PEPFAR and Clinton Foundation programmes.

Annex 3

BBSRC RESEARCH PORTFOLIOS—HIGHLIGHTS

BBSRC “Combating Avian Influenza” Initiative

BBSRC has committed £4.5 million for its “Combating Avian Influenza” Initiative. The aim of the initiative is to enhance understanding of the virology, pathology, host-pathogen interactions and epidemiology of avian influenza in its animal hosts, with a view to generating the underpinning scientific knowledge that will enable the development of more effective methods for its control.

BBSRC has also recently launched a collaboration with China relating to research on the transmission of the avian influenza virus. Activities have included workshops between IAH, the Chinese Academy of Sciences Institute of Microbiology and the Harbin Veterinary Research Institute. Further priorities include exchange of reagents and information; reciprocal access to laboratory containment facilities and exchange of researchers. Priorities for the joint activity include studies on virus pathogenicity, host-range restriction, identification of protective epitopes and development and assessment of novel vaccines.

“Coordination of European Research on Emerging and Major Infectious Diseases of Livestock” (ERA Net EMIDA)

BBSRC is also to be a part of an ERA net likely to be funded and start later this year; “Coordination of European Research on Emerging and Major Infectious Diseases of Livestock” (ERA Net EMIDA). This is led by Defra, and both BBSRC and Scottish Government are involved. “The scope of the project will include emerging and major infectious diseases of production animals, including fish and bees and including those conditions which pose a threat to human health but excluding food safety issues relating to the handling of livestock products and diseases of wildlife except where they act as reservoirs of infection for humans or production animals.” There are four work packages:

- WP1. Project coordination, management, communication and dissemination.
- WP2. Mapping and analysis of existing research and current needs and information on the commissioning and management of joint programmes.
- WP3. Develop, test, evaluate and refine instruments (Pilots).
- WP4. Developing a strategic trans-national animal health research agenda.

Sustainable Agriculture Research for International Development

BBSRC is now developing proposals with DfID and others, for funding of a future joint programme in Sustainable Agriculture Research for International Development to support high-quality basic and strategic research including on research on Animal Health, with an anticipated final overall budget of more than £8 million. This proposed animal health call is expected to include a possible focus on zoonoses.

Institute for Animal Health redevelopment

In conjunction with the Department for Environment, Food and Rural Affairs (Defra), BBSRC is investing £120 million in upgrading the IAH Pirbright facility. These plans will also build upon the Detection and Identification of Infectious Diseases Foresight Programme.

Annex 4**ESRC RESEARCH PORTFOLIO—HIGHLIGHTS***DFID—ESRC Scheme—Launched August 2005*

This £13 million joint research grants scheme aims to fund world class scientific research on issues relating to economic development and quality of life in less developed countries with the potential for impact on policy and practice for poverty reduction. This focuses in particular on:

- understanding and creating the socio-economic conditions that are necessary to facilitate the alleviation of poverty;
- new theoretical and conceptual thinking about the nature of development and the conditions under which development and poverty alleviation can be delivered;
- methodological challenges posed by international comparative work in different social, economic and cultural settings; and
- paucity of datasets, especially micro-level or longitudinal data.

EXAMPLES OF AWARDS*Identifying barriers to TB diagnosis and treatment under a new rapid diagnostic scheme, Dr Luis Cuevas, Liverpool School of Tropical Medicine*

Start Date: 01/04/2008 End Date: 31/03/2011

Tuberculosis is the main cause of adult death due to infection in developing countries and its diagnosis in these settings requires the examination of multiple sputum samples using smear microscopy. Although smear microscopy was described more than 100 years ago, front line facilities still rely on it as a low cost, relatively simple and robust diagnostic test in the absence of alternatives. But it has substantial limitations: it identifies only 40–75% of adults with pulmonary tuberculosis and the examination of multiple specimens is costly in time and economic expense for both services and patients. Individuals often have to travel long distances and sell personal assets to access services. Many patients are unaware of the number of days required for diagnosis and, as several visits are necessary, are unable to adhere. As patients can only initiate treatment if they have been formally diagnosed, improving the efficiency of the process is crucial for increasing access to treatment. Accelerated diagnostic approaches are recognised as a promising way of improving TB diagnosis by the Stop TB Partnership's Task Force on Retooling and are likely to become global policy for TB control in the future. This research team has designed an accelerated scheme in which specimens are collected one hour apart from each other. This scheme provides test results on the day of consultation and those who tested positive can be referred for treatment within the centre, or elsewhere, within a few hours. Following promising findings in preliminary studies, the WHO/TDR is undertaking a multi-country evaluation, coordinated by LSTM, to validate the scheme and inform both national and international policy. This research is sensitive to the necessity of identifying the non-financial barriers (including poverty, gender, attitude health workers, perceptions of health services) surrounding patients' uptake of diagnosis and treatment when assessed with a new accelerated diagnostic approach.

Demographic and poverty dynamics in an African population with high AIDS mortality and implications for social policy, Professor Ian Timaeus, LSHTM, Professor Jane Falkingham, Professor Julian May

Start Date: 09/10/2006 End Date: 08/12/2009

The ADaPT (AIDS, Demographic and Poverty Dynamics) project aims to: improve the understanding of the impact of deaths of working-age adults on household welfare, households' responses, and the determinants of differential vulnerability and resilience examine the effects of demographic change, including the AIDS epidemic, on poverty dynamics across the life course in South Africa assess the social policy interventions designed to mitigate the impact of the epidemic and their distributional implications across the life course. The project will analyse data from two large panel datasets from KwaZulu-Natal. The project will investigate whether adult deaths primarily affect household welfare by aggravating money poverty or in other ways. Finally, micro-simulation will be adopted to model the impact of different social benefits and services that might mitigate the impact of the AIDS epidemic.

Impact Evaluation of Performance-based Contracting for General Health and HIV/AIDS Services in Rwanda, Dr Stefano Bertozzi, National Institute of Public Health, Mexico, Professor Paul Gertler, Professor Sergio Bautista, Dr Paulin Basinga

The global shortage of human resources for health care delivery is reaching crisis conditions in the poorest countries. The deficit of well trained and highly motivated health care workers in developing countries is a reflection of the high levels of absenteeism and worker emigration to richer countries. This research will provide some of the first rigorous empirical evidence on whether Performance Based Contracting (PBC) for health services is a feasible method for improving quality of care, increasing access to quality health care services, and significantly increasing health outcomes. It will also be the first study of PBC in the African context. The knowledge generated by this research will not only fundamentally serve the Rwandan government, World Bank and other donor agencies as they prepare for expansion of PBC for health services within Rwanda, but also the international community as it searches for more effective means for addressing the human resource crisis in health care.

ESRC-HEWLETT SCHEME

The William and Flora Hewlett Foundation (Hewlett) and the Economic and Social Research Council (ESRC) have formed a strategic partnership to provide a new joint funding scheme. This scheme aims to enhance the quality and impact of social science research addressing the key international development issue of how population dynamics and reproductive health outcomes impact economic growth and poverty reduction. The new scheme will fund world class scientific research on issues relating to economic development and quality of life in less developed countries with the potential for impact on policy and practice for economic development and improved reproductive health. This joint scheme has a total budget of £2 million over four years.

EXAMPLES OF AWARDS

Effects of Reproductive Health on Poverty in Malawi, Dr Marcos Vera Hernandez, Dr Emla Fitzsimons, Dr Alice Mesnard, Professor Hans-Peter Kohler, Professor Jere Behrman, Professor Constantine Meghir, Professor Orazio Attanasio, Dr Winford Masanjala

Start Date: 01/01/08 End Date: 31/12/10

The challenge of this research is to disentangle the causal effect of reproductive health on poverty.

Research hypotheses being tested include:

- Parental HIV-infection reduces child schooling but may reduce or increase child work. As a consequence Volunteering Counselling and Testing might also increase schooling and affect child work.
- Collectively-generated information about reproductive health increases contraceptive use and reduces HIV infection of women.

*Enhancing the economic, health and social capabilities of highly vulnerable youth, Dr Kelly Hallman,
Start Date: 01/12/07 End Date: 30/11/10*

Young people in South Africa face high risks of HIV, teenage pregnancy, school dropout, and unemployment, and are further disadvantaged by the actual or potential loss of one or both parents to HIV and extreme conditions of poverty. These circumstances make the transition from childhood to adulthood especially difficult, and many of the most disadvantaged young people are in danger of falling even farther behind socially and economically due to illness, stigma, and the loss of key supportive adults.

The proposed research aims address the specific conditions of young people's lives and testing an intervention that includes strategies to help young people build economic assets and protect themselves against HIV and early pregnancy.

Annex 5

MRC RESEARCH PORTFOLIO—HIGHLIGHTS

Identifying and evaluating innovative strategies to prevent infectious diseases (MDGs 5 & 6)

Research by the MRC Unit in Uganda working with the MRC Clinical Trials Unit (CTU) and other partners in Africa, the UK and the US established the safety of a new vaginal microbicide product, PRO2000, a naphthalene polymer. The Microbicide Development Programme (MDP) is currently evaluating acceptability and effectiveness of PRO2000 in protecting women from acquiring HIV. It has already established that populations in Africa find the use of the product highly acceptable. The Programme is also creating substantial new capacity in Africa for future trials as new microbicide products become available. The MDP is managed by the CTU and Imperial College and funded by DFID and MRC.

Adopting innovative treatment strategies to the context of resource poor countries (MDG 6)

The work of the Uganda Unit has already shown that it is possible to cut substantially mortality due to AIDS in Africa. The MRC Clinical Trials Unit and the Uganda Unit are building on that work with other African and UK partners to identify effective strategies for monitoring ART in patients in resource poor settings without reliable laboratory support (the DART Trial: **D**evelopment of **A**nti**R**etroviral **T**herapy for Africa). The Uganda Unit is also investigating how best ART can be rolled out effectively in such settings, and whether HIV treatment can be integrated with HIV prevention activities cost-effectively. These studies also generate insights into how these interventions work. DART is co-funded by MRC, DFID, the Rockefeller Foundation and drug donations from pharmaceutical companies.

Pioneering an effective vaccine for malaria (MDG 6)

The Gambia has been the site of the most extensive intervention studies on what is currently the most efficacious vaccine against malaria, the RTS,S/ASO2A vaccine developed by MRC and GlaxoSmithKline (GSK). The results from the Gambia have led to further studies for phase I and II trials in Mozambique with support from the Malaria Vaccine Initiative (MVI). Pioneering MRC studies, such as the malaria vaccine trials carried out under the MRC/DFID concordat, often lead to further studies in countries where the MRC has no direct research investment.

Providing the evidence for national HIV prevention strategies (MDG 6)

Uganda has been at the forefront in reducing the incidence of HIV. But a longitudinal study of the trend in the HIV epidemic signalled that the prevalence and incidence of HIV were no longer declining. In some population subgroups cases are increasing. Although the study outcome presented a difficult message, the MRC Unit and the Ugandan Ministry of Health worked closely together, contributing substantially to the Government launching a new prevention strategy in 2006–07.

Exploiting genomic technologies to combat drug resistance and develop effective vaccines

Revolutionary advances in genome research provide unprecedented opportunities to overcome the hurdles of drug resistance through the discovery of natural mechanisms of protective immunity and by identifying the molecular tricks employed by parasites and microbes to evade the human immune system and resist drugs. The MRC Centre for Genomics and Global Health at the University of Oxford aims to exploit these opportunities by integrating state-of-the-art genome research methods into large scale studies of diseases in affected populations.

The full global health research portfolio is available on request from MRC

Annex 6**STFC RESEARCH PORTFOLIO—HIGHLIGHTS****DIAMOND LIGHT SOURCE LTD**

Professor Dame Louise Johnson, Director of Life Sciences

Diamond is funded by the government (86%) through the DIUS administered by STFC and by the Wellcome Trust (14%). Diamond works closely with all the research councils, the Wellcome Trust and the other funding agencies both through their formal representation on advisory committees and through their funding of users.

Diamond Light Source provides an intense source of light and X-rays that are used in a range of experiments in the life and physical sciences. Diamond began operation as a User facility in 2007. Through its user programme in structural biology with the Macromolecular Crystallography (MX) beam lines, Diamond will contribute to the fight against the four communicable diseases of the inquiry (influenza, tuberculosis, HIV/AIDS and malaria). The MX beam lines exploit the intense X-rays to irradiate crystals of biological macromolecules. The diffraction patterns from these crystals allow the determination of the structures of the biological macromolecules at the atomic level. Knowledge of structure provides insights into biological function and the basis for a structure based design of new therapeutic agents. Several academic user projects, which are described in more detail below, are contributing to drug design against specific targets from the causative organisms of the four diseases.

Diamond will commence its industrial programme in March 2008 and results from this will be driving the drug discovery process to market. All the major pharmaceutical companies and many of the small biotech companies have a structure based drug design programme as a key component for new drug discovery, although few companies are targeting TB and malaria.

In summary although Diamond Light Source does not have its own programme to combat disease, Diamond is key to the UK programme in structural biology by providing world-class synchrotron radiation facilities and MX beam lines. The structural biology results inform biological function and provide a basis for logical drug design. Diamond is most suitably configured for this role.

INFLUENZA

The two available anti-flu drugs, Relenza and Tamiflu, approved in 1999 were both designed based on the knowledge of the structure (determined in Australia) of the influenza virus surface protein, neuraminidase. These successful drugs represent one of the high points of structure based drug design.

New work is directed towards understanding how the avian influenza virus can infect humans. The influenza virus binds to its host cell through the binding of its second surface protein, haemagglutinin (HA), to sugars on the surface of target cells. In order to infect humans, avian influenza HAs need to acquire changes in sequence that will allow them to bind to the specific sugars (□ 2,6 linked siallosaccharides) on human cells. Understanding this switch in preference is a key to understanding how avian viruses acquire the ability to pass between humans and become pandemic. Scientists at the MRC National Institute for Medical Research some years ago determined the structure of the HA from the human virus that caused the 1918 Spanish flu pandemic and from the structure they were able to explain why this strain was so virulent (1). More recently in a user programme that will exploit Diamond Light Source, their programme continues with a study of avian H1 HAs and the HAs from the H5N1 avian viruses and from viruses extracted from human patients. The results will explain how H5 HA adapts to preferentially bind human receptor. A promising start has been made (2).

TUBERCULOSIS

Although effective drugs exist for TB, current therapy requires prolonged treatment, leading to compliance problems and the emergence of multidrug resistance. There are further problems in that the organism, *Mycobacterium tuberculosis* (*Mtb*) can exist in a dormant state to be reactivated later. In the non-replicating persistent state, the organism is believed to undergo a switch in metabolism, using host lipid as an energy source. Current drugs target the actively growing bacteria and are largely ineffective against the dormant state.

The publication of the complete sequence for *Mtb* in 1998 with the identification of ~ 3,900 open reading frames that encode proteins has led to increased effort to functionally annotate the proteins and to seek new drug targets that differ from their counterparts in the human genome. Many distinctive and unusual features have been noted, including a large number of enzymes involved in lipid biosynthesis and metabolism (possibly associated with dormancy) and a large proportion of the genome dedicated to two families of unknown function. It has been estimated that ~65% of gene products are of unknown function.

The genome information has stimulated an international consortium for TB Structural Genomics formed in 2000. The work of the consortium and other academic users has resulted in ~200 unique *Mtb* protein structures and a further ~250 ligand complexes. This information has allowed the integration of data from many other sources to illuminate the biological function of proteins of previously unknown function (reviewed in (3)). The information has also been used to develop a new series of *Mtb* protein inhibitors (4).

In the user programme at Diamond, several groups (from the Universities of Leeds, Birmingham and Cambridge, Kings College and Birkbeck College) are addressing *Mtb* proteins that include those that are targets against multi drug resistance (DNA topoisomerase), those involved in mycolic acid and bacterial cell wall pathways, those from the dormancy regulon, and a number of other targets that also relate to worldwide international initiatives to combat these diseases. The first paper from the MX beam lines at Diamond (Lack *et al* (2007) *Acta Cryst.F* 64, 2–7) described the structure of HsaD, a steroid-degrading hydrolase, from *Mbt*. The enzyme is critical for the survival of M tuberculosis inside human macrophages and is a potential target for therapy. The work from a group at Oxford showed how the structure might be exploited toward drug design.

It is anticipated that the structural biology programmes will contribute to a better understanding of *Mtb* biology and provide the basis for drug design. In order to bring potential compounds to the clinic, new initiatives will be needed to provide funding for the diseases of the poor.

HIV/AIDS

HIV/AIDS represents a second good example where structure biology has led to effective drugs in the clinic. These include the HIV protease inhibitors where intense effort first based on the structures of a related retrovirus and then on the HIV protease itself led to the commercially available products such as Viracept, Agenerase and Aluviran approved in 1999–2000 and which are effective in the clinic.

In the user programme at Diamond further targets are being pursued. The HIV reverse transcriptase is already a target for therapy and is being further investigated (University of Oxford) with new non-nucleoside and nucleoside inhibitors (5). The HIV integrase executes the insertion of viral DNA into the host cell genome, an essential multi-step process of the retroviral life cycle involving host cell proteins (6). Structural studies on the HIV integrase and cellular interacting proteins (Imperial College) are leading to the definition of the mechanism of action of new inhibitors.

MALARIA

Malaria poses an extraordinarily difficult disease for drug design because of the complicated life cycle of the parasite, its interactions with different hosts and the emergence of drug resistant strains. Molecular targets for drug design include proteases that hydrolyze hemoglobin, protein farnesyltransferase, heme detoxification pathway, polyamine pathways, dihydrofolate reductase, artemisinin-based combination therapies (ACTs), and enzymes of metabolic pathways that are essential for parasite survival. Plasmodial surface proteins have important roles in host cell invasion and are responsible for antigenic diversity in this organism. In the longer term, the answer to malaria is likely to come from vaccine development. Vaccine development has yet to exploit structural approaches and the interplay between antigen and immune response is more complex than the interplay between a drug and its target protein. Nevertheless knowledge of the three-dimensional structure of surface proteins can facilitate our understanding their biological function, and contribute to the development of therapeutic and vaccine strategies against malaria (7).

Groups at the University of Oxford and at York are using Diamond to tackle a number of specific proteins from *Plasmodium falciparum* that include protein kinases that are distinct from human protein kinases and which lend themselves as good drug targets following the success of protein kinase inhibitors for cancer treatment (8). Other targets include those proteins involved in invasion of the red blood cell by the parasite, a mitochondrial enzyme that is already a drug target, an enzyme that is expressed in a stage specific manner in the parasite, in addition to the enzymes dUTPase and thymidylate kinase and their complexes with anti-malarial drug analogues.

