



**The Bigger Access to Medicines
Picture – Life beyond TRIPS**

co-hosted by

Gareth Thomas , Parliamentary Under Secretary of State

and

Richard Horton, Editor of The Lancet

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1. BACKGROUND

The UK Government's policy on ATM was launched in 2004 with the publication of "Increasing Access to Essential Medicines in the Developing World: UK Policy and Plans". Since then there has been continual interest in ATM issues from various sectors.

This seminar was the first of two seminar days jointly hosted by Gareth Thomas (Parliamentary under Secretary of State, DFID) and Richard Horton (Editor of The Lancet). The objective of the seminars was to generate debate about the policy work actions and support that DFID and others should pursue in relation to Access to Medicines (ATM) over the next ten years. The two-day forum explored, with industry, civil society, and academic and donor expertise, the question "are we doing everything possible to promote access to medicines?"

2. INTRODUCTORY REMARKS

In their introductory remarks the joint hosts made the following points:

- a single preventable death is intolerable;
- by implication, when we ask the question, "are we doing all that is possible?" we imply that we are not doing enough to meet the deficit in the number of people with access to medicines;
- access to medicines is a political issue as well as a technical issue;
- whilst there are political and resource problems in providing access to medicines there are specific barriers that prevent consumers gaining access to some vital medicines;
- the solution lies with governments, academia, international organisations, non-government organisations (NGOs), industry, civil society organisations and others;
- NGOs have often been the ones raising questions about lack of access to medicines and the problems with intellectual property (IP) but there is new interest and activity in collaboration between governments, international organisations and industry;
- the UK Government is committed to work with the private sector and form partnerships;
- DFID intends to carry forward the ideas from these meetings with an international advisory group on ATM to help develop new solutions.
- health is not made enough of a priority in many African countries, with two-thirds of countries spending less than 10% GDP on health
- neglected tropical diseases have not attracted research and development (R&D) because of limited markets
- corruption and fraud undermine good systems and the effective supply of essential medicines
- there is a need for adjustment of approaches to try and ensure the availability and affordability of the needed items using new business models not just donations and special deals;

They also posed the following questions:

- how can we galvanise greater effort and involvement?
- should we look for new incentives?

- can stakeholders soften their fixed positions to reach compromise for progress?

3. “FINDING INNOVATIVE SOLUTION – WHAT IS HAPPENING ALREADY”

Five speakers addressed the morning session;

- Professor Anthony So (Duke University)
 - “Reengineering the Value Chain for Global Health: Innovation to Access”
- Professor Trevor Jones (King’s College/ former head of ABPI)
 - “The Changing Landscape for Big Pharma: where’s the heart?”
- Mr Dilip G. Shah (Indian Pharmaceutical Association)
 - “Generics – what is the outlook?”
- Ms Rosette Mutambo (Executive Director of HEPS, Uganda)
 - “No medicines/no future”
- Mr Jonathan Mwiindi (Ecumenical Pharmaceutical Network)
 - “The weakest link: the supply chain in developing countries”

Anthony So reviewed the value chain (range of activities to bring a product from R&D to the market) and noted the various hurdles to drug access (therapeutic, financial and structural). In doing so he reflected on the contrast of R&D activity related to tropical and neglected diseases in the years 1975-99 (only 1% of new entities) and 2000-4 (63 neglected-diseases projects underway). He noted that for the R&D industry the net present value (NPV) was a significant driver in the search for new entities and products, and that the period required for return on investment is affected by the timing of generic entry. R&D risks can be diminished by the involvement of public-private partnerships in the investment phase. However, once generic products are on the market there are significant price reductions; this was particularly noticeable for antiretroviral products.

There have been different approaches to re-engineering the value chain. Dual markets (e.g. Eflornithine), where the high cost of a specialised product for a limited market (sleeping sickness) has been offset by an alternative use of the product in the popular beauty market (facial hair removal). “Bootstrap philanthropy” was used by a consortium, with Gates Foundation funding, to research and develop artemisinin products. An alternative process innovation for praziquantel, which for Bayer was proving uneconomical, by a South Korean company enabled them to supply the demand at an economical price. In the case of penicillin, multiple company partnerships and government contribution eliminated patent options and as a result it was widely produced and used and costs fell.