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THE ROLE OF E-SCIENCE IN COMBATING INFECTIOUS DISEASES

The drug discovery process is being greatly accelerated by the use of GRID computing infrastructures. The GRID infrastructures supported by STFC, EGEE (Enabling Grid for E-Science) and GridPP (Particle Physics Grid), have been involved in studies of Avian Flu and Malaria—and also of other infectious diseases. Both of the infrastructures have substantial EC FP7 funding.

The Drug Discovery application software, where scientists carry out “in silico” docking, has been running on the EGEE production service since December 2004. In silico docking enables researchers to compute the probability that potential drugs will dock with a target protein. On a single computer, a study involving 100,000 potential drugs might require six months to complete—but can be accomplished in days using EGEE. The next step in the development of GRID Software will be to increase the performance of the application and compute millions of potential drugs in only a few weeks.

In 2006, a collaboration of Asian and European laboratories analysed 300,000 possible drug components against the avian flu virus H5N1 using the EGEE Grid infrastructure and similar facilities. To study the impact of small scale mutations on drug resistance, a large set of compounds was screened against the same neuraminidase target but with various, slightly different structures. For the docking of 300,000 compounds against eight different target structures of Influenza A neuraminidases, 2000 computers were used over four weeks—the equivalent of 100 years work on a single computer. Consequently, potential drug compounds against avian flu are now being identified.

The WISDOM (Wide In Silico Docking On Malaria), challenge identified over 46 million docked ligands during a one month period in 2005—the equivalent of 80 years work on a single PC. In this case, 1000 computers were simultaneously used in 15 countries around the world.

The DENGUE project is also using in silico docking to identify new potential compounds directed against proteins that mediate essential functions for dengue virus infection and replication whilst the AFRICA@home project is a grid based project aiming at improving epidemiological monitoring of Malaria in Africa.

These grid projects have the potential to transform into true e-Science projects, integrating in silico research with experimental biology and chemistry.

Memorandum by RESULTS UK

2. What reliable data exists regarding the number of people infected globally with the four diseases on which the committee is focussing particular attention? What trends are discernable in both number of those infected and the patterns of infection? And what are the main underlying causes of infection and any of changes in its incidence and pattern?

The World Health Organization compiles annual reports which include some of the most up to date figures available for tracking the global incidence of tuberculosis. However, due to the complex and time consuming nature of the work involved in compiling such data these figures are mostly two years out of date by the time they are published. For example the 2007 report uses data from 2005. This is significant because, for example, the *Global Plan to Stop TB* only came into force in 2006 so the 2007 report will not be able to reflect any advances made since that date until 2008/09 at the earliest.

The WHO report, *Global Tuberculosis Control: Surveillance, Planning, Financing* (2007) provides detailed statistics on the scale, direction and impact of the epidemic, expressed in terms of incidence, prevalence and deaths for 22 high-burden countries, for the six WHO regions, for selected sub regions and for the entire world.

The 2007 report notes a total of 5.1 million new and relapse cases of TB that had been reported to the WHO. The actual number of new cases was thought to be closer to 8.8 million (illustrating the difficulty in compiling accurate, verifiable data). WHO noted that the African Region (23%), South-East Asian Region (35%) and Western Pacific Region (25%) together accounted for 83% of all notified new and relapse cases.

Having compiled data on TB for eleven consecutive years, WHO are able to effectively establish patterns and trends in global TB incidence. Perhaps the most encouraging trend to emerge has been the stabilisation or decline of TB incidence in each of the six WHO regions, suggesting that global TB incidence may have “reached a peak”. However it must still be noted that overall numbers of new cases continues to slowly rise because the case-load continued to grow in the African, Eastern Mediterranean and South-East Asia regions.

In the few remaining areas where incidence of TB is continuing to rise, including Sub-Saharan Africa, it has been found that the resurgence in TB can be directly attributed to high HIV/AIDS prevalence in those areas.

4. Given the continuance of current or planned intergovernmental programmes to prevent or control the four diseases, what predictions can be made of their likely spread and pattern over the next 10 years?

The Stop TB Partnership’s *Global Plan to Stop TB, 2006-2015* is a comprehensive strategy developed with the explicit aim of combating the spread of TB worldwide. If the Global Plan is implemented fully and successfully it is projected that 14 million lives will be saved. Furthermore 30 million cases of TB will have been prevented and the number of new cases will reduce to less than six million in 2015, thus meeting and even exceeding the MDG target of “halting and ultimately reversing the incidence of” TB worldwide. The Global Plan’s own ambitious target of halving the prevalence and death rates from the 1990 baseline will also have been met.

However it must be noted that many significant challenges must first be overcome if such significant advances are to be made. HIV and multi-drug resistant strain of TB remain perhaps the biggest challenge, alongside wider societal and health system issues. Long-term investment and commitment is essential to ensure that the Global Plan remains on track to meet these goals. To ultimately eradicate TB a new, more effective vaccine will be required. It is very unlikely however that this will be developed in the next 10 years.

5. What do you consider to be the principal blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?

Despite being responsible for the deaths of over eight million people every year, TB often fails to attract the political attention that other diseases, notably HIV/AIDS attract. This is particularly problematic as it is evident that TB will only be brought under control if there is the political will to do so. The UK should be at the forefront of global efforts to highlight the serious threat posed by the global TB epidemic, helping to push the issue of TB up the global political agenda.

Political will must be matched by a significant scaling up of the funding available to TB control. Furthermore, funding must be made more consistent and predictable. The total cost of the Global Plan is US\$56.1 billion over 10 years. This includes US\$9 billion for new tools working groups and US\$47 billion for implementation working groups. Today, only about 45% of the total cost or an estimated US\$25.3 billion is likely to be available. The estimated funding gap is US\$30.8 billion (note: this does not include additional resources needed to address the more recent emergence of Extensively Drug-Resistant TB or XDR-TB). Existing gaps in funding and uncertainty about future financing impede planning and implementation for both treatment and research. Governments, international organisations and NGOs should act in a coordinated way to ensure long-term, stable and sustainable funding for TB prevention, treatment and research.

Drug resistance poses a serious and growing threat to global TB control, threatening to undermine all the progress that has been made to date. Drug resistance can be avoided if the current DOTS strategy is implemented properly. To prevent the further spread of drug-resistant TB more money should be made available to fund the expansion of effective DOTS-plus programmes. The UK should also encourage and support high burden countries to develop effective national policies for the treatment and prevention of drug resistant TB.

TB has formed a deadly partnership with the HIV virus and the HIV/AIDS epidemic is responsible for fuelling the TB epidemic in certain parts of the world, particularly in Sub-Saharan Africa. Neither epidemic can be effectively addressed without dealing with the two diseases in a coordinated and collaborative manner. Testing TB patients for HIV and HIV patients for TB would be a good start and would dramatically improve detection rates for both diseases and early detection will in turn help to save lives.

New tools are desperately needed to take advantage of new technologies and scientific breakthroughs as most tools used now are outdated: the BCG vaccine is only partially effective; the main diagnostic test for TB dates back to the 1880s and lacks precision, and no new TB drugs have been developed since 1966. The advent of XDR-TB had publicly exposed the limitations of existing tools—as well as underlining the need for collaboration between TB and HIV services—and reinforced the need for a new approach to TB control. There have already been welcome advances in this area but more investment is needed to accelerate progress.

Above are mentioned just some of the major blockages to effective prevention and control of TB. If TB is to be brought under control and ultimately eliminated it is important that TB is dealt with in a holistic way, taking into consideration all of the above factors.

6. What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?

RESULTS is an international grassroots advocacy organisation working to create the public and political will to end hunger and the worst aspects of poverty. RESULTS currently operates in seven countries: Australia, Canada, Germany, Japan, Mexico, UK and USA. Current campaigns include microfinance, education, sanitation and global health.

RESULTS has campaigned for many years to generate increased political will to eradicate diseases of poverty, including TB, malaria and HIV. Through our network of volunteers we have written and met with numerous Members of Parliament to raise awareness and promote policies and initiatives that address these epidemics. RESULTS UK is a member of, and works closely with, the Stop TB Partnership, Stop TB Partnership for Europe, Malaria Consortium, Coalition Against Malaria and UK Consortium on AIDS and International Development.

For the past three years, RESULTS UK has been engaged in a project to address and help reverse the global TB problem through policy analysis, education of policymakers and advocacy. The “Advocacy to Control Tuberculosis Internationally” (ACTION) project is currently being implemented by a consortium of non-governmental organisations in Canada, France, India, Japan, Kenya, UK and USA. Policy guidance and technical assistance is provided by experts from the World Health Organization and Stop TB Partnership. RESULTS UK organises regular educational visits to high TB burden countries for parliamentarians and currently supports the secretariat of the All-Party Parliamentary Group on Global Tuberculosis.

Synergy between non-governmental organisations in high-income countries and intergovernmental governmental organisations has been strong and effective to date in relation to TB. Two areas where synergy could be strengthened are (a) between organisations in high-income countries and organisations in middle/low income countries; and (b) between organisations working on TB and organisations on HIV. In both cases, there is great potential for further collaboration and sharing of knowledge and skills.

7. What are the main non-health causes (e.g. global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four diseases? To what extent can intergovernmental action in non-health fields contribute to the alleviation of their spread? What action is taking place or planned in

these areas? And what more needs to be done? Do you consider that there is sufficient “joined-up” thinking in approaching the problem?

“TB is the child of poverty—and also its parent and provider”. This quote by Archbishop Desmond Tutu seems to accurately encapsulate the inextricable link that exists between TB and poverty. Whilst TB is by no means exclusively a disease of the poor it is certainly more prevalent in poor communities and it is the poor who are least equipped to deal with its consequences.

Conditions of poverty, especially overcrowding continue to fuel the TB epidemic. People who live in dark, unventilated and crowded rooms prove to be particularly susceptible to the disease and such conditions allow for the rapid spread of the disease from person to person. Malnutrition is another factor that is conducive to the spread of TB. Poorer communities are also more heavily afflicted by HIV, which reduces a person’s resistance to TB significantly, allowing the spread of TB amongst an already vulnerable population.

TB continues to thrive in areas of poverty because the poor often have diminished access to medical facilities and ensuring a full programme of treatment proves to be far more difficult to accomplish. People’s ignorance of the disease and the continued stigma attached to it also hinder both treatment and efforts at prevention.

TB also perpetuates the cycle of poverty and deprivation with families afflicted by TB often losing 20–30% of their annual income due to loss of work whilst being treated and because of travel costs to and from clinics. If a patient dies the family loses on average 15 years of income. Poverty alleviation strategies rarely deal with the issue of TB explicitly, which is an oversight that should be rectified if the root causes of TB and its spread are to be effectively dealt with.

8. Cases of tuberculosis fell progressively in the UK until the mid-1980s but started to rise again in the early 1990s. Around 6,500 cases are now reported each year, an increase of about a quarter since the early 1990s. What are the main factors of the revival of tuberculosis infections in Britain? And how could intergovernmental action help to reverse the trend?

According to the Health Protection Agency, a total of 8,497 cases of TB were reported in 2006 in the UK (7,862 cases in England, 189 in Wales, 62 in Northern Ireland and 384 in Scotland).

Levels of TB among the general population continue to be low (14 cases per 100,000 population) but in some areas of the UK, such as London and the West Midlands, rates of TB remain high. The majority of TB cases in the UK occurred in young adults aged 15–44 years with the London region accounting for the largest proportion of cases (40%) and the highest rate (44.8 per 100,000).

72% of TB cases were found among people born outside of the UK. Among the non-UK born population, most cases belonged to the Indian, Pakistani and Bangladeshi communities (45%), and the highest rate was among those belonging to the black African ethnic group (395 cases per 100,000 population). Immigration is commonly cited as the reason for growing rates of TB in the UK but many other countries in Western Europe experience equal or higher rates of immigration. Further research is required by the UK government, in collaboration with relevant intergovernmental organisations into the correlation between the ethnic origin of TB patients and patterns of migration to the UK and other Western European countries.

Only one out of five non-UK born cases arrived in the UK in the two years prior to their TB diagnosis. 30% had entered the UK two to four years prior, 21% five to nine years prior and 29% had entered 10 or more years prior. These statistics suggest that the majority of patients became infected with TB in their country of origin and carried the latent TB infection for many years. Further research is needed to establish why latent TB infection becomes active disease, for example if there are correlations with poverty, malnutrition, HIV or other conditions. Furthermore, further research is required into more effective and systematic ways of identifying individuals who enter the UK with latent infection so that they can be treated before developing active disease. Global and national awareness campaigns are needed to encourage patients (and health professionals) to recognise the symptoms of TB, to reverse stigma and to increase both case detection and treatment success rates.

In order to reverse the revival of TB infections conclusively, national governments should work in partnership with intergovernmental organisations to control TB worldwide. As patterns the UK’s experience demonstrates, controlling TB in one country will not prevent it from returning in the future. A global approach must be taken to tackling a disease that knows no borders.

9. Tuberculosis is potentially curable by long-term antimicrobial therapies. Yet the number of reported cases worldwide seems to be rising. Are the necessary medicines not getting through to patients? What are the barriers to effective long-term therapy? Are we now seeing infections which stem from other conditions e.g. HIV/AIDS? Or are there other reasons why a treatable disease should be spreading? How might intergovernmental action help to deal with this situation?

Much progress has been made in improving the distribution of Drugs to treat TB. The Global Drug Facility (GDF) has been a particularly useful mechanism for helping to increase access to life-saving drugs at comparatively affordable prices. In addition to continuing to provide first-line treatments—a projected additional 15 million first-line treatments will be provided from 2006 to 2015—the GDF will expand its catalogue to include second-line and paediatric drugs as well as diagnostic kits. This will be a welcome development that will no doubt save many lives. However, numerous barriers continue to exist which impede efforts to ensure that these drugs reach those in need.

Firstly, detection rates for TB remain unimpressive despite improvement in many areas. Many countries continue to fall short of the 70% target detection rate set by WHO. This not only results in infected people not receiving the treatment they need, but also increases the risk of the infected person passing on the disease to other people, helping to fuel the spread of TB. The earlier the disease is detected, the easier it is to treat.

The drugs regimen for treating TB is complex and long, lasting on average six to eight months. Without correct supervision an alarming number of patients fail to successfully complete their course of drugs, a factor that is fuelling the spread of MDR and XDR-TB worldwide. Efforts to simplify and shorten TB treatment should be supported and well funded to increase the success rate of such treatments and reduce the risk of drug resistance.

As has already been mentioned, the HIV epidemic is continuing to fuel the TB epidemic. Despite this fact being almost universally acknowledged, efforts at tackling both diseases remain largely independent of one another. This oversight is continuing to cost lives. If either disease is to be dealt with effectively more TB/HIV collaboration is needed. Much more intergovernmental effort is needed to promote a more collaborative approach to the two diseases and the UK should be at the forefront of such efforts.

12. To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?

The emergence of drug resistant forms of TB has been a worrying development. Multi-Drug Resistant TB (MDR-TB) is a form of TB that does not respond to standard treatment using first line drugs and is now present in virtually all countries recently surveyed by WHO. Treatment for MDR-TB is much longer than treatment for standard TB, lasting about two years. It is also many times more expensive and has many more side-effects for the patient. If the treatment of MDR-TB is mismanaged, even more deadly strains of TB can develop, most notably Extensively Drug Resistant TB (XDR-TB) which is virtually untreatable.

The World Health Organization estimates that up to 50 million persons worldwide may be infected with drug resistant strains of TB. Also, 300,000 new cases of MDR-TB are diagnosed around the world each year and 79% of the MDR-TB cases now show resistance to three or more drugs.

If the emergence of drug resistance TB is not dealt with effectively, the number of cases could spiral out of control, posing a health risk to millions of people throughout the world. Efforts have been made to ensure that this does not happen and the WHO has made MDR-TB surveillance and control an important component of its overall TB strategy. It has developed what is known as “DOTS-plus” and the “green light committee” as a means of effectively combating MDR-TB and it is important that the UK supports such efforts to ensure that they can be implemented swiftly and effectively.

19. What resources does the UK Government commit to intergovernmental bodies to help in the fight against the four diseases listed?

The Department for International Development (DFID) currently provides support for TB control through the following international technical organisations and global health partnerships:

- £100 million committed to the Global Fund to Fight AIDS, TB and Malaria (GFATM) for 2007 bringing the UK’s total contribution to date to £359 million. In September 2007, the Secretary of State announced a further eight-year pledge of £1 billion to the GFATM (including £360 million for the period 2008–10).
- DFID provides core resources to the World Health Organisation (currently £12.5 million per annum), leaving it to WHO to determine the allocation of resources to the AIDS, TB, and Malaria cluster within WHO.
- DFID supports the Stop TB Partnership and is committed to providing a total of £8.98 million from 2002–08. This will help the partnership to advocate for commitment to the *Global Plan to Stop TB, 2006–2015* and monitor progress.
- DFID is a founder member of UNITAID (International Drug Purchase Facility), which was launched in September 2006 at the United Nations General Assembly. UNITAID funds drugs and diagnostics for AIDS, TB and malaria. The UK has made a 20-year commitment, starting with £15 million in 2007, and, subject to the outcome of a joint assessment of the performance of

UNITAID, rising to £40 million a year by 2010. UNITAID will provide additional funding for drugs to treat multi-drug resistant TB (MDR-TB) as well as paediatric formulations of TB drugs.

- DFID currently funds two research programme consortia on communicable disease with London School of Hygiene and Tropical Medicine and Nuffield Centre for International Health at Leeds University. Both programmes will receive £5 million each over five years.
- DFID supports the research and development of TB drugs and diagnostics via WHO's programme on Tropical Disease Research (TDR) and the public/private Product Development Partnership (PDP), the Global Alliance for TB drugs. The Global Alliance will receive £6.5 million from 2005–08 for the development of new drugs.

1 February 2008

Memorandum by the Royal College of Physicians and Surgeons of Glasgow

RESPONSE TO THE PRINCIPAL ISSUES ON WHICH THE COMMITTEE WELCOMES VIEWS:

1. There will always be new infections, new problems with older infections, and new challenges. A crisis may not only be medical but may also be economic. For example, vCJD has not been mentioned in the pre-amble, yet this was an infection caused by a class of organisms which had not hitherto been known to exist and which has had enormous economic impact as well as medical impact. We may concentrate on four key diseases, but the principles applied and control systems developed by the UK should be robust enough to cope with those unexpected challenges which come along from time to time, as SARS did “out of the blue” in 2003, leading to disaster. Adequate resources in terms of finance, manpower and expertise have to be made available if such crises are to be averted.