Trevor Jones recognised that the R&D pharmaceutical industry had significantly changed in its response to the public health needs of developing countries and its contribution to research into the treatment of neglected and tropical diseases. He identified various private-public partnerships (totalling 4.4 billion dollars) that were contributing to delivering access to medicines, especially accelerating access initiatives in relation to treatment for HIV/AIDS, malaria and tuberculosis. There were several vaccine initiatives that were encouraging, however he emphasised that despite the contribution of PPPs for the three big diseases there was a 1 billion dollar gap in funding to develop products for delivery to point of need.

He noted that there were nine tropical diseases (including filariasis, leishmaniasis, trypanosomiasis, buruli ulcer, dengue fever) where sustainable financing for treatment development through PPPs was needed, because industry could not fund these developments alone. Also that much more work was urgently needed to develop diagnostics tools. He encouraged the development of more “me-too” products that provided alternative formulations of products to improve their stability and efficacy.

He noted the following problem areas; difficulties for industry to match production to need without commitment from the purchasers; the need for a level playing field and best practice in the area of procurement; poor management, governance and performance in government logistics and delivery systems; the absence of adequate R&D in developing countries and the need to provide incentives for the R&D industry to form partnerships. He suggested that the following will not be successful approaches in relation to R&D work; the pooling of patents, transferable intellectual property rights, use of “prizes” to encourage industrial innovation, systems for transferable fast-track product registration, tax breaks. He expressed doubts about the success of advance market commitment (AMC) except for products that were at the stage of clinical trials.

He concluded that there should be much more focus on solving the problems of storage and delivery at country level and that there was scope to draw on private sector experience.

Dilip Shah listed the patent law situation in India and illustrated the dramatic growth and development of the India generic pharmaceutical industry from 1990 (15% production exported) to 2005 (71% production exported). This growth had had a major impact on improving access to medicines worldwide as well as an estimated reduction of 1.7 million dollars to the world market because of the absence of intellectual property rights laws in India. He observed that the introduction of patent products will adversely affect access to medicines in India because patent products will only service an estimated 20% of 250000 pharmacies in India. He questioned the necessity for harmonisation of patent law when generics contributed only 10% total of the world market. He suggested that Indian companies will continue to service global demand for generic products; and that a few companies will develop as R&D industry.

Rosette Mutambi described the WHO/HAI Africa collaborative project (funded by DFID) in Uganda which had resulted in a collaborative working group involving MOH, WHO, and HEPS (a local civil society organisation representing HAI). The rationale for the activities is to make existing medicines work for the poor people. The outputs have included a baseline survey of the pharmaceutical sector, a survey of medicines prices, continuous monitoring of medicines prices, development of IEC materials on RDU and support for review of the law on patents and IPR in Uganda. The medicines prices survey used the WHO/HAI International methodology of collecting data on prices and their components and calculating treatment costs in relation to local income. The findings (one of which was the high and variable mark-ups being applied in the private sector) are published and disseminated and are being used to inform policy and advocacy concerning access to medicines. She concluded that there were opportunities for work to make existing medicines available by strengthening in-country alliances and providing international support.

Jonathan Mwiindi noted that whilst the supply chain is essentially simple and should work in theory, the actual situation is very different with lots of middlemen (reps, agents,

etc.) involved in all areas of the supply chain. He explained how middlemen play games by tendering advice to officials (including kickbacks), conducting unethical audits (pharmacists, prescribing etc.), using payment based discounts (if payment quick enough and also based on community links), and incentives to purchase and stock certain products (perks and freebies). He suggested that in Africa medical representatives are now mainly used as unregulated sales representatives based on incentive based pay related to volume of sales. He urged the restoration of sanity to the supply chain where unethical practices and lack of integrity in the process existed but was mostly invisible.