2. Health Protection Scotland (HPS) and the Health Protection Agency (HPA) in England are, in effect, part of a world-wide network of epidemiological services. However, rather like military and diplomatic services require adequate intelligence so as to be able to function optimally, public health and clinical medicine also require the same sort of service in terms of data collection regarding what is going on and expert analysis of that data. HPS and HPA are the epidemiological eyes and ears of healthcare, and allow for appropriate planning for the future, including appropriate apportioning of resources.

3. Open and honest sharing of information across international borders is vital if outbreaks are to be controlled or, better still, prevented. An example of this would be the 2003 case of the existence of SARS being known within mainland China prior to its wider recognition throughout the world only after the virus had entered Hong Kong. To become optimally effective, international groups like WHO have to be in a position to access data from wherever and whenever they need it, and achieving this sort of state of affairs will require a high-quality level of international diplomacy to be brought to bear. Other ways of spotting the emergence of infection problems with potential wider consequences must be sought out by the international scientific community. HPS and HPA would have an important role to play in this process.

4. There is always the potential for problems, or even for disaster, if considerable attention is not paid towards controlling the four key diseases. For example, AIDS/HIV has been known about for a quarter of a century, and the modes of its transmission between human beings have been abundantly clear for a very long time, and yet the disease continues to spread in many parts of the world. The extent to which social (including gender), morality and political issues, as well as medical and economic issues, are responsible for this continuing spread need to be the subject of high-quality investigation, as a vaccine (even if one comes along in the near future) may not be the whole answer, as has been the case in the past with many other diseases, such as TB. Fostering and development of cooperation within and between countries—“joined up thinking”—with respect to prevention initiatives, travel health, the work of major British agencies such as the Royal Colleges and accreditation schemes such as Trent etc. is likely to prove fruitful. Medical tourism may become an important factor with respect to the spread of antimicrobial resistance around the world, and the UK is involved in this.

5. Economic and social deprivation are certainly key factors in our inability to eradicate these diseases. International cooperation of the sort which is being sought to control global warming would seem to be appropriate. Resources devoted towards development of vaccines, including improved vaccines for TB and commercially viable vaccines which currently don't exist such as malaria, hepatitis C, dengue and HIV might be fruitful, as this would assist with control.

6. The Royal College of Physicians & Surgeons of Glasgow is a charitable organisation. The College collaborates with the NHS, with other Royal Colleges and Faculties, with specialist societies, with universities (including medical schools), and through such collaboration seeks to create the optimal environment to tackle the four diseases, on all the relevant fronts including clinical, research and teaching/education. Within its

membership are specialists from various fields of infection, including infectious diseases, tropical medicine, travel medicine (including the Faculty of Travel Medicine), microbiology and virology. It also has surgeons and dentists among the membership.

The College is outward-looking, and fosters links overseas. It has a substantial number of members and fellows based overseas, and an active International Committee. The College hosts the MRCP(UK) and MRCS(UK) exams overseas, giving it substantial links and contacts in a wide variety of countries in all of the continents. The College supports and promotes research in infectious diseases and works to improve teaching and training of infection specialists.

7. "Health tourism" is an issue, which may be stimulated in part through poverty and lack of access to adequate treatment and clinical care. This can only be remedied through a world-wide initiative to improve people's standards of living and to help provide with access to adequate non-judgemental healthcare in their countries of domicile.

Despite years of public education, greater openness about and rational discussion of sexual issues and the problems associated with unsafe practices could still be achieved. HIV remains a sexually transmitted disease of great potency.

Better promotion in the UK of the speciality of Travel Medicine would be of assistance.

In many Far Eastern airports (eg Hong Kong, Singapore), the body temperature of arriving visitors is checked electronically as an initiative to help pick out patients potentially suffering from dangerous infections, such as influenza or SARS.

8. It is partly a function of greater international movement of human beings for whatever reason. While it is probably not a great contributor to case numbers at the moment, immigrant healthcare workers (including doctors) are sometimes found to have tuberculosis or HIV, and it would seem prudent to deal with this issue prospectively rather than wait till problems occur. The lack of an effective vaccine (BCG is a poor one) is an impediment.

9. Apart from prevention, diagnosis is the main factor. However, unless the condition is actively considered by the infected patient's doctor, it will usually not be diagnosed, as special tests have to be conducted to make a definitive diagnosis. This is an issue requiring improved training and education. It may be worth considering checking for TB among healthcare workers, including immigrants. Again the lack of an effective vaccine is a problem.

10. The control of mosquitoes and other biting arthropods does not only control malaria but also controls other important infectious diseases, such as dengue, elephantiasis, yellow fever, and numerous arboviruses (such as West Nile fever, which afflicted the USA very badly within the last few years). Whether or not the various international conventions are of value or not, the issue of vector control will require constant consideration and revisiting for the foreseeable future.

11. Influenza is important, but too narrow a focus may miss the problem. For example, H₅N₁ influenza may not turn out to be the main problem. Better vaccines, and ways of delivering vaccines, as well as new drugs for influenza to help combat the drug resistance problems which will inevitably develop, all merit attention. Robust international systems to spot trends in influenza and other relevant respiratory infections (SARS is an example) will remain important for the foreseeable future. It would be helpful to foster the strongest possible political and medical links with China and its associated territories (Hong Kong, Macau, Taiwan etc) as part of this process, as China is key in the influenza story (Royal College activities and UK sourced hospital accreditation may be able to help with this).

12. Resistance to antimicrobials (not just antibiotics but also antivirals, antimalarials and antifungals) is a growing phenomenon worldwide. As well as being driven by inadequate practice and different legislative approaches to healthcare around the world (eg "over the counter" sales of antimicrobials are the case in some parts of the world), such resistant organisms can be transferred around the world in or on the bodies of human beings. This phenomenon needs constant epidemiological surveillance. Continuing research into the development of new antimicrobial agents is vital. Vaccine development can help with this, as the use of vaccines effective against organisms with a tendency to manifest antimicrobial resistance can help prevent people acquiring the problem in the first place. An effective vaccine against *Staphylococcus aureus* (including MRSA) and *Clostridium difficile* may yield dividends.

13. Not enough. There is free passage of TB and HIV around the world, with very little testing for these conditions among people crossing international borders. The issue would benefit from serious, honest and open debate. Also, hospital acquired organisms can be transferred around the world in or on the bodies of human beings, for example during repatriation of patients from overseas. This issue again merits consideration.

14. We live in a market economy, and have to recognise that industry needs to make a profit and to reward its shareholders. Government investment in this area is valuable however, and greater centrally-led encouragement of UK hospitals and trusts to become more involved in research (not just concentrating on university departments) would open up enormous resources of expertise, manpower and patient numbers. Clinically-led research within NHS hospitals is currently not as common and productive as it should be.

15. This could be facilitated both through governmental cooperation, as well as through NGO cooperation (eg Royal Colleges, hospital accreditation groups). The Royal Colleges such as the RCPSGlasgow are major organisations in the educational field and possess world-wide high profiles. Also, the commercial sector can be of value here too, for example through the development of international consultancy in the field of healthcare utilising the special skills and knowledge of healthcare and related staff to educate and train overseas. The NHS could share more of its expertise with the rest of the world through this mechanism.

16. Public education, and the co-opting of the public as a rational partner in the control of infection, is key. Intelligent cooperation with the mass media, and rational use of the internet, will be of ever-increasing importance. The NHS and other relevant groups such as the Royal Colleges may benefit from greater training in the use of the mass media.

17. Humanity faces a global threat from this. Adequate training of healthcare and other relevant professionals (including police and military) to be able to spot episodes of potential deliberate release of infectious diseases into the UK is mandatory. The maintenance and development of appropriately located and adequately funded physical set-ups (eg isolation units, specialised ambulances, trained staff etc) to cope with such events is mandatory.

18. Attention to high quality surveillance systems, the training of adequate numbers of high-quality staff to operate such systems and to analyse and interpret the data generated, and better international cooperation would be valuable. Enhanced and effective cooperation between medical and veterinary, agricultural, pharmaceutical and other commercial organisations, and other relevant data collection bodies would be valuable.

19. Joined-up thinking with respect to the training of doctors and other healthcare workers, and the international dimensions, is key. The UK government would be wise to look at the extent to which the UK currently interacts with the training and professional development of healthcare colleagues domiciled in overseas countries, and look at how this potentially valuable resource could be optimised (eg Royal Colleges, hospital accreditation groups). The RCPSGlasgow has considerable overseas links in place and a strong track record in education and training.

20. Great Britain could take a lead of education and training, such as facilitating the dissemination of Royal College influence and thus spreading good practice, and good governance, around the world.

Research is important, but so is the education and training of staff.

An encouragement of the international movement of doctors would be valuable, for example allowing doctors domiciled outside the European Union to enter the UK for a period of time to allow them to acquire specialist training prior to returning home to take up their senior postings—this would allow greater exchange of information and insight between the different national medical groups working around the world and would facilitate networking between the UK and key groups elsewhere which would last for a long time. Such a state of affairs would be advantageous to efforts to control the international spread of infection and antimicrobial resistance. The British Postgraduate examinations, such as MRCP(UK) and MRCS(UK), have high international standing but are possibly becoming less popular outside of the European Union as doctors who are successful in these prestigious exams nevertheless have relatively small chances of being able to achieve postgraduate training in the UK to better equip them for a career in their own country. On the other hand, the USA encourages this type of activity, and welcomes overseas doctors into their country to train.

Also, the UK may find it helpful to look at the model of the Joint Commission in the USA, which is a private non-profit company which works both nationally and internationally to spread good practice in hospitals, including with respect to infection control. Accreditation helps to ensure quality and adequate standards within hospitals and healthcare provider organisations, and ensure their maintenance. The UK's NHS is well equipped to play this game, especially in countries with socialised medical systems, and is used to working in such a way that available resources are used most rationally—the Trent Accreditation Scheme, an experienced international accreditation scheme based within the UK NHS, is well-equipped to develop a similar international role to that of the Joint Commission.

Initiatives such as the Faculty of Travel Medicine and the International Committees of the various Royal Colleges also have a role to play in effective international infection control.

A rational look at the growing phenomenon of medical tourism is warranted, as this is growing in the UK and represents one means by which infection can spread around the world.

Tourism companies selling holidays overseas currently appear to have no clear duty (for example in their promotional literature) to warn their clients that they may be at risk of acquiring infectious diseases such as malaria—this may be worth consideration.

January 2008

Letter from the Royal Society

We were interested to note the recently launched inquiry into the effectiveness of action carried out through intergovernmental organisations to control the global spread of communicable diseases and considered that you may wish to note a joint study by the Royal Society and Academy of Medical Sciences on Pandemic influenza: science to policy.

The report of this study recommends actions that should be taken by intergovernmental organisations for improving the surveillance of avian influenza and data sharing including:

- the development by the World Organisation of Animal Health (OIE) or Food and Agriculture Organisation of the United Nations (FAO) of sentinel networks of farmers or villages in areas lacking animal disease surveillance infrastructure for outbreak reporting;
- the Department of Health and Defra, in collaboration with the World Health Organisation (WHO) should review the potential applications of the data collected in infectious disease surveillance generally; and
- the UK government should lead efforts to coordinate plans for real-time data collection and data sharing during a pandemic, at the EU, EU and G8, and WHO/UN level.

18 January 2008

Memorandum by Target Tuberculosis

INTRODUCTION

Target TB is a specialist agency which targets the causes and effects of TB. It was set up in 2003 in response to the growing crisis posed by TB but grew out of an older organisation, the Ryder-Cheshire Foundation, which had been running or supporting TB projects since 1966. At present the organisation works with 11 partner organisations spread across India, Pakistan, Bangladesh, Zambia, Malawi and East Timor. These are all countries with a high burden of TB. Our partners are all working within the National Tuberculosis Control Programmes of their countries. We provide partners with access to financial support and also help them to build their capacity to operate effectively. Through our partner network we aim to build up a stock of knowledge which can be used as examples of best practice in the planning and implementation of other TB control programmes. The principles which we share with our partners are that we are working to raise awareness of TB, helping people to find a diagnosis, supporting them through treatment and trying to break down the stigma associated with the disease. We recognize the close relationship between TB and HIV and encourage our partners to integrate services to address the impact of these dual epidemics. We are also working to address the poverty so closely associated with TB, for example by helping to train affected people in income-generating activities to improve their overall welfare.

THE ISSUES

The questions which the AHCIO has posed will be answered from the perspective of Target TB, and referring only to Tuberculosis, in the order in which they appear and with the same numbering:

1. It is certainly true that the earlier optimism that communicable diseases would be eradicated has been unfounded as we see more TB cases globally now than at any other time and, in some areas of the world, the rates of TB infection are increasing. It is true to say that the global situation is deteriorating and certainly not an exaggeration to say that there is a crisis. The crisis is exacerbated by the increasing incidence of drug resistance in TB which is reflective of poorly managed TB control programmes.
2. Data on TB infection are based on projections and estimates as it is the general belief of most people involved in TB control that we are not reaching many patients, hence there are no accurate figures for the extent of infection. As TB particularly affects countries with poorly developed, or declining, public health services the quality of data gathered is poor.

Numbers infected with TB are thought to be increasing and while the WHO believes that rates of infection have stabilized in most parts of the world the trend in sub-Saharan Africa is of rising rates. There is a particularly close association of TB with HIV so increasing rates of the latter directly affect the incidence of the former. This is compounded by reporting issues around dual diagnosis where reported AIDS deaths may also be reported as TB deaths. TB is also closely associated with poverty and it has been suggested that the most effective method of controlling TB would be to eradicate poverty. Even in countries with high rates of TB it is the poor who tend to become infected rather than the rich. Poor people are much more likely to be malnourished, living in crowded conditions and under stress caused by merely trying to survive all of which are likely to compromise immunity.

3. I can't comment on this in any detail

4. TB has confounded expectations and while there has been an expectation since the mid-20th Century that TB would be eradicated it has continued to grow in extent. Future spread of the disease is likely to be affected by the growing problem of drug resistance and the success or otherwise of public health developments throughout the world. Until TB is conquered wherever it is found it will remain a threat to all—see the theme for World TB Day 2007 “TB Anywhere is TB Everywhere”. The close association of TB and HIV has already been mentioned. We believe that while rates of HIV infection continue to rise, so will cases of TB related to HIV.

5. Poverty and the parlous state of the health services in many countries are major blockages. With greater prosperity we might see the development of more effective health services. I do not feel that health developments should be seen in isolation but need to be integrated into more general development programmes aiming at increasing prosperity throughout the world.

6. Target TB works, of course, to combat Tuberculosis but because of its close association with HIV and poverty it also work to address these associated issues. The principal work of the organisation is to educate people about TB, to encourage people to recognize TB symptoms, to help people obtain a proper diagnosis through recognized government health services and to support them through the long period of anti-biotic treatment. Target TB currently supports 11 projects in India, Bangladesh, Pakistan, East Timor, Zambia and Malawi and all are implemented through local partner organisations. An underlying principle of our work is that it should be integrated into and be complementary to the national TB control programmes of these countries.

We believe a holistic approach to combating TB is the correct approach. A medical approach to TB eradication is not enough, factors such as poverty which make people vulnerable to infection must also be considered. Social issues such as stigma and discrimination must also be tackled.

Target TB is a growing charity which relies on fundraised income. We have found that TB is a forgotten disease and many donors, including the general public, are unaware of the severity of the worldwide TB epidemic. This can make fundraising difficult, and core costs to support the organisation are always challenging. Nevertheless Target TB is very fortunate to have recently received significant grants from Big Lottery Fund, Comic Relief, and the states of Jersey, Guernsey and the Isle of Man which support our work.

Target TB collaborates closely with other organisations, this includes other UK and International NGOs, academic institutions, and governments in the countries in which we work. We encourage our partners to take the same approach within the TB control projects we support in order to avoid duplication of effort.

7. I have already mentioned the close association of poverty and TB. While the world's population continues to grow there will be a growth in the actual numbers of TB cases unless rates of TB can be reduced. As global warming seems destined to exacerbate poverty then I see it as a potential contributory factor to high levels of TB in future. Where global warming, for example in Bangladesh, appears to be contributing to flooding and the displacement of people who will be crowded together then I see that this will encourage the spread of TB. The displacement of people by natural or man-made disasters often precipitates outbreaks of TB, as we have found from work in a post-conflict environment in East Timor which has extremely high TB incidence rates.

Increasing international travel provides a means of spreading TB. In recent months, for example, there has been a high profile case in the United States of an individual with Extensively Drug Resistant (XDR) TB travelling on a number of international flights against the advice of his doctors. A case such as this does help to raise the profile of TB but can have negative effects such as causing panic amongst air passengers and demonisation of the patient. Relatively cheap international travel also allows immigrants in the UK to maintain close links with their countries of origin, where TB may be endemic, and this may account for relatively high levels of TB amongst certain groups. This is, again, a very sensitive issue and, in the wrong hands, an association between TB and immigration is unhelpful and possibly harmful to TB control efforts.

Intergovernmental action to address poverty should be undertaken as a priority. It is in TB, perhaps more than with any other disease, that improvements in the socio-economic conditions affecting people will have a greater impact than any other factor. This has already been proven when you looking at the decline in TB in the UK—the disease was already in decline due to improved socio-economic conditions, prior to the development of antibiotics to treat it.

8. Greater international travel may be a contributory factor in that people travel more than ever to areas of the world where TB is endemic. Immigration of people from high TB burden countries also raises issues around the increasing TB rates in the UK. TB in the UK is not an area in which Target TB has detailed knowledge and responses from organisations working in the UK such as TB Alert are able to address this issue more comprehensively.

9. Much of the work of Target TB is in ensuring the TB patients receive the medicines that they need and that they complete the full course of antibiotic therapy, through recognized health services. There are problems in some countries with intermittent supplies of drugs however these have largely been removed due to the Global Drug Facility.

The greatest problem with the current TB treatment is that it requires a combination of up to 5 drugs taken over a period of between 6 and 8 months. For some people the drugs cause major side-effects such as nausea and some patients are so weak that getting to clinics to collect their medicine is very difficult. Ensuring that people complete the full course is one of Target TB's main aims and much of our work focuses on training community volunteers who can support patients during this time. The situation would certainly be improved by the development of new drugs which can cure TB over a much quicker time.

Access to health services is also a major issue. Whilst some countries have excellent TB services, the ability of people to access these is often limited due to a large number of factors including geographic isolation, economic isolation and socio-cultural barriers.

The health services of many of the countries in which we work operate at minimal capacity, with staff and equipment shortages being major problems. Without trained medical staff with the necessary equipment to diagnose TB, access to the anti-TB treatment is again limited.

Again this suggests that a more holistic approach to tackling TB is needed, and any interventions to improve TB treatment must be coupled with efforts to reduce the barriers to accessing health services which can be very complex.

10. N/A

11. N/A

12. Increased drug resistance is a major problem. We believe this issue is also under-reported due to insufficient resources, such as testing equipment and trained personnel, to accurately assess levels. Resources to address drug resistant TB are even more limited than those for non-resistant TB, making any efforts to address this issue extremely difficult. Some intergovernmental action is being undertaken namely the funding of the Global Alliance for TB Drug Development. It is notable that pharmaceutical companies are having to be paid to undertake research into TB drugs rather than investing in this to any great degree with their own funds.

13. N/A

14. I believe that all TB treatments are now so old that they are not covered by patents.

15. Intergovernmental action which leads to a co-ordinated approach to all aspects of TB control would be welcomed.

16. I cannot comment in any detail.

17. I cannot comment in any detail.

18. I cannot comment in any detail.

19. I cannot comment in any detail.

20. No thank you

February 2008

Memorandum by TB Alert

QUESTION 1:

HIV, Tuberculosis and Malaria have been given high prominence within the context of the Millennium Development Goals (MDGs). Of the 8 goals, set by the UN General Assembly in 2000, 3 relate specifically to health; known as the health MDGs. There is wide-spread recognition, even from Margaret Chan herself (WHO Director General), that the goals least likely to be achieved are the health MDGs. The health goals are severely off track, particularly in sub-Saharan Africa where some indicators are now behind 1990 base-levels.

If the MDGs are to be achieved, considerable additional financing must be found and deployed immediately. The Commission on Health and Macroeconomics estimated that in order to achieve the health MDGs an additional \$27 bn would have to be made available by 2007—this target was not achieved. The Commission also stated that adequate investments in global health would equate to governments providing 0.1% of GNI as Official development Assistance (ODA) for health. The UK government currently provide 0.04% of GNI as ODA for health. Hence, within the UK context we would require an immediate doubling of ODA for health to meet the global financing target.

QUESTION 2:

The World Health Organisation produces a yearly Global Tuberculosis Control report which represents the best and most reliable source of epidemiological data on the TB pandemic.

QUESTION 3:

Tuberculosis is a notifiable diseases and the Health Protection Agency (HPA) is responsible for the surveillance of Tuberculosis in England and Wales. At local level, Consultants in Communicable Disease control (CCDCs), usually attached to Health Protection Units, are responsible for the management of TB cases in the public health context. Statutory notifications are sent to CCDCs, making them aware at early stage of emerging patterns of disease in their area. The system is however, entirely reliant on the diagnosing clinician completing the notification and on its website, the HPA acknowledges that “.. since 2001 there has been a decline in notifications and in 2002 cases reported through Enhanced Tuberculosis Surveillance exceeded NOIDs notifications for the first time. Recent trends in tuberculosis notifications should be interpreted with caution since the decline in notifications is not uniform across the country and is most likely attributable to changes in surveillance practice at local level”. It is also important to note that a notification only requires clinical suspicion of TB, rather than confirmed diagnosis. Confirmed culture diagnosis of TB can take up to six weeks, although liquid culture results can be returned in ten days. Were liquid culture standard in laboratories, improvements in accurately predicting outbreaks could be achieved.

QUESTION 5:

Since new reports by the United Nations and Action for Global Health highlight that European governments are failing to fulfill their commitments on improving health in developing countries, Gordon Brown's government can act now and show leadership within Europe by ensuring that at least 15% of all aid to developing countries is allocated to providing better health care for all.

Present global health inequalities mean that 28 times more children die before their fifth birthday in sub-Saharan Africa than in Britain. The Millennium Development Goals (MDGs), to be reached by 2015, are a one-off opportunity to change this and build the health systems of developing countries. Europe cannot stand by and let them fail.

The new report from Action for Global Health highlights that Official Development Assistance (ODA) to health from European governments is far below what is needed to achieve the health MDGs. Gordon Brown can show leadership by committing more money to ODA to close the gap, and by committing to allocate 0.1% of Gross National Income for global health by 2013.

QUESTION 6:

TB Alert works to increase access to good Tuberculosis treatment since, around the world, too many people die from lack of access to care. Too many people get inadequate treatment, raising the danger of multi-drug resistance.

TB Alert always looks to work through local partner organisations which themselves operate in close collaboration with the TB programme of the government health services. This is extremely important with an infectious disease like TB to ensure that our effort is a part of achieving good treatment for a whole country. To help ensure our relatively small funds have real impact we tend to concentrate on projects which support the community, nursing and paramedical aspect of TB programmes—adding a human and social dimension to good tuberculosis care.

In the UK our activities concentrate on raising awareness of TB to ensure that patients are diagnosed quickly, as well as helping patients to complete the minimum of six months-long treatment (non-completion can result in drug resistance). We work closely with the Department of Health, Health Protection Agency and NHS teams to try and ensure that materials and messages on the disease are consistent and feel that the work we share with these agencies has a very good degree of synergy.

QUESTION 7:

There are many factors involved in the global resurgence of Tuberculosis; in developing countries with high-TB incidence we often see a combination of mass urbanisation with sub-standard housing, overcrowding and poverty, as well as disrupted, under-resourced and overworked health systems. In the former Soviet countries a particular issue leading to a major increase in drug- and multi-drug resistant TB was the disruption and breakdown of the health system.

The government needs to prioritise long-term, sustainable investment in health systems in developing countries. It can do this by increasing the number of countries with which it has 10-year partnership arrangements, and use this as a model for investment by other European governments. The government should also structure its development policies and strategy on health around the health MDGs.

European countries contribute more than half of total official development assistance globally, and have a critical role to play in meeting the millennium development goals. Yet a report by Action For Global Health, a new partnership of 15 non-governmental organisations, shows that today only four out of 15 European countries are on track to allocate 0.7% of gross national income to official development assistance (Sweden, Luxembourg, Netherlands and Denmark).

European governments can still do their part to make the millennium goals a reality, but they need to act now by: closing the funding gap of \$27bn by 2009; allocating 0.1% of gross national income to address global health; and ensuring that any increases in funding prioritise the strengthening of health systems for long-term sustainability. Gordon Brown can take the lead by ensuring that at least 15% of all aid to developing countries is allocated to providing better healthcare for all.

QUESTION 8:

There were around 8,500 cases of TB reported in the UK in both 2006 and 2007, rather than the 6,500 cases stated in the question. In England and Wales alone, TB notifications have exceeded 6,500 each year since 2000. In 2004 70% of TB cases were diagnosed in non-UK born people. This reflects a broader pattern but is not in itself a simple explanation for the increase in the UK, since 77% of these cases are diagnosed more than two years after arrival—45% more than five years after arrival.⁴⁵ Black and Minority Ethnic communities need to be encouraged to access health services and to seek diagnosis; too often already heavy stigma surrounding TB within these communities is added to by the focus on blame attribution, as well as changes to access to the National Health Service affecting those without legal residency status.

In October 2005 the UK commenced pre-entry TB screening for those applying for visas in certain high-TB incidence countries. This is a policy not evidenced by epidemiology and, on the whole, port of or pre-entry screening is not supported by associated professionals⁴⁶. It may be appropriate for the government to consider instead a policy of “enlightened self-interest” and instead focus investment on reducing the burden of Tuberculosis in high-TB incidence countries which have strong migration links to the UK.

⁴⁵ Migrant Health, Infectious diseases in non-UK born populations in England, Wales and Northern Ireland. A baseline report, Health Protection Agency 2006.

⁴⁶ Port Health and Medical Inspection Review Report from the Project Team, Health Protection Agency, March 2006.

Furthermore, whilst a large proportion of cases come from the non-UK born population, it has been evidenced that in London, where approximately 40% of cases are diagnosed, those who pose a greater risk regarding transmission of the disease are more likely to be from the homeless, prison or substance misuse sectors⁴⁷. A pilot project (Find and Treat, Department of Health) is now underway in London which seeks to work closely with complex, hard to treat cases and support them through their course of treatment.

February 2008

Letter from UNICEF

With reference to the Call for Evidence of 10 December 2007, I am pleased to enclose the response of UNICEF.

UNICEF has already contributed to the detailed responses provided through UNSIC and UNAIDS. UNICEF also recognizes that the World Health Organization, UNSIC and UNAIDS are the most appropriate agencies to take the lead in providing detailed information and data in response to the issues raised in the Call for Evidence. Therefore, in the interests of avoiding duplicating the work of our partners, we have confined our response to describing UNICEF's specific contributions in the areas of HIV/AIDS, malaria and Avian Influenza, with a focus on Issue 6: *What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?* and we enclose our response accordingly.

UNICEF welcomes the opportunity to contribute to this important initiative of the United Kingdom Government in creating a new Select Committee of the House of Lords. UNICEF looks forward to seeing the results of this work and assures you of our willingness to contribute further information in future if required.

13 February 2008

Annex A

Issue 6. What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?

AVIAN INFLUENZA

What role does your organisation play in combating Avian Influenza?

UNICEF, as part of a coordinated UN response, has been supporting national governments in their response to avian influenza (AI) and pandemic preparedness since late 2005. The main area of work to date has been in communication for behaviour change and social mobilisation. UNICEF works closely with the UN System Influenza Coordinator (UNSIC) and contributed to the consolidated response on these issues to the committee.

Do you believe that it is correctly configured and adequately resourced to do the job?

Communication for behaviour change is a complex and challenging area that requires considerable resources to undertake. UNICEF was initially well funded to undertake this work, and was able to develop a range of resources. For the current year, resources are more limited.

With which other organisations do you collaborate? How would you assess the degree of synergy?

UNICEF has an extensive global presence with active field offices in all the countries with entrenched H5N1 virus circulation. UNICEF works with FAO and WHO, the lead technical agencies for animal and human health to ensure an appropriate and coordinated approach in its communication strategies. The relative strengths of the agencies can thus be used to good effect.

⁴⁷ Tuberculosis in London: the importance of homelessness, problem drug use and prison, A. Story *et al* for the London Tuberculosis Nurses Network, January 2007.

MALARIA

What role does your organisation play in combating malaria?

At global level, UNICEF is a key partner in malaria prevention and control. UNICEF is a founding member of the Roll Back Malaria partnership and is currently Vice-Chair of the RBM Executive Committee. UNICEF is an active member of several of the RBM Working Groups, and is Co-Chair of the Harmonization Working Group and the Monitoring and Evaluation Reference Group. At global level, UNICEF contributes to global advocacy, policy-setting, resources leveraging, partnership development and other “upstream” activities. Through its Supply Division, UNICEF is a major partner in procurement and supply of malaria commodities, particularly insecticide-treated nets. UNICEF is the largest procurer of nets worldwide, procuring around 24 million in 2006, 20 million in 2007. In 2007, UNICEF procured approximately 17 million artemisinin-based combination therapies for malaria treatment.

At Regional level, UNICEF supports policy development and resource mobilization and provides technical and implementation support to national malaria partnerships including through RBM sub-regional networks and other bodies.

At country level, UNICEF Country Offices in malaria-endemic countries are heavily involved in advocacy, policy setting, resources leveraging and implementation support to assist national partnerships to scale-up effective malaria prevention and control programmes and to develop community capacities to effectively recognize, prevent and treat malaria.

Much of UNICEF’s support to malaria control at country level is through integrated services for maternal and child health such as through antenatal care and with childhood vaccination programmes. Example of malaria control and prevention integrated into child and maternal health service include:

- Long Lasting Insecticidal Nets (LLINs) and Intermittent Preventive Treatment for pregnant women delivered through Antenatal Care and Prevention of Mother to Child Transmission services.
- LLINs through national integrated campaigns. Approximately 33 million nets are planned for distribution through campaigns in 2008.
- LLINs through routine immunization.
- Malaria treatment through IMCI (facility and community) including Home Management of Malaria.
- LLINs and access to effective treatment for children affected by HIV/AIDS.

UNICEF is also supporting operational research on Intermittent Preventive Treatment in infants in six sub-Saharan Africa countries.

Do you believe that it is correctly configured and adequately resourced to do the job?

Before the launch of Roll Back Malaria in 1998, malaria control was seriously under-financed and under-prioritised. International funding for malaria control has risen more than ten-fold over the past decade, with the most significant increases occurring in just the last few years. UNICEF resources in support for malaria programming come from a number of key donors including GFATM, PMI, World Bank, European Union, UNITAID and others. Prior to 2006, global shortages in malaria commodities, including insecticide-treated nets and artemisinin-based combination therapies were the principal bottlenecks to scaling-up malaria interventions. These bottlenecks have now been effectively addressed and there has been significant progress in scaling up malaria prevention and control with a renewed effort to achieve the malaria related MDGs. Some of the major challenges remaining are availability of secured and sustained financing to support and maintain scale-up. Increased donor harmonization in support of national malaria scale-up plans and in line with the 2005 Paris Declaration on Aid Effectiveness is a key factor in ensuring that the financing and technical support is available to national malaria partnerships. Additionally, it is becoming increasingly important to improve access to malaria prevention and treatment through integrated community based interventions, including community capacity development and enhanced social and behaviour change communication.

With which other organisations do you collaborate? How would you assess the degree of synergy?

UNICEF collaborates with all major malaria partners through the Roll Back Malaria partnership, at all levels, including the GFATM, WHO, World Bank, PMI, NGOs and private sector, with much of the work co-ordinated around national plans, and through the RBM harmonized workplan and global strategy. The collaborations described ensure a high degree of synergy in malaria programming between major partners.

HIV/AIDS

What role does your organization play in combating the four diseases?

UNICEF's engagement in the response to HIV/AIDS began in 1996 with a focus on prevention of HIV among young people and the prevention of mother to child transmission of HIV in 11 pilot countries. Based on lessons learnt in 2005, UNICEF, UNAIDS and partners launched Unite for Children, Unite against AIDS to put children more prominently on the global AIDS agenda. Unite for Children, Unite against AIDS offers a practical and useful programming framework around prevention of mother to child transmission of HIV, pediatric treatment, HIV prevention among adolescents and protection and care for children affected by AIDS. While UNICEF's work in the area of PMTCT and pediatric treatment are health-related interventions, its efforts in HIV prevention among adolescents and care and support for children affected by AIDS address the structural and social drivers of AIDS, such as facilitating access to education for boys and girls, supporting access and use of HIV information and services, mitigating the impact of AIDS on children and households. At headquarter, regional and country level UNICEF provides advocacy, technical, financial and procurement support.

Do you believe that it is correctly configured and adequately resourced to do the job?

UNICEF is one of the ten co-sponsor agencies of the UN Joint Programme on AIDS (UNAIDS) and works through regional and country offices, structures and mechanisms that include the interagency task teams (IATT) and Joint UN teams on AIDS that are facilitated by the UNAIDS Country Coordinators. UNICEF is correctly configured but under-resourced to provide adequate support to significantly scale up responses that address the needs of children and young people living and affected by HIV/AIDS.

With which other organizations do you collaborate?

The work of the 10 UNAIDS Cosponsors is coordinated by the UNAIDS secretariat. UNICEF in particular collaborates with bilaterals, national governments and with a number of NGOs, faith based organizations and the private sector at headquarters, regional and country level through various mechanisms such as the inter-agency task teams, global partner forums as well as through formal agreements such as memorandum of understanding and country and regional programmes.

How would you assess the degree of synergy?

The UN Joint Programme on AIDS (UNAIDS), comprising 10 UN Co-sponsors and the UNAIDS Secretariat offers a unique framework for joint action on AIDS. Over the last couple of years UNAIDS and stakeholders worked towards strengthened coordination, alignment and harmonization in the context of the "Three Ones", the UN Reform and Global Task Team recommendations for making the money work for universal access to prevention, treatment, care and support. Scaling up interventions at the country level remains challenging. Partnerships that focus on the provision of comprehensive multisectoral responses to AIDS are essential and need to be further strengthened if the MDGs are to be achieved by 2015.

Memorandum by the United Nations Association of the UK (UNA-UK)

UNA-UK'S SUBMISSION OUTLINES HOW DIFFERENT AGENCIES IN THE UN SYSTEM PLAY PIVOTAL ROLES IN COMBATING AND CONTROLLING THE SPREAD OF COMMUNICABLE AND INFECTIOUS DISEASE, AND THE NEED FOR STRONG CONTINUING SUPPORT FOR COORDINATED ACTION AT AN INTERNATIONAL LEVEL

INFECTIOUS DISEASE—"A PROBLEM WITHOUT A PASSPORT"

1. Intergovernmental organisations are fundamental to formulating effective strategies for preventing the spread of infectious and communicable diseases. Communicable and infectious diseases are easily transmitted in today's interdependent world; they are spreading geographically much faster than at any time in history. Since 1967, at least 39 new pathogens have been identified. Other old threats, such as pandemic influenza, malaria and tuberculosis, continue to pose a risk to health through a combination of mutation, rising resistance to medicines and weak health systems. Many other diseases, long considered eradicated or non-fatal in the developed world—remain prevalent in developing countries.

THE WHO—ITS CENTRAL ROLE IN SAFEGUARDING INTERNATIONAL PUBLIC HEALTH

2. The WHO coordinates national and international efforts to contain public health emergencies and protect global health security. In 2003, for example, WHO's leadership was pivotal in stopping the spread of SARS.
3. The WHO builds country-level capacity to detect and respond to outbreaks of disease through the provision of technical support and ethical evidence-based policy options. The WHO generates and disseminates health research, helping to identify priorities.
4. The WHO monitors the evolution of infectious diseases, providing early warning about actual or potential outbreaks of disease. WHO has unrivalled access to ministries of health and national statistical institutions, enabling it to provide region-specific analyses of data on health trends.
5. The WHO sets international norms and standards in public health. This helps standardise the terminology used for the diagnosis and treatment of diseases, as well as for substances, technologies, methods and procedures, making possible the comparison of data on a worldwide basis. The WHO International Health Regulations establish rules that countries must follow to identify disease outbreaks and stop them from spreading.

THE WHO—ITS RECORD OF SUCCESS

6. As the only organisation with a truly global reach the UN—and specifically its World Health Organization (WHO)—is best equipped to meet such pervasive threats to international public health. Its successes are notable and concrete. By 1980 a WHO-led effort had eradicated smallpox, saving an estimated \$1 billion per year in vaccination and monitoring costs—a return of almost 300%. Over the last two decades, over 20 million lives have been saved through immunisation campaigns against preventable diseases. Immunisation rates for the six major vaccine-preventable diseases—polio, tetanus, measles, whooping cough, diphtheria and tuberculosis—have risen from under 5% in the early 1970s to about 76% today. Deaths from measles declined by approximately 50% from 1999 to 2005. Immunisation against tetanus saved hundreds of thousands of mothers and newborn children, and 104 developing countries have eliminated the disease altogether.

CONTINUING PROGRESS TOWARDS ERADICATING INFECTIOUS DISEASE—THE EXAMPLE OF POLIO

7. The WHO and its partners (including UNICEF, Rotary Club International and the US Centers for Disease Control and Prevention) are currently on the verge of eradicating poliomyelitis (polio), a disease now largely eliminated but endemic in four countries. Polio is a highly infectious viral disease which mainly affects young children. The virus is transmitted through contaminated food and water, and multiplies in the intestine, from where it can invade the nervous system. Many infected people have no symptoms, but excrete the virus in their faeces, thus transmitting infection to others. In a small proportion of cases the disease causes paralysis, which is often permanent and can lead to death. There is no cure for polio—it can only be prevented by immunisation: polio vaccine, given multiple times, can protect a child for life. It is estimated that just \$1 is needed to immunise a child for life.
8. WHO and its partners have immunised more than two billion children worldwide. In 2005 alone, more than 400 million children were immunised in 49 countries. This is testament to the WHO's global reach, and its ability to penetrate even the most remote areas or regions affected by conflict.
9. WHO's efforts have produced clear results: the number of cases of polio has been cut by more than 99%—from an estimated 350,000 cases in 1988 to 1,951 in 2005. As a result, five million children are today walking, who would otherwise have been paralysed, and more than 1.5 million childhood deaths have been averted.

THE NEED FOR EVEN STRONGER INTERNATIONAL COORDINATION

10. But as long as anyone is infected with polio, there remains a risk that the disease could become resurgent. The virus could easily be imported into a polio-free country where it could spread rapidly through an unimmunised population. Between 2003 and 2005, 25 previously polio-free countries were re-infected due to importations. In 2007, the world's four remaining endemic countries (Afghanistan, India, Nigeria and Pakistan) and the six re-infected countries (Angola, Chad, Democratic Republic of Congo, Niger, Myanmar and Somalia) continued to report cases.
11. Thus, the WHO and other relevant parts of the UN system (see below) will remain key to effectively addressing the threat of infectious disease. The WHO's greatest strength is its international legitimacy, which stems from its perceived political neutrality, and its efficacy and expertise in international public health matters. In combating communicable and infectious disease, from polio to SARS, the WHO is able to

intervene in the domestic affairs of states in a way that would be unthinkable if conducted by another country or non-governmental actor. In the case of the SARS outbreak of 2003, the WHO combined scientific and technical assistance with frank but well-judged public criticism of China's early treatment of the disease, and was able to effect a significant policy change by the Chinese government. This was a major accomplishment and potentially prevented a large-scale international epidemic.

UNAIDS—THE JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS

12. UNAIDS provides coherent leadership within global efforts to combat HIV/AIDS. It draws on expertise across the UN family, bringing together ten UN system organisations which act as co-sponsors of UNAIDS: the ILO, UNDP, UNESCO, UNFPA, UNHCR, UNICEF, UNODC, WFP, the WHO and the World Bank.

13. UNAIDS supplies countries with strategic information and technical assistance to strengthen and guide national AIDS responses. It is the leading resource for AIDS-related data and analysis. UNAIDS policy recommendations promote a rights-based approach to HIV/AIDS with a dual focus on reducing stigma and on legal reform to protect the rights of people living with HIV, the rights of women, and the rights of marginalised groups.

14. UNAIDS undertakes surveillance of the epidemic and evaluates the efficacy of responses to it. More than 50 UNAIDS country advisers help strengthen national monitoring and evaluation capacity by building local expertise in the collection, analysis and interpretation of data.

15. UNAIDS fosters broad partnerships in efforts to tackle HIV/AIDS, harnessing the energies and complementary strengths of governments, civil society organisations, the private sector, and labour organisations. UNAIDS also mobilises celebrities, special envoys and the media to keep AIDS a priority issue on the global political agenda.

16. UNAIDS mobilises financial, human and technical resources for HIV/AIDS initiatives. One way it does this is by helping countries access funds from the Global Fund to Fight TB, Malaria and HIV/AIDS. UNAIDS also tracks expenditure on AIDS and issues projections of resources needed, giving donors a precise understanding of funding gaps.

UNAIDS—EXAMPLES OF HOW IT STRENGTHENS NATIONAL HIV/AIDS RESPONSE

17. In 2006, UNAIDS and the Jamaica Council of Persons with Disabilities ran a country-wide programme to ensure that information on HIV prevention, treatment and care was available to deaf women and girls. UNAIDS assisted the Belarusian ministry of internal affairs in formulating a comprehensive HIV prevention programme for prisons. In Mauritius, UNAIDS helped develop the HIV Preventive Measures Act, which mandates the implementation of a national programme for needle exchange and an expansion of access to voluntary and confidential HIV testing and counseling. And in Croatia UNAIDS helped conduct a legislative review to identify gaps in protection for HIV-positive people and determine whether any provisions discriminated against them.

UNFPA—THE UNITED NATIONS POPULATION FUND

18. UNFPA defends reproductive rights and promotes better reproductive health for all, with a focus on women and girls. UNFPA works with local and national governments to formulate development strategies which encourage postponement of marriage, girls' retention in schools, and sexual and reproductive health education in school curricula.

19. UNFPA equips young people to protect themselves from HIV/AIDS. Every day, 14,000 young people are newly infected, half of whom are under the age of 25. UNFPA provides "safe spaces" where adolescents can access information about HIV/AIDS, receive counselling and undergo voluntary testing.

UNFPA—AN EXAMPLE OF ITS RIGHTS-BASED APPROACH TO HIV PREVENTION

20. Female condoms represent the only existing female-controlled means of effectively preventing pregnancy, HIV and other sexually transmitted diseases. Yet use remains low—including in those countries hit hardest by the HIV epidemic. Greater investment is needed in order to increase the supply and affordability of female condoms; advocacy is needed to stimulate demand for them. Studies show that increasing use of the female condom would be a cost-effective public health intervention: a model focusing on South Africa, for example, forecast that, at a unit cost of \$0.77 and assuming an uptake of 4 million, 1,740 HIV infections could be

prevented, with a net saving to public health care of \$980,000. Preventive HIV strategies are estimated to be 28 times more cost-effective than treatment.

In 2005, UNFPA and partners launched a multi-year effort to scale up availability of female condoms by working with governments to develop and improve female condom programming. In 2006, 23 countries were participating in the initiative; 15 of these had established “national condom programming teams”, tasked with identifying means of scaling up supply and distribution of female condoms, and in four countries the health ministry had appointed national condom coordinators.

As a result of these efforts, the global procurement of female condoms increased by 41%.

UNICEF—THE UNITED NATIONS CHILDREN’S FUND

21. UNICEF promotes young child survival and development. Every year an estimated 9.7 million children under the age of five die of entirely preventable causes like pneumonia, diarrhoea and malaria. To prevent unnecessary maternal and child deaths and reduce undernutrition, UNICEF undertakes proven interventions which are low-cost but high-impact: for example, vaccines, antibiotics, micronutrient supplementation, insecticide-treated bednets, improved breastfeeding practices and promotion of safe hygiene practices.

UNICEF—AN EXAMPLE OF ITS IMMUNISATION WORK IN SOMALI

22. The absence of a functioning government in Somalia poses huge challenges for the provision of essential health services to the country’s population. Social indicators for Somali children are among the worst in the world. One in eight dies before the age of five, one in three is chronically malnourished and just 30% goes to school. Almost no children under the age of five have received the full recommended course of vaccinations.

UNICEF is the world’s largest provider of vaccines for developing countries and reaches 40% of the world’s children. In December UNICEF immunised 100,000 children and women living in camps in the Afgoye-Mogadishu corridor in southern Somalia. UNICEF uses immunisation as an opportunity to maximise the positive impact of the intervention on the child: in addition to vaccinating children under five against measles, polio, diphtheria, tetanus and tuberculosis, UNICEF administers vitamin A to boost immunity and gives iron supplementation and tetanus toxoid immunisation to women of reproductive age.

In this way UNICEF and WHO plan to reach 3.5 million Somali women and children over the next two years and estimate that this will cost \$15 per person.

21 January 2008

Memorandum by the United Nations High Commissioner for Refugees

1. UNHCR is very pleased to have the opportunity to contribute to the Committee’s review of the effectiveness of action undertaken by international organizations in response to the global spread of communicable diseases.
2. Because of his mandate and responsibilities vis a vis the refugees and internally displaced persons, UNHCR will limit its evidence to refugee communities assisted through care and maintenance programs delivered mainly in camps.
3. UNHCR doesn’t have an intergovernmental approach and its programs are linked to an inter Agency perspective mainly with its traditional partners in operations, WFP, UNICEF and WHO.
4. UNHCR is not in a position to give appropriate answers to most of the questions listed as issues in the Call for Evidence and will present its Evidence by treating each of the four main infectious diseases to be considered, Tuberculosis, Malaria, HIV and Avian Influenza, separately.
5. UNHCR delivers public health program to Refugees accommodated in camps through medical implementing partners, Non governmental Organizations, NGOs, for most of them, having a medical presence and capacity at camp level. Public Health programs implemented are always in full compliance with the objectives and the policies of the National Health Plan elaborated by governmental authorities in a given country.
6. Refugees and other Persons of Concern, PoC, to UNHCR are unique groups which often have special needs due to their circumstances (eg trauma and violence including sexual violence, different languages and cultures, issues related to durable solutions, dependancy upon external support and limited economic opportunities). Existing policies, guidelines and protocols for persons in resource-poor settings may need to be modified accordingly and in some cases specifically developed.

TUBERCULOSIS

7. Tuberculosis (TB) is a major global public health problem that causes an estimated two million deaths annually. These deaths comprise 25% of all avoidable adult deaths in developing countries. The incidence of TB globally is increasing by 1% per year. Co-infection with HIV is a major contributing factor in many countries, mainly those of sub-Saharan Africa. Today, TB control is complicated by the emergence of multi drug-resistant (MDR) TB, particularly in countries of the former Soviet Union. However, substantial progress has been made in the implementation of effective TB control programmes in a growing number of countries worldwide.

8. Refugees and internally displaced persons (IDPs) are at increased risk of developing TB and often have poor access to anti-TB treatment. Conflict is the most common cause of population displacement, which often results in relocation to temporary settlements (camps). Malnutrition and overcrowding in camp settings further increase their vulnerability. For example,

- (a) In 1985, 26% of deaths among adult refugees in Somalia and between 38–50% of all deaths among refugees in camps in eastern Sudan were attributed to TB.
- (b) In north-east Kenya in 1994, the incidence of new infectious TB patients in camps was four times the rate in the local population.
- (c) In Ingushetia in 2000, the TB notification rate for displaced Chechens was almost twice as high as the resident Ingush population.

9. A TB control programme should be implemented only if the security situation is sufficiently stable to enable implementation of activities (especially short-term therapy) and if no major movements of the camp or the population served are anticipated in the near future; otherwise drug resistance may occur. At a minimum, programme funding should be sufficient to enrol patients for 12 months (although short term therapy is for six months in many countries) and complete the treatment of all members of this cohort—a minimum of 18 months.

10. To provide guidance to humanitarian agencies (eg NGOs) on the implementation of effective TB programmes for refugees and IDPs, WHO and UNHCR collaborated to produce an interagency field manual (1st edition 1997, 2nd edition 2006). Its aim is to encourage implementation of TB control programmes in these populations wherever possible, while ensuring they meet accepted standards of quality and outcome. Despite the challenges of these settings, experience over the past 10 years in the implementation of TB control programmes has shown that they can be effectively diagnosed and treated among these vulnerable populations.

11. The basis of an effective TB control programme is the WHO “Stop TB” Strategy. The goal is to dramatically reduce the global burden of TB by year 2015 in line with the Millennium Development Goals and Stop TB Partnership targets. This new strategy has six components, one of which includes five basic key elements—the most relevant in refugee and IDP situations:

- Political commitment and sustained financing.
- Case detection through quality-assured bacteriology.
- Standardized short-course chemotherapy with supervision and patient support.
- Effective drug supply and management system.
- Monitoring and evaluation system, and impact measurement.

12. TB activities in the refugee camps are **always** implemented in line with the National TB Programme (NTP). The NTP often provides medicines, other supplies and technical support to the refugee programmes. In turn the refugee programmes facilitate travel of NTP Officers. Similarly, urban refugees access TB treatment from the national programmes, although language and other barriers limit access of refugees to these services. The characteristics of the NTP in the country of origin should also be taken into consideration if refugees are likely to be repatriated. Inter-country coordination in the planning stage is critical to minimise the risk of patients interrupting treatment when camps or populations are moved.

13. The priorities of a TB programme are first to identify and treat infectious TB patients and those with severe forms of the disease. The diagnosis and cure of infectious TB cases is the most effective method of preventing TB transmission and controlling the disease in the community. Due to limited investigation capacity in the camps, admission of patients to the programme is based on sputum testing. Clinical judgment is used for admission of under-five children and for those with extra-pulmonary disease.

14. Many refugees and displaced persons may come from, or seek refuge in, countries with a high prevalence of infection with HIV. The prevalence of HIV among the refugees in Kenya is lower than that of the surrounding population (5% vs. 12%) while in Tanzania, it is similar to that of the surrounding local

populations (between 5-10%). Although accurate data are not available, the incidence of TB has increased in the past several years. Hence TB/HIV co-infection may be prevalent in these populations. TB is among the leading cause of death among people infected with HIV worldwide. In some countries, particularly sub-Saharan Africa, up to 70% of TB patients are co-infected with HIV. Patients diagnosed with TB should be offered and HIV test and conversely, those diagnosed with HIV should be screened for TB. TB patients co-infected with HIV respond well to standard anti-TB treatment. UNHCR HIV/AIDS Strategy puts high emphasis in the coordination of HIV/AIDS and TB control programmes.

15. Provision of food may be important in TB programmes in malnourished populations and can serve a useful function as an incentive to support adherence and treatment completion. The treatment in the camps is based on directly observed therapy (DOTs) strategy where patients are required to take the medications under observation, at least during the intensive phase. To support this policy, the refugee programmes provides supplementary food to TB patients in the intensive phase.

16. Cure rates in the camps are generally close to the national targets of 85% (the data available for 2006 shows a cure rate of 92% in Tanzania, 88% in Kenya, and 89% in Ethiopia). However, case detection rates and smear positivity rates are generally lower than the national targets, thereby, reflecting the need for the refugee programme to improve these areas and strengthen coordination and monitoring of these activities. For example in Tanzania the number of cases detected in the camps represents only the 50% of the ones expected. In Kenya the detection rate could reach the 79%.

17. In camps, most patients are treated and followed up as outpatients, while those who are severely ill and cannot walk to clinics, and those who are smear positive with bacteria count of 3+, are kept in the TB wards for a limited period of time.

18. TB programmes continue to focus on treatment of sputum positive patient, who transmit the disease to other persons, and much less on sputum negative patients who might be also suffering from TB. Chest X-rays are not routinely used for diagnosis (because they are not available in most refugee and IDP situations) and thus, clinical evaluation of the progress of the patients is undertaken. Therefore, although the refugee programme lacks behind the national target in the case detection rate, the cure rate is quite commendable.

19. In West Africa, for the overall repatriation activities of Liberian refugees, TB is apart of the repatriation health plan. Returnees are accessing the TB national Program units, as the rest of population. In 2006, the National Program in Liberia treated 3,452 cases of TB (68% smear positive pulmonary TB). The outcome of the cohort registered 9- 12 months earlier showed a treatment success rate of 80%. In Ghana in 2006, a total of 168 cases were detected among refugees in the camps (90% smear positive pulmonary TB). All of them were taken in charge by the National TB Program. The outcome of the cohort registered 9- 12 months earlier showed a treatment success rate more than 95%.

20. Programme implementation may be interrupted as a result of unplanned population movements or breakdowns in security. The unique problems of continuity faced by programmes delivered under insecure circumstances must be taken into account; firstly in the decision to institute a programme and secondly in contingency plans adapted to the specific situation. For example:

- (a) During a prolonged period of low intensity war and recurrent insecurity in south Sudan in 2001, arrangements were made to prepare for each patient at programme entry a "runaway bag" containing one month's supply of anti-TB drugs. The runaway bags could be rapidly distributed in the event of insecurity when expected to last more than a few days. Contingency plans were made to contact local staff on the ground and arrange regrouping to resume treatment within a month.
- (b) In Maela refugee camp in Thailand, a TB programme began in 1997. To ensure treatment compliance, TB patients were admitted to a "TB village" next to the camp where they stayed with their family for the whole duration of treatment. They were housed in bamboo huts similar to the ones in the camp. Food was provided by the programme during the entire duration of treatment. As for all health services, TB diagnosis and treatment were free of charge. Regular health education messages were provided. Treatment was given daily under strict supervision by medical personnel.

21. Although most patients are expected to complete treatment at the site in which they began the treatment, a plan should be devised to deal with patients who transfer into or out of the programme. It is very important that continuity of treatment occurs during and post movement. Contact with the new treatment centre should be made by the clinic staff, if possible, prior to transfer. Forward planning and liaison between staff is particularly important if a large population is being transferred. For example, in 2003, Eritrean refugees on TB treatment who were repatriating from Sudan were provided with 4 weeks of medications and followed up by the NGO in Sudan, to be linked into the Eritrea's NTP once they reached their final destination.

MALARIA

22. Malaria remains an important cause of illness and death among refugee and displaced populations. The majority of today's refugees live in malaria endemic areas, this situation has not been reversed during the last years, in the contrary, and some new factors as climate change, natural disasters and population displacement have triggered changes in mosquito behaviors and malaria epidemiological profiles in different countries. Still of the almost 33 million persons of concern to the office of the United Nations High Commissioner for Refugees (UNHCR), almost two-thirds (63%) live in malaria endemic areas.

23. Many factors may promote vulnerability to malaria illness and death among refugees. Pregnant women and young children are particularly at risk of severe illness and death: women of child bearing age and children make up the majority of the population in many refugee situations. Refugee camps are often sited on marginal lands that promote breeding sites for malaria vectors. Refugees may be malnourished, particularly in the phase immediately following flight. Travel may take refugees through or to areas of higher malaria endemicity than their place of origin. Control programmes may have broken down (associated with the conflict that caused population flight) or never been implemented.

24. A significant change in approach to malaria control, particularly in Africa, has taken place over the last decade. Funds for malaria control have become available on a scale not seen since the days of the eradication campaign 50 years ago. These new resources are being used largely to support a supply of artemisinin combination therapy to replace ineffective chloroquine and sulphadoxine pyrimethamine for first line treatment of malaria and for the provision of long-lasting, insecticide treated bednets.

25. Intermittent preventive treatment in pregnancy (IPT) has been shown to be of significant benefit in reducing potential malaria-related pregnancy complications in moderate to high transmission settings. The AIDS epidemic interacts with malaria: HIV infection increases susceptibility to malaria and has an adverse effect during pregnancy. Malaria may increase the viral load of HIV infections.

26. The globally-accepted "best practices" for malaria control incorporating a mix of the SPHERE⁴⁸ common standards for intervention and WHO-endorsed malaria specific interventions,⁴⁹ are reflected in the eight key strategic objectives.

The key objectives are as follows:

- (a) Protection: To protect the right of UNHCR's Populations of Concern (PoCs), with specific reference to malaria.
- (b) Coordination, Integration, and Partnership: To effectively coordinate and integrate malaria control policies and programmes in a multi-sectorial approach for PoCs by strengthening and expanding strategic partnerships with key stakeholders, including implementing partners.
- (c) Advocacy: Increase awareness, knowledge, and recognition within UNHCR, governments, donors, and other decision makers on the negative impact of inadequate malaria control on the survival, development, and quality of life of PoCs. To mobilize resources, internally and jointly with partners, with an emphasis on non-traditional UNCHR donors to enable achievement of the multi-year objectives of this strategic plan.
- (d) Access to Early Diagnosis, Prompt and Effective Treatment, and Prevention: To ensure that UNHCR PoCs living in the malaria endemic areas have access to prevention, early diagnosis, and prompt and effective treatment, according to international standards.
- (e) Durable Solutions: To develop and incorporate malaria control strategies and interventions into policies and programmes for durable solutions.
- (f) Capacity Building: To build and strengthen specific malaria-related knowledge and skills as well as to provide necessary technical tools to PoCs and those staff working with them.
- (g) Assessment, Surveillance, Monitoring and Evaluation, Operational Research: To regularly monitor and report on the status of malaria within the PoC population to inform programmatic planning and implementation in a timely manner. To evaluate programme performance and achievements using a results-based management approach. To develop and carry out operational research on new approaches and technologies in malaria control.
- (h) Participation: To promote beneficiary participation in malaria control programmes.

⁴⁸ Sphere Project, Humanitarian Charter and Minimum Standards in Disaster Response, The Sphere Project, Geneva, 2004.

⁴⁹ World Health Organization (2005) Malaria control in complex emergencies: an inter-agency field handbook. Geneva: World Health Organization.

HIV/AIDS

27. There are an estimated 20.8 million refugees and displaced persons globally, many of whom reside in countries heavily affected by AIDS. Approximately four million of these persons live in sub Saharan Africa. Displacement as a result of conflict or other disasters can increase vulnerability to HIV by reducing access to HIV prevention services, information, and commodities. Basic HIV-related health care may not be available and people may become vulnerable to HIV infection. In addition, social support networks are often disrupted, exposure to sexual violence may be increased, and poverty may lead to the exchange of sex in return for food or shelter.⁵⁰ However, displacement may reduce the transmission of HIV due to reduced mobility to high prevalence areas; isolation and inaccessibility of some displaced populations; and in some circumstances, especially in the post-emergency phase, the availability of better protection and other HIV-related services than in countries or areas of origin. The extent to which UNHCR's POCs are adversely affected by HIV has been increasingly examined in recent years. There is now adequate evidence demonstrating that in many situations HIV prevalence among populations affected by conflict and displacement is not necessarily higher than that of the surrounding host population; on the contrary it is lower in many settings.

28. To support and promote HIV and AIDS policies and programmes in order to reduce morbidity and mortality and to enhance the quality of life among refugees, IDPs, returnees and other POCs to UNHCR, Eight HIV/AIDS Strategic Objectives have been identified:

- Protection—To ensure that the human rights of UNHCR's POCs are protected in HIV/AIDS prevention, treatment, care and support programmes.
- Coordination, integration and partnerships—To coordinate and effectively integrate HIV/AIDS policies and programmes in a multi-sectoral approach for POCs by strengthening and expanding strategic partnerships with key stakeholders.
- Advocacy—To advocate for UNHCR's POCs to be integrated into HIV-related policies and programmes within UNHCR, Government, donors and by other decision makers.
- Prevention—To reduce HIV transmission and morbidity through scaling up effective prevention interventions to UNHCR's POCs with an emphasis on community participation, especially among women, children and people with special needs to ensure they have access to HIV prevention information and services.
- Care, support and treatment—To ensure that POCs living with HIV and AIDS have access to timely, quality and effective care, support and treatment services including access to anti-retroviral therapy at a level similar to that of the surrounding host populations.
- Durable Solutions—To develop and incorporate HIV/AIDS strategies and interventions into policies and programmes for durable solutions in order to mitigate the long term effects of HIV and AIDS.
- Capacity Building—To build and strengthen HIV/AIDS knowledge and skills as well as to provide necessary technical tools to POCs and those staff working with them.
- Assessments, surveillance, monitoring and evaluation, operational research—To ensure that data on UNHCR's POCs are reflected in national HIV surveillance, monitoring and evaluation systems, to monitor and report on a regular basis POCs's access to HIV prevention and treatment programmes in camp situations, to evaluate programme performance and achievements using a results-based management approach, and to conduct operational research on new approaches to providing HIV prevention and treatment services to refugees and displaced populations.

AVIAN INFLUENZA

29. UNHCR has the mandate and humanitarian responsibility to ensure preparedness and pandemic mitigation for refugees and other persons of concern (eg refugees, internally displaced persons (IDPs), asylum seekers and returnees). A majority of these persons in camps are hosted by countries where the management and response to the avian and human influenza (AHI) pandemic threat is already an enormous task to meet the needs of the national population. While it is possible that urban refugees will be included in national plans, extension of planning and implementation of preparedness and mitigation measures to camps is unlikely. It will be incumbent on UNHCR to be the convening agency in such refugee settings to ensure timely and efficient management of the situation.

⁵⁰ UNAIDS and UNHCR (2005) Strategies to support the HIV related needs of refugees and host populations, Geneva.

30. Taking into account the environment as well as in many cases the poor living conditions and access to general services, refugees and populations displaced by conflict may be particularly vulnerable to a human influenza pandemic, especially in countries which have weak infrastructure to deal with such a pandemic.

31. High population densities in refugee settings combined with close habitation with livestock and poor nutrition, barriers to accessing health facilities, high prevalence of other communicable diseases, poor sanitation, remoteness of locations (many within active conflicts), poor links to national disease surveillance systems and the lack of trained staff to investigate and detect clusters could result in higher infection and mortality rates than in other populations.

32. In the event of a pandemic, limited resources for infection control and disease management are unlikely to be directed towards refugees and other persons of concern to UNHCR. Communication efforts may not take into account specific linguistic and cultural needs. Refugees and other persons of concern risk being stigmatised or blamed for diseases transmission. Restriction of population movements and quarantine of whole camps may follow, without logical or understandable justifications. Without strong advocacy, refugees, IDPs and other persons of concern to UNHCR risk being excluded from national and regional AHI preparedness planning.

33. UNHCR, together with the host Government, will be responsible for protection and assistance activities of refugees if an influenza pandemic occurs. Although UNHCR normally seeks to implement these programmes through an implementing partner, there are circumstances in which it may be necessary or clearly in the interest of refugees for UNHCR to assume greater operational responsibility.

34. In order to limit the negative impact of a potential AHI pandemic, the UNHCR Country Offices, in coordination with national governments and UN country teams, are already actively working on the preparation of country-level contingency plans dealing with both staff and beneficiaries.

1 February 2008

Letter from United Nations Population Fund (UNFPA)

I am writing with reference to your email communication of 5 February requesting a response to the Call for Evidence of 10 December 2007.

As you know, on 21 January 2008, a joint response of the Joint United Nations Programme on HIV/AIDS (UNAIDS) was forwarded to Mr. Preston. UNFPA, The United Nations Population Fund, as one of the 10 cosponsor agencies of UNAIDS was very much involved in that response. The detailed response is attached for your convenience.

However, given the importance of linkages between sexual and reproductive health and HIV, we would like to take this opportunity to provide some additional detail regarding the recommendation '*Support closer integration of HIV services with other health programmes especially for sexual and reproductive health, and to strengthen health systems more widely*' as set forth in the UNAIDS response under Issue 5 related to principal blockages to achieving progress in the prevention of HIV.

It is well documented that the majority of HIV infections are sexually transmitted or associated with pregnancy, childbirth and breastfeeding. The presence of sexually transmitted infections (STIs) can increase risk of HIV acquisition and transmission. And importantly, sexual and reproductive ill-health and HIV share root causes, including poverty, gender inequality and social marginalization of the most vulnerable populations. Linking SRH and HIV services will improve clinical care outcomes and community health with the understanding that linkages are bi-directional, require multiple models and should address policy, systems and service delivery. Potential wide-reaching benefits of linking sexual and reproductive health and HIV include:

1. Improved access to, and uptake of key HIV and sexual and reproductive health services;
2. Better access of people living with HIV to sexual and reproductive health services tailored to their needs;
3. Reduced HIV-related stigma and discrimination;
4. Improved coverage of under served and marginalised populations with sexual and reproductive health services;
5. Greater support for dual protection against unintended pregnancy and sexually transmitted infections (STIs), including HIV;
6. Improved quality of care; and
7. Enhanced programme effectiveness and efficiency.

One of the most prominent examples of linkages is the rapid and widespread adoption of prevention of mother-to-child transmission (PMTCT) programs as an example of an integrated service initiative that addresses a recognized need in a comprehensive and well-accepted structure. Comprehensive PMTCT is defined as a four-element intervention, including:

1. Primary prevention of HIV;
2. Prevention of unintended pregnancy;
3. Prevention of HIV transmission from an infected mother to her child; and
4. Provision of care and support for HIV-infected mothers and their infants, partners, and families.

Although political commitment to linkages has been steadily gathering force, including with the 2005 World Summit Outcome reaffirming the global commitment to achieving universal access to reproductive health by 2015, including its role in achieving the Millennium Development Goal (MDG) dealing with HIV, far too many policies and programmes addressing either sexual and reproductive health or HIV have failed to link these two global commitments. In addition, further practical guidance on what and how to link is needed to implement on a national scale including overcoming issues such as:

1. Reproductive health commodities (HIV test kits, STI drugs, female and male condoms, safer delivery kits, PEP kits, contraceptives etc.) are still not readily available and accessible;
2. Special efforts are required to reach priority populations most under-served by current programmes, including poor women, young people and marginalised populations;
3. Greater and more effective involvement is needed of all potential beneficiaries, especially people living with HIV, women and young people, in the design, governance and delivery of sexual and reproductive health and HIV initiatives;
4. The sexual and reproductive health needs and human rights of people living with HIV are still not adequately promoted and supported;
5. Although over 100 countries globally implement PMTCT programmes, most responses tend not to be comprehensive (neglect primary prevention and sexual and reproductive health of women living with HIV) and are often not well integrated into maternal health and other core sexual and reproductive health programmes; and
6. International debate on reproductive health and rights is rarely over technical issues but is over cultural/political issues. Efforts must be made to identify positive cultural values that are present in all societies and contribute to human rights, and empower people to change those practices that violate these rights. Elimination of gender-based violence and child marriage are examples of how linking SRH and HIV can occur not only at service delivery but also at a policy level.

Finally, as we move further in strengthening the linkages between sexual and reproductive health and HIV, it is important to recognize that linked services cannot be delivered by “one size fits all” programs and that linking HIV and SRH goes beyond just combining services. Comprehensive linkages require change at the policy and societal levels in order to address issues such as child marriage, gender-based violence, and the lack of male involvement in SRH issues.

3 March 2008

Memorandum by UN System Influenza Coordination (UNSIIC)

1. I am very pleased to have the opportunity to contribute to the Committee’s review of the effectiveness of action undertaken by international organizations in response to the global spread of communicable diseases.

Assessment of the overall position: is the global situation deteriorating? Is there a Crisis?

2. Humanity has always been vulnerable to the disease risks posed by newly emerging microbes: recent examples include HIV and the SARS virus. In 1996, a new lineage of the Influenza A (H5N1) virus emerged in South East Asia. At that time it was found to be highly pathogenic among poultry to be capable of infecting and causing disease among humans. It re-emerged in 2003 as it spread widely first in Asia, and then Europe and Africa. It is now seen recognized as the most serious avian influenza virus ever identified: it has already affected poultry or wild birds in more than 60 countries and resulted in more than 200 million bird deaths. Although its spread has been controlled in most of the over 60 countries that have reported infection, the virus remains entrenched in bird populations of at least six countries and others face the threat of new outbreaks at any time. If these are not promptly and effectively controlled the virus may become entrenched in poultry and prove very hard to eliminate.

3. Fortunately, human cases of H5N1 infection are sporadic and sustained human to human transmission has not been reported. Although there have only been about 350 confirmed human H5N1 infections, around two thirds of them have died. H5N1, like other influenza viruses, undergoes frequently mutations: if a mutation were to enable it to move easily between people, it would then have the potential to cause a pandemic with the potential for large-scale loss of life. Currently available scientific data do not allow policymakers to predict—with any certainty—whether or not H5N1 will become easily transmissible between humans, when this might happen or how severe the consequences would be. The World Health Organization predicts that there will be influenza pandemic at some time, and anticipates that other pathogens, with the potential to cause pandemics, will appear at intervals in the foreseeable future.

4. The World Bank estimates that in addition to causing millions of deaths, the next influenza pandemic could well be a global catastrophe with an overall cost to the world economy in excess of 2 trillion US dollars. Because of the potential for the next influenza pandemic to threaten to global human security, action now underway should be sustained and intensified so as to prepare the world so as to detect it as soon as it starts, to limit its scope and spread and to mitigate its consequences—both within and beyond the health sector. These preparations are vital now, even though subject is receiving much less attention from media in 2008 than it was two years ago.

5. The current situation is characterized by the continuing transmission of HPAI H5N1 among poultry and the ongoing possibility that this virus might change and become capable of causing a pandemic. This risk certainly qualifies as a potential global crisis, and the risk persists despite major efforts to bring it under control over the last two years. But the impact of the next pandemic can be reduced if people and their nations are properly prepared. Given the uncertainty about when and how it will start, all concerned institutions should be ready, as soon as possible, to take prompt action and reduce the risk and limit the magnitude (and consequences) of the next pandemic. The emphasis of my work is on ensuring that there is a concerted and coordinated effort to reduce the likelihood of, and then mitigate the potential impact of, the next influenza pandemic.

Overcoming blockages to achieving progress in the prevention or control of avian influenza and a potential influenza pandemic: focus on better-targeted and better-coordinated intergovernmental action?

6 One of the main challenges in responding to a complex global threat is to ensure that all the different elements of the response are implemented in a joined-up and effective manner. International organizations have key normative roles and have recognized the importance of coordinating their interactions with each other and with national governments. The specialized technical organizations (UN Food and Agriculture Organization (FAO), the World Organization for Animal Health (OIE) and WHO) provide strategic and technical leadership for global and country efforts to address HPAI, to respond to human cases of H5N1 and to implement the International Health Regulations in ways that protect communities from the consequences of a pandemic. UNICEF provides strategic and technical leadership for social mobilization of communities and their legislators around the risks posed by HPAI and the threat of a pandemic. UNDP assists with coordinated responses by national governments and the international community. Given the evident social, economic and governance implications of the influenza threat posed by influenza, other parts of the UN and its partners have key roles to play when engaging with national governments, private entities and non-governmental organizations on these issues. These include humanitarian bodies (WFP, IFRC and OCHA), those concerned with finance and banking (IMF), travel and tourism (WTO, ICAO).

7. In September 2005 the Secretary General of the United Nations, after consultations with the Directors General of WHO and FAO, responded to increasing political concern—among member states—about the challenges posed by avian influenza and the threat of an influenza pandemic. He appointed an Influenza Coordinator for the UN system (UNSIC) in New York to help ensure that the different technical, development, humanitarian and political elements of the UN system, together with their partners, work in synergy and achieve the greatest possible impact on global threats posed by influenza viruses. The coordinator was seconded from WHO. He is supported by a small staff (usually totaling 10), loaned either from within the UN system or by national governments, who operate out of New York, Geneva and Bangkok.

8. At that time the UN Deputy Secretary General established a high-level Steering Committee made up of senior-level officials in the UN system—including the UN secretariat, specialized agencies (FAO, WHO, ILO, UNWTO, ICAO), UN funds and programmes (UNICEF, UNDP, WFP)—as well as the OIE, and the World Bank. Meeting every two months, the committee supervises the work of the coordinator, checks the UN system's preparedness for a pandemic and ensures synergy between different elements of the UN on these

issues. This approach was deliberately chosen as an alternative to the creation of an independent UN body (on the lines of UNAIDS), which was not thought to be warranted. It gives pride of place to the apex technical bodies—FAO, OIE and WHO—that offer strategic guidance on this issue.

The role played by the international community in helping relevant institutions to combat avian influenza and prepare for the next pandemic: comments on UNSIC configuration and resources, collaborative linkages and resulting UN system synergy

9. The broad strategy for global action on avian and human influenza was developed by FAO, WHO, OIE and the World Bank on the basis of experiences and needs reported by countries at a well-attended partners' meeting in Geneva in November 2005. The European Union's programmes on avian and human influenza and the UN-supported International Partnership on Avian and Pandemic Influenza undertook to offer substantial assistance to nations and the framework for international financial support was agreed at the International Pledging Conference in Beijing January 2006. Over the subsequent two years, political leaders have pledged approximately 2.7 billion US dollars to control highly pathogenic avian influenza and prepare for the next influenza pandemic. They agreed that these resources should be invested into the immediate efforts to try contain H5N1 so as to reduce the damage caused by the virus to poultry production, and in the longer term to decrease the likelihood that H5N1 would be the cause of the next pandemic and enhance generic systems to reduce the threat of emerging diseases from the animal kingdom. As of December 2007, more than one billion dollars had been disbursed to countries, international organizations and regional bodies.

10. In the aftermath of the Beijing pledging conference UNSIC encouraged different UN system agencies, IOM and the OIE, to spell out the purpose and content of their influenza work within the context of this global strategy: The resulting *UN System Consolidated Action Plan* is subject to regular review by UNSIC (the most recent review was completed in September 2007 and is available on UNSIC website).

11. UNSIC has supported coordination of country level efforts by the international system, in close cooperation with national governments, working through the UN country teams (which include the country directors of FAO, WHO, UNDP, WFP and UNICEF and the OCHA representative). Field coordinators, financed by UNDP, have been recruited and placed in the office of the Resident Coordinator in a small number of countries that face particular challenges. UNSIC also supports inter-governmental action on influenza by offering the 80 or so nations who have been working together in partnership on avian and pandemic influenza a single focal point for their dealings with the UN system. This has been utilized by the governments that have organized successive conferences in Washington, D.C. (October 05), the Beijing pledging conference (January 06), Vienna Senior Officials' meeting (June 06), the Bamako conference organized by the African Union and European Commission (December 06) and the New Delhi International Conference on Avian and Pandemic Influenza (December 07).

Comments on the overall outcome achieved as a result of the coordinated global effort

12. A massive coordinated effort has been initiated since mid 2005 to improve the health of poultry and wild birds, to sustain the livelihoods of those depending on poultry for their income, to improve disease surveillance and public health (along the lines of the International Health Regulations), initiate social mobilization, coordinate national and international actors, ensure social and economic continuity in the event of a pandemic and prepare humanitarian services to respond to the needs of millions of potential beneficiaries. Hundreds of thousands of people were involved within most of the world's countries, as well as many regional bodies and the international agencies: the effort has been described as a global movement and technical leadership has been provided by international organizations. The UN system and World Bank have produced regular reviews of progress with HPAI control and pandemic preparedness. As noted in the December 2007 report "Responses to Avian Influenza and State of Pandemic Readiness", many countries have increased the speed and effectiveness with which they can respond to H5N1 outbreaks with improvements in surveillance and diagnostic systems globally. Countries in which HPAI transmission is continuous have intensified their control efforts. The number of countries newly infected with HPAI, and the number of human cases of H5N1 during 2007 was less than reported in 2006. The impact of the international effort on animal health services and capacity to respond to H5N1 outbreaks has clearly been substantial (though long-term improvements are still required). Pandemic preparedness was reported to be patchy with many countries giving insufficient attention to the impact of a pandemic beyond the health sector.

13. The UN-World Bank analysis concluded that national-level results are most promising if there is political commitment at the highest level, well organized capacity for a surge response; joint working by veterinary and public health staff; effective collaboration between government, the private sector and voluntary agencies; incentives for people to report outbreaks of disease (including compensation) and effective public information and communications systems.

What intergovernmental action is planned or in hand for early detection of the transmission of Avian Flu from birds to humans and of human-to-human transmission in potential source countries? Is this proving sufficiently effective to prevent an Influenza pandemic? What more could be done?

14. The work of FAO, OIE, WHO and UNICEF is at the heart of the international effort to increase capacity for better livestock health (specifically control of HPAI), prevent human H5N1 infection and get ready for the next pandemic. [I know that those groups have been requested to provide information and I anticipate that the technical information on action in hand for the early detection of avian influenza in birds and humans (and possible human-to-human transmission) will be provided (and critically assessed) by them]. From the UNSIC perspective, the following contributions are particularly notable. The specialized agencies have tracked and assessed the H5N1 situation (including evolving risks and the status of control or prevention), and responded by developing protocols for surveillance and response, improving systems for sharing data and biological materials and for data analysis and laboratory assessment, increasing capacity to report on global progress, and identifying locations where needs are intense and/or the response needs enhancement.

15. FAO and OIE have also taken the lead in contributing to improved capacity of veterinary services to respond to animal health concerns. They have particularly focused on HPAI, and the establishment of adequate bio-security standards worldwide. They have provided support to countries as they respond to suspected HPAI outbreaks in poultry and waterfowl, established and then maintained the global cohesive framework and examined—at country, regional and global levels—links between pandemic agents and livelihoods.

16. The UN system, with the OIE and the World Bank, has contributed to establishing mechanisms to protect and sustain livelihoods of those affected by avian influenza impacts. They investigated and developed an improved understanding of optimal mechanisms for compensating those who lose birds and/or property through the application of control measures: they are helping to apply these findings within countries—including Egypt, Vietnam and Nigeria.

17. The UN and partners, under the aegis of WHO, are intensifying their efforts to help countries build and maintain sound systems for safeguarding the health of human populations during a pandemic. Surveillance and early warning systems are being improved and expertise provided to countries for the implementation of the International Health Regulations. Much remains to be done but there are encouraging signs of positive outcomes with regards to influenza virus sharing as well as vaccine stockpiles as negotiations are underway to devise optimal policies and design sound mechanisms.

18. The containment of avian influenza and, when it appears, of a potential pandemic influenza virus, requires full involvement of affected communities, the engagement of a range of professionals and leadership from both senior officials and legislators. Long-practiced behaviours have to change and new ones adopted. The changing of behaviour is often a long term process: it must be supported by accurate messaging and effective social mobilization. The UN system, with technical leadership provided by UNICEF, has helped identify and better understand the different dimensions of communications for avian and pandemic influenza. This includes communication support for social mobilization around risks posed by avian influenza and pandemic preparedness. The collective communication support provided by the UN agencies and their partners is starting to yield positive results and the impact has been seen in a range of countries—including Cambodia, Vietnam and Thailand.

19. The UN system has established a dedicated team to assist both international organizations and governments with the development of contingency plans to ensure that they can retain operational continuity in the event of an influenza pandemic. The Pandemic Influenza Contingency team has been set up with a hub in OCHA Geneva and regional branches in Asia, Africa, Eastern Europe and Latin America to track progress at country level (through an on-line tracking system): it assists with technical advice, support for simulations and encouragement of inter-governmental action. It works closely with humanitarian organizations and private entities, and seeks to ensure that all concerned are able to pursue similar action when preparing for disease outbreaks and the next pandemic—whatever the cause.

20. The UN System Influenza Coordinator's Office has provided the necessary impetus for coordination that moves from intermittent meetings to harmonized and synergized action with each entity contributing where it can add value within the context of a shared vision based on evidence and technical expertise. This has been

made possible through the engagement of the UN agencies and regular technical review meetings (most recently in Rome 2007), through strategic placement of dedicated coordinators at the country level, through the development and agreement of the UN system Consolidated Action Plan (and a financing mechanism that backs it, the Central Fund for Influenza Action) and support to international conferences (including through the series of Progress Reports). Much work remains to be done to contain the threats posed by H5N1. The virus is tenacious and continues to circulate, and this indicates that despite the efforts, and progress, the risk of continuing H5N1 outbreaks remains. The global community must continue to be vigilant, to respond rapidly when outbreaks are detected, and do all they can to avoid the virus becoming continually transmitted. As a pandemic is a threat to all nations, continued efforts to control avian influenza (as well as other diseases) is an activity that contributes to the good of the global public.

What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of infectious diseases? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient “joined-up” thinking in approaching the problem?

21. It seems inevitable that the world will continue to be at threat as a result of emerging infectious diseases. Reducing the threat posed by emerging infectious diseases, and the possibility of pandemics, is complex now but is likely to become even more so in the next few decades. Ecosystems are changing as human populations seek new habitats within which to live, struggle with changing climate and precipitate changes in the natural environments within which wild animals live. Projections by FAO and the International Food Policy Research Institute indicate that as the world population increases and becomes wealthier, demand for meat is increasing dramatically. The long term challenge is to ensure that livestock production systems in all nations pay adequate attention to animal health and hygiene, and that the ever-changing interactions between humans and animals do not increase the potential for humans to be affected by microbes from the animal kingdom. Pathogens from domestic and wild animals will continue to threaten the human race, so as well as reducing the risk that they will emerge and cause disease, care should be taken to sustain adequate human health defenses. This calls for well organized veterinary health systems working closely with personnel concerned with public health, environmental health and food safety, within a framework of national and international regulations as set out by the OIE, FAO, and the WHO-led International Health Regulations. These systems, and the framework within which they work, should be developed in a way that enables countries to maintain national and cross-border health security. At the same time, disaster preparedness plans—whether for whole nations or for localities—need to take account of the potential crises that would result from major disease outbreaks (which could lead to sickness and absenteeism, and major social and economic consequences).

22. At the most recent Ministerial Conference in New Delhi (December 2007), representatives of more than 100 governments reviewed the progress of the work undertaken on Avian and Pandemic Influenza (focusing on immediate action to control HPAI and medium term efforts to improve animal health services and bio-security). They agreed the importance of “one world: one health”—an emphasis on threats to human security as a result of diseases that can emerge at the interface between animals and humans. They requested the UN systems organizations and World Bank to develop both the medium term strategy and options for implementing it. This work is now underway and will be completed before the next International Conference on Avian and Pandemic Influenza scheduled for October 2008 in Cairo, Egypt. At that time, the shape of the global effort to address avian influenza and other animal derived infections is likely to evolve substantially.

Though much of our work is focused specifically on known infectious diseases, what can be said about the global threat from new or previously unrecognised ones and from the transmission of infections from animals to humans.

23. According to the FAO, the OIE and the US Centres for Disease Control and Prevention, new disease-causing microbes are emerging at the rate of about two per year. Three quarters of these come from the animal kingdom. Because infectious diseases do not respect borders between nations, and are spread through travel and trade, an infectious and dangerous new microbe in one country will have the potential to affect all nations and become a global threat. AIDS, yellow fever, SARS, Ebola, rift valley fever and pandemic influenza are all examples of diseases that affect humans but have their origins in animals.

“One world, One health, One legacy”

24. The challenges posed by the H5N1 virus are an example of the wider global insecurity posed by microbes that primarily affect animal species but—as the delicate ecosystems of our world are subject to continuous change—are increasingly capable of causing severe illness among humans. Infectious diseases have the potential to undermine attempts by the human race to adapt to the impact of climate change. To respond to

these risks, governments and the international community should encourage convergence of the scientific practice, analytical approaches and policy guidance being provided by animal health, environmental health, plant health, food safety and human health professionals. This will improve our collective capacity to safeguard future generations.

21 January 2008

Memorandum by the Wellcome Trust

INTRODUCTION

The Wellcome Trust is the largest charity in the UK. It funds innovative biomedical research, in the UK and internationally, spending around £600 million each year to support the brightest scientists with the best ideas. The Wellcome Trust supports public debate about biomedical research and its impact on health and wellbeing.

We are pleased that the Committee has chosen to examine the important topic of controlling communicable diseases. We would be happy to discuss any of the issues raised in our response in further detail if that is helpful.

1. *A recent report on Communicable Diseases by the UK Department of Health stated that “post-war optimism that their conquest was near has proved dramatically unfounded”. What is your assessment of the overall position? More specifically, is it simply that not enough progress is being made in reducing the spread of such diseases? Or is the global situation actually deteriorating? Would it be an exaggeration to talk of a crisis?*

Although great progress was made to reducing human mortality from infectious disease over the course of the 20th century, it is unrealistic to expect the “conquest” of communicable diseases in the foreseeable future. The adaptation of microorganisms to infect humans and evade anti-microbial agents means that new treatments and/or vaccines must continually be developed and delivered. In those places where HIV/AIDS has drastically reduced life expectancy in the space of several decades, crisis is an accurate description. Other infectious diseases have the potential to cause crises in other parts of the world, in ways that we cannot foresee. International collaboration on monitoring and research is essential to stay ahead of this threat, and to prepare ourselves to meet it.

New infectious diseases are constantly emerging—many arising from the transmission of animal diseases to humans. Indeed, two of the four diseases that the Committee identified as special interests have jumped the animal-human species barrier within the past 100 years (ie, HIV/AIDS and influenza). Improving our understanding of animal diseases is one of the best ways to prepare for the emergence of new infectious diseases in humans.

2. *What reliable data exists regarding the numbers of people infected globally with the four diseases (HIV/AIDS, TB, Malaria and Avian Influenza) on which the Committee is focusing particular attention? What trends are discernible in both the numbers of people infected and the patterns of infection? And what are the main underlying causes of infection and of any changes in its incidence and pattern?*

HIV/AIDS: UNAIDS coordinates the global estimates and the underlying data provided by countries is improving.

Tuberculosis: WHO collects and makes available this data on global TB incidence.

Malaria: There is a lack of good information on malaria incidence across much of Africa. Until the recent increase in donor funding for malaria treatment, epidemiological data on malaria in Africa was of mostly academic interest and good systems were not developed for collecting it. Now, with funding for malaria interventions available from the Global Fund and other international sources, there are greater opportunities for delivering prevention and treatment programmes. Better data on the distribution of infections is needed to target these resources effectively and track progress. The Wellcome Trust is funding the Malaria Atlas Project⁵¹ to develop a detailed model of the special limits of *P. vivax* and *P. falciparum* malaria at a global scale and its rate of occurrence within this range. This is a joint project between the Centre for Geographic Medicine in Kenya and the University of Oxford in the UK.

Avian Influenza: Cases are reported to WHO.

⁵¹ Malaria Atlas Project website: http://www.map.ox.ac.uk/MAP_overview.html

3. *What intergovernmental surveillance systems exist to give early warning of outbreaks of infectious diseases? Are these systems adequate? And what improvements might be made?*

The World Health Organization's International Health Regulations (2005) provide the framework for global infectious disease surveillance and response. The International Health Regulations 2005 (IHR 2005) replaced and improved upon the previous International Health Regulations, which had been last updated in 1969. The IHR(2005) seek to identify an outbreak of infectious disease at its source and to control it before it has a chance to spread. This is a marked improvement over the earlier approach, which sought to stop infectious diseases from spreading across national borders by focusing on ports of entry. The IHR(2005) require countries to report to WHO any "public health emergency of international concern", which can include infectious diseases as well as other threats such as release of chemical or radiological material. In a break from the previous International Health Regulations, the IHR(2005) also give the WHO new powers to take action based on information from non-state entities. This can be important if governments are reluctant to publicise health problems for fear of economic or political damage.

We agree with the approach of WHO's IHR(2005). Continuous health surveillance in all countries and rapid targeting of outbreaks is the most promising way to control the global spread of infectious diseases. The Health Protection Agency serves this role for the UK. However, as the WHO has recognised, countries where infectious disease outbreaks most often occur are among the poorest in the world, with the weakest health surveillance systems. In order for the global surveillance network to perform as intended, capacity for surveillance in those countries must be strengthened. In many cases, strengthening basic health service systems is a prerequisite for strengthening surveillance.

5. *What do you consider to be the principle blockages to achieving progress in the prevention or control of the four diseases? And how might these blockages be removed by more, or better-targeted or better-coordinated intergovernmental action?*

The development of better medical technologies and better health service delivery systems in resource poor countries would help control the four diseases. It is also very important to support research into the biological mechanisms underlying these diseases, as this is a precursor to new interventions and treatment strategies. Intergovernmental organisations such as the WHO play an important role in coordinating international research programmes. Multilateral organisations outside of the UN system, such as the Global Fund to Fight AIDS, TB and Malaria and the Product Development Public-Private Partnerships (PDPs), also play a crucial role in developing and delivering interventions for HIV/AIDS, TB and malaria. Researchers funded by the Trust found that PDPs have proven very effective at combining the strengths of R&D capacity in the public and private sectors, in the North and the South to advance products that have their primary demand in income markets.⁵² A number of PDPs are active in taking forward products to prevent and treat HIV/AIDS, TB and malaria. However, there is now a real deficit in funding the PDPs as they move promising products into large-scale clinical trials. Furthermore, with about half of PDP funding coming from just one source (the Gates Foundation) there is an urgent need to diversify their funding base. Bilateral and multilateral donors are needed to fill this gap.

6. *What role does your organisation play in combating the four diseases? Do you believe that it is correctly configured and adequately resourced to do the job? With which other organisations do you collaborate? How would you assess the degree of synergy?*

The Wellcome Trust supports a large portfolio of basic biomedical research that aims to improve our understanding of human health and disease. A substantial fraction of the Trust's research investment focuses on health problems that are of particular concern for developing countries, such as the four diseases highlighted in this consultation. Collaborations with other organisations are an important part of our strategy for supporting research on global health threats. Trust-funded researchers also participate on many WHO working groups and committees. Listed below are some of the Trust's activities and collaborations in the context of each of the four diseases.

⁵² Mary Moran et. al. (2005) "The New Landscape of Neglected Disease Drug Development" <http://www.wellcome.ac.uk/assets/wtx026592.pdf>

Cross-cutting

- PDP Funders Group: The Trust is a founding member of the PDP Funders Group, which brings together government, philanthropic and corporate donors that currently support Product Development Public-Private Partnerships. The PDP Funders group aims to facilitate decisionmaking by individual donors in this field and to strengthen the base of financial support for PDPs to ensure that they achieve their goals.

HIV/AIDS

- In the five years 2002–06 the Trust spent £59 million on HIV research.
- We have supported the UK Consortium on HIV Vaccine Research, which is a collaboration with the UK Medical Research Council.
- Mark Walport, Director of the Wellcome Trust, is on the Coordinating Committee of the Global HIV Vaccine Enterprise.
- Jimmy Whitworth, Head of International Activities for the Wellcome Trust, serves on the UNESCO Advisory Committee for education for prevention of HIV and STDs.

TB

- In the five years 2002–2006, the Trust spent £39 million on Tuberculosis research. Through a number of different grants, the Trust supports the development of new TB vaccines (eg, support for Helen McShane of Oxford University), new diagnostics (eg, support for David Moore of Imperial College) and new therapeutics (eg, Doug Young of Imperial College).
- The Trust is a founding Stakeholder of the Global Alliance for TB Drug Development.

Malaria

- In the five years 2002–06, the Trust spent £140 million on malaria research. The Trust supports five of the top ten most highly cited malaria researchers. In addition to basic biomedical research on malaria and development of new medical interventions, the Trust supports substantial health services research and health policy research related to malaria control.
- The Trust provides funding for the Medicines for Malaria Venture, a PDP create to discover, develop and deliver new antimalarial drugs. The Trust and DFID made a joint commitment to provide £10 million each to MMV, and together provide approximately 18% of MMV's funding.
- The Trust also provides funding for a programme of malaria research at the Novartis Institute for Tropical Diseases in Singapore. This is a partnership with MMV, the Economic Development Board of Singapore and Novartis.
- The Trust has been represented in the WHO Malaria Vaccine Advisory Committee and in the development of the Malaria Vaccine Technology Roadmap.

Avian Influenza

- The Trust is funding research to advance the scientific understanding of potential pandemic strains (eg H5N1) and the medical technology available to prevent and treat an emergent pandemic. In October 2005, the Trust adopted procedures to fast-track funding for urgent influenza research.
- The Wellcome Trust's Major Overseas Programme in Vietnam has been an important site of research on H5N1 avian influenza in humans. Jeremy Farrar, the Vietnam Programme Director, is a leading expert on the virus.
- The Trust is an international partner in the Southeast Asia Clinical Research Network, a multi-lateral, collaborative partnership of hospitals and institutions in Indonesia, Thailand, United Kingdom, United States, and Vietnam. Other international partners in the network include the WHO, the US NIH and Oxford University.
- Following on from discussions of the Heads of International Research Organisations (HIROs) group,⁵³ the Trust is hoping to fund an Influenza Research Coordinator on behalf of the group, to map out what influenza research is already taking place and what more needs to be done.

⁵³ This is an informal group that brings together the major government and philanthropic biomedical research funders from around the world.

7. *What are the main non-health causes (eg global warming, poverty, changes in land use, international travel, lifestyle, population) of the spread of the four disease? To what extent can intergovernmental action in non-health fields contribute to alleviation of their spread? What action is taking place or planned in these areas? And what more needs to be done? Do you consider that there is sufficient “joined up” thinking in approaching the problem?*

These four diseases, as well as other health problems in developing countries, are driven by a combination of factors—many falling outside of the health sector. There does need to be more “joined up” thinking in approaching these problems. To advance this at a UK level, we welcome the newly established UK Collaborative on Development Sciences (UKCDS), of which the Trust is a founding member. UKCDS provides a framework to better coordinate development science research for the UK and with international partners, in order to support sustainable improvements in the lives of the poorest people and countries. Founding members include the Research Councils (MRC, ESRC, BBSRC, NERC), the Department for Innovation, Universities and Skills, and the Department of Health, with the Gates Foundation as an observer.

UKCDS has identified climate change as one of its first areas of work. Climate change is likely to have a particularly strong impact on vector-borne infectious diseases, including malaria. The Intergovernmental Panel on Climate Change (IPCC), in its fourth assessment report, concluded with very high confidence that climate change will have mixed effects on malaria; in some places the geographical range will contract, elsewhere the geographical range will expand and the transmission season may be changed.

Modelling of the health impacts of climate change remains very limited. The IPCC and WHO, in its report “Climate change and human health—risks and responses” (2003), have identified a number of research priorities to improve the modelling and better inform the development of adaptation policies. There are still significant gaps in the evidence base for developing countries, and the scenario models for African countries especially are particularly poor.

A range of other factors will also affect the transmission of malaria—these may be socio-economic (for example increasing population movements, the use of control interventions, drug resistance); or environmental (including changes in land use, deforestation, changing agricultural practices and water management, or increasing urbanisation). The interaction between these factors is often complex.

12. *To what extent do you consider that the rise in infections in the four diseases is attributable to increased microbial resistance to antibiotics? What intergovernmental action is taking place in this area?*

The continual evolution of microbial resistance is a real problem for HIV (resistance to antiretrovirals), TB (resistance to antibiotics) and malaria (resistance of malaria parasite to antimalarial drugs). There are treatment strategies that slow the development of drug-resistance, but the development of drug resistance is difficult to block entirely. For this reason, we are likely to need continual research and development of new treatments. In addition to our investments in HIV/AIDS, TB and malaria research & development discussed previously, the Trust and GSK have recently entered into a partnership for gram-negative antimicrobial development.⁵⁴

15. *What interchange exists between States in regard to knowledge of and training in the diagnosis and treatment of the four diseases or regarding preparations for dealing with outbreaks? What improvements might be made through intergovernmental action?*

Efforts to build capacity in developing countries for diagnosis and treatment of the four diseases identified in this consultation must continue to increase. Although targeted efforts to build capacity for diagnosis and treatment of those focal diseases may be helpful in some situations, they must be integrated into a more general programme of health system strengthening in order to be effective.

Capacity strengthening partnerships in which the Trust is involved include:

- The *Health Research Capacity Strengthening Initiative in Kenya and Malawi* initiative aims to strengthen the capacity for the generation of new health research knowledge within Kenya and Malawi, and to improve its use in evidence-based decision making, policy formulation and implementation. This initiative began with an agreement between the Wellcome Trust and DFID to commit £10 million each towards a joint programme of health research capacity strengthening in Africa. The International Development Research Centre, Canada (IDRC) joined the initiative as a funder and implementing partner. In Kenya and Malawi the initiative funds nationally-led health research grant-giving bodies which aim to meet local health research needs. National task forces established work plans, now signed off by the Trust and DFID.

⁵⁴ Project description: <http://www.wellcome.ac.uk/doc/%5Fwtx037132.html>

- The Wellcome Trust has just launched an *Research Capacity Strengthening in Africa*. This funding scheme aims to support the creation of consortia and networks that will link African universities and research institutes with institutions in the UK (or in other countries with a developed market economy). The aim is to forge partnerships between institutions with complementary scientific, clinical or administrative strengths that can add significant value and create a robust research environment to strengthen the research-base in Africa, particularly in African Universities. Consortia will be Africa-led and include a mix of African institutions with well-established research activities, as well as promising African institutions that are developing their research potential.

16. *The International Health Regulations 2005 are intended to provide a global framework for the rapid identification and containment of public health emergencies. How effective do you consider this response system to be? Do improvements need to be made?*

As discussed in our response to question 3, the IHR(2005) provide a good framework for global information sharing. However, as mentioned above in response to question 3, quick identification and containment of infectious diseases requires stronger health systems than are yet available in many developing countries. Capacity building in these countries is needed to help the global system function well.

Resource poor countries need to have confidence that participating in the global system of information sharing and collaboration will benefit their own efforts to contain public health emergencies. As demonstrated by Indonesia's refusal to share all of its Avian Influenza samples on the basis that it may not have access to a resultant vaccine, this can be a problem.

17. *What intergovernmental planning has been undertaken to cope with the impact of an outbreak of infectious disease caused by deliberate release of microorganisms into the environment? Is there adequate liaison between the various agencies involved, including intelligence, law enforcement and health care professionals? How could action by intergovernmental bodies help further?*

Identifying and coping with the impact of infectious diseases caused by deliberate release of microorganisms requires similar systems and strategies as coping with natural diseases outbreaks. Strong monitoring and response systems are the foundation for both.

18. *Though our remit is focused specifically on known infectious diseases, we would be interested to know how you view the global threat from new or previously unrecognised ones and from the transmission of infections from animals to humans.*

As discussed in our response to question 1, we view the threat from emerging infectious diseases to be very serious—particularly the risk of animal diseases crossing the species barrier to infect humans. Humans and animals live in extremely close proximity in many parts of the world, making this essentially inevitable.

January 2008

Memorandum by World Trade Organisation

We would like to thank you for your E-mail of 30 January 2008 addressed to the Director-General's office with regard to the Call for Evidence sent out by the Committee with 20 questions on the topic "Acting through intergovernmental organisations to control the spread of communicable diseases", on which the WTO, among other intergovernmental organisations, has been asked to provide a written submission.

The WTO's submission refers to question 14 as follows:

WTO Members have devoted considerable effort, both at the time of the negotiation of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) and subsequently, to ensuring that the WTO rules on the protection of intellectual property are properly balanced, especially in the light of concerns about access to medicines in developing countries.

The TRIPS Agreement itself contains considerable flexibility in regard to patent rights, for example transition periods, compulsory licensing, government use, other limited exceptions and parallel imports. A short description can be found in Annex 1.

In 2001, following an extensive debate in the WTO on the implication of the TRIPS rules for access to medicines, the WTO Members adopted a Ministerial Declaration on the TRIPS Agreement and Public Health (Annex 2). The main thrust of this was to emphasize the flexibility available in the TRIPS Agreement for

Members to meet these challenges, their right to use it to the full and the need for a pro-public health interpretation and implementation of TRIPS rules. The Declaration also contained some important clarifications of TRIPS flexibilities, notably in regard to compulsory licensing and parallel imports.

Following up on this Declaration, WTO Members have adopted a number of Decisions: in 2002, two Decisions were adopted to extend the transition period for least developed countries in regard to pharmaceutical products to 2016 (Annexes 3 and 4). In 2003, a waiver Decision was adopted to provide additional flexibility in one area where it had been agreed that the TRIPS rules did not provide sufficient scope for addressing public health problems. This gives additional flexibility for countries to be able to provide compulsory licences specifically for the purposes of producing or exporting to address public health problems in other countries which do not have sufficient manufacturing capacity to be able to produce under a compulsory licence themselves (Annex 5). In 2005, Members agreed to amend the TRIPS Agreement to make the system established under the waiver Decision a permanent feature of the TRIPS Agreement (Annex 6).

You will find annexes 1 to 6 attached and further information can be found on the following WTO website dedicated to TRIPS and public health: http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm.

Thank you for inviting the WTO to contribute in this topic.

March 2008

Annex

WORLD TRADE ORGANIZATION
20 NOVEMBER 2001

Ministerial Conference
Fourth Session
Doha, 9—14 November 2001

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
 - (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
 - (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
 - (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

WORLD TRADE ORGANIZATION
1 JULY 2002

Council for Trade-Related Aspects of Intellectual Property Rights

EXTENSION OF THE TRANSITION PERIOD UNDER ARTICLE 66.1 OF THE TRIPS AGREEMENT FOR LEAST-DEVELOPED COUNTRY MEMBERS FOR CERTAIN OBLIGATIONS WITH RESPECT TO PHARMACEUTICAL PRODUCTS

Decision of the Council for TRIPS of 27 June 2002

The Council for Trade-Related Aspects of Intellectual Property Rights (the “Council for TRIPS”),

Having regard to paragraph 1 of Article 66 of the TRIPS Agreement;

Having regard to the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 7 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the “Declaration”);

Considering that paragraph 7 of the Declaration constitutes a duly motivated request by the least-developed country Members for an extension of the period under paragraph 1 of Article 66 of the TRIPS Agreement;

Decides as follows:

1. Least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016.
2. This decision is made without prejudice to the right of least-developed country Members to seek other extensions of the period provided for in paragraph 1 of Article 66 of the TRIPS Agreement.

WORLD TRADE ORGANIZATION
12 JULY 2002

LEAST-DEVELOPED COUNTRY MEMBERS—OBLIGATIONS UNDER ARTICLE 70.9 OF THE TRIPS AGREEMENT WITH RESPECT TO PHARMACEUTICAL PRODUCTS

Decision of 8 July 2002⁵⁵

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization (the “WTO Agreement”);

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

⁵⁵ Adopted in accordance with the Decision-Making Procedures under Articles IX and XII of the WTO Agreement agreed by the General Council in November 1995 (WT/L/93).

Noting the decision of the Council for TRIPS on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with respect to Pharmaceutical Products (IP/C/25) (the “Decision”), adopted by the Council for TRIPS at its meeting of 25-27 June 2002 pursuant to the instructions of the Ministerial Conference contained in paragraph 7 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the “Declaration”);

Considering that obligations under paragraph 9 of Article 70 of the TRIPS Agreement, where applicable, should not prevent attainment of the objectives of paragraph 7 of the Declaration;

Noting that, in light of the foregoing, exceptional circumstances exist justifying a waiver from paragraph 9 of Article 70 of the TRIPS Agreement with respect to pharmaceutical products in respect of least-developed country Members;

Decides as follows:

1. The obligations of least-developed country Members under paragraph 9 of Article 70 of the TRIPS Agreement shall be waived with respect to pharmaceutical products until 1 January 2016.
2. This waiver shall be reviewed by the Ministerial Conference not later than one year after it is granted, and thereafter annually until the waiver terminates, in accordance with the provisions of paragraph 4 of Article IX of the WTO Agreement.

WORLD TRADE ORGANIZATION
2 SEPTEMBER 2003

IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

*Decision of 30 August 2003*⁵⁶

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization (“the WTO Agreement”);

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the “Declaration”) and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

Decides as follows:

1.2 For the purposes of this Decision:

- (a) “pharmaceutical product” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included;⁵⁷
- (b) “eligible importing Member” means any least-developed country Member, and any other Member that has made a notification⁵⁸ to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other

⁵⁶ This Decision was adopted by the General Council in the light of a statement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.

⁵⁷ This subparagraph is without prejudice to subparagraph 1(b).

⁵⁸ It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members⁵⁹ and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

- (c) “exporting Member” means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

1.3 The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

- (a) the eligible importing Member(s)⁶⁰ has made a notification² to the Council for TRIPS, that:
- (i) specifies the names and expected quantities of the product(s) needed;⁶¹
 - (ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and
 - (iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision;⁶²
- (b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:
- (i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;
 - (ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and
 - (iii) before shipment begins, the licensee shall post on a website⁶³ the following information:
 - the quantities being supplied to each destination as referred to in indent (i) above; and
 - the distinguishing features of the product(s) referred to in indent (ii) above;
- (c) the exporting Member shall notify⁶⁴ the Council for TRIPS of the grant of the licence, including the conditions attached to it.⁶⁵ The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

1.4 Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

1.5 In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion

⁵⁹ Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

⁶⁰ Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

⁶¹ The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

⁶² This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.

⁶³ The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.

⁶⁴ It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

⁶⁵ The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

1.6 Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

1.7 With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

- (i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question; and
- (ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

1.8 Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

1.9 The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

1.10 This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

1.11 Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

1.12 This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on

this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

Annex

ASSESSMENT OF MANUFACTURING CAPACITIES IN THE PHARMACEUTICAL SECTOR

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

- (i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector; OR
- (ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

WORLD TRADE ORGANIZATION 29 JULY 2005

IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Decision of 30 August 2003

Corrigendum

The asterisked note at the bottom of page 1 should read as follows:

** Secretariat note for information purposes only and without prejudice to Members' legal rights and obligations: This Decision was adopted by the General Council in the light of a statement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.*

WORLD TRADE ORGANIZATION 8 DECEMBER 2005

AMENDMENT OF THE TRIPS AGREEMENT

Decision of 6 December 2005

The General Council;

Having regard to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in the proposed amendment of the TRIPS Agreement, the importance of a rapid response to those needs consistent with the provisions of the proposed amendment of the TRIPS Agreement;

Recalling paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health;

Having considered the proposal to amend the TRIPS Agreement submitted by the Council for TRIPS (IP/C/41);

Noting the consensus to submit this proposed amendment to the Members for acceptance;

Decides as follows:

1. The Protocol amending the TRIPS Agreement attached to this Decision is hereby adopted and submitted to the Members for acceptance.
2. The Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.
3. The Protocol shall take effect in accordance with the provisions of paragraph 3 of Article X of the WTO Agreement.

Attachment

PROTOCOL AMENDING THE TRIPS AGREEMENT

Members of the World Trade Organization;

Having regard to the Decision of the General Council in document WT/L/641, adopted pursuant to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Hereby agree as follows:

- 1.13 The Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") shall, upon the entry into force of the Protocol pursuant to paragraph 4, be amended as set out in the Annex to this Protocol, by inserting Article 31bis after Article 31 and by inserting the Annex to the TRIPS Agreement after Article 73.
- 1.14 Reservations may not be entered in respect of any of the provisions of this Protocol without the consent of the other Members.
- 1.15 This Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.
- 1.16 This Protocol shall enter into force in accordance with paragraph 3 of Article X of the WTO Agreement.
- 1.17 This Protocol shall be deposited with the Director-General of the World Trade Organization who shall promptly furnish to each Member a certified copy thereof and a notification of each acceptance thereof pursuant to paragraph 3.
- 1.18 This Protocol shall be registered in accordance with the provisions of Article 102 of the Charter of the United Nations.

Done at Geneva this sixth day of December two thousand and five, in a single copy in the English, French and Spanish languages, each text being authentic.

Annex

TO THE PROTOCOL AMENDING THE TRIPS AGREEMENT

ARTICLE 31BIS

1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.
2. Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.
4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.
5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f).

Annex

TO THE TRIPS AGREEMENT

1. For the purposes of Article 31*bis* and this Annex:
- (a) “pharmaceutical product” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included;⁶⁶
 - (b) “eligible importing Member” means any least-developed country Member, and any other Member that has made a notification⁶⁷ to the Council for TRIPS of its intention to use the system set out in Article 31*bis* and this Annex (“system”) as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members⁶⁸ and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency; and
 - (c) “exporting Member” means a Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member.
2. The terms referred to in paragraph 1 of Article 31*bis* are that:
- the eligible importing Member(s)⁶⁹ has made a notification² to the Council for TRIPS, that:
- (iv) specifies the names and expected quantities of the product(s) needed;⁷⁰
 - (v) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to this Annex; and
 - (vi) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Articles 31 and 31*bis* of this Agreement and the provisions of this Annex;⁷¹

⁶⁶ This subparagraph is without prejudice to subparagraph 1(b).

⁶⁷ It is understood that this notification does not need to be approved by a WTO body in order to use the system.

⁶⁸ Australia, Canada, the European Communities with, for the purposes of Article 31*bis* and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States.

⁶⁹ Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 3 of Article 31*bis* on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

⁷⁰ The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.

⁷¹ This subparagraph is without prejudice to Article 66.1 of this Agreement.

- (d) the compulsory licence issued by the exporting Member under the system shall contain the following conditions:
- (i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;
 - (ii) products produced under the licence shall be clearly identified as being produced under the system through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and
 - (iii) before shipment begins, the licensee shall post on a website⁷² the following information:
 - the quantities being supplied to each destination as referred to in indent (i) above; and
 - the distinguishing features of the product(s) referred to in indent (ii) above;
- (e) the exporting Member shall notify⁷³ the Council for TRIPS of the grant of the licence, including the conditions attached to it.⁷⁴ The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. In order to ensure that the products imported under the system are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

4. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted to their markets inconsistently with its provisions, using the means already required to be available under this Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

5. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products, it is recognized that the development of systems providing for the grant of regional patents to be applicable in the Members described in paragraph 3 of Article 31bis should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of this Agreement, including in conjunction with other relevant intergovernmental organizations.

6. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of this Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS.

⁷² The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to the system.

⁷³ It is understood that this notification does not need to be approved by a WTO body in order to use the system.

⁷⁴ The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.

7. The Council for TRIPS shall review annually the functioning of the system with a view to ensuring its effective operation and shall annually report on its operation to the General Council.

APPENDIX TO THE ANNEX TO THE TRIPS AGREEMENT

ASSESSMENT OF MANUFACTURING CAPACITIES IN THE PHARMACEUTICAL SECTOR

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

- (i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector; or
 - (ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.
-