He described the approach of the mission sector to the provision of health services (to an estimated 110 million people in Africa) including the rationale for charges (on the basis of payment after provision of the service) to patients, including the charges for medicines. In mission health provision, charges were mainly levied on “tangibles” and therefore there was cross-subsidisation for “non-tangible” services and those who could not afford to pay. Mission services operate on a cash accounting basis with very few subsidies for running costs from government and other funding agencies.

He concluded by observing that product price alone was not a determinant of access and that there are many other types of opportunity cost that are disincentives and that influence access to medicines.

About 20 individuals made comments during the plenary session and they covered the following areas;

- Other associated issues that must not be forgotten:
 - the long term problems of ensuring sustainable supplies of existing, cheap health technologies, there are still huge areas needing the basic essential medicines, there is much concern and investment at R&D at the “top” of the supply chain but a big need for investment at the “bottom” end;
 - the dual need to eliminate the illegal trade in medicines and to build capacity and support primary health care delivery
 - failure to address the need to support and improve logistic and management systems in public sectors that are compromised in many ways
 - research into the performance and problems in the private sector management and supply/sale of medicines on the basis that the private sector (both the formal and informal) is the major supplier in many countries.
 - Development of a code of practice for the promotion of medicines
- The importance of the development of more rapid and user-friendly diagnostic tests, an area where the use of prize funds might prove more effective but also with a need to ensure their affordability and access
- Mark-up levels are not the only factor influencing the prices of medicines and innovative ways of providing remuneration for good quality services must be explored
- Lengthy processes and costs in the registration of products (often duplicating work elsewhere) needs to be addressed as a perverse incentive to industry in providing access to medicines

- In all the discussion of the needs of LDCs and communicable diseases in Africa do not forget the needs of middle income and transition countries for improved ATM, especially in relation to non-communicable diseases
- Industry's observation, after working with a malaria product that is essential and subsidised in price, is that patients do not benefit from early chain benefits; in addition, payment delays are a major problem when linked with expiry dates. There are many exceptions to quality levels that confuse and mess up the system
- It was queried whether generic manufacturers will move their production to other countries after the introduction of patent law, but the response was that the alternative countries would have to provide a large enough domestic market (e.g. Nigeria, Bangladesh) and provide the necessary infrastructure and technical capacity, and weaknesses raise the capital investment costs and may not justify the investment.
- Whilst commending the proposed UK interventions in doctor/nurse salaries in Malawi the medium and long term benefits of this are not known and need to be carefully evaluated.
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4. "MAKING IT HAPPEN – FROM POLICY TO ACTION ON THE GROUND"

Five speakers addressed the afternoon session;

- Dr Elil Renganathan (WHO, Executive Secretary PHI Secretariat)
 - "Innovation for the Future"
- Dr Venugopal (Director, International Operations for MMV)
 - "Putting IP in it's place"
- Dr Catherine Royce (Drugs for Neglected Diseases Initiative)
 - "Generics – what is the outlook?"
- Professor Sunil Shaunak (Professor of Infectious Diseases, Imperial College, London)
 - "Ethical Pharmaceuticals"
- Dr Tom Ellman (Medicins sans Frontieres)
 - "The NGO Perspective"

Elil Renganathan began by recounting positive changes that had taken place in Malaysia over the years and he concluded that making improvements in access to medicines (both availability and affordability) was achievable but the way forward was complex and it is part of a bigger issue. He described the development and progress of the Inter-Governmental Working Group (IGWG) on public health, innovation and intellectual property. The Working Group's mandate is to prepare a global strategy and plan of action on essential health research to address conditions affecting developing countries disproportionately. The resulting global plan of action will be presented to the World Health Assembly in mid-2008. He noted the need to engage more member states (especially low income), to continue dialogue among member states and other stakeholders including civil society, industry, academia, PDPs and the need to rekindle the "spirit of Geneva".

In plenary discussion it was suggested that on the plus side the IGWG links IP with access but that it is focused on type 2 and 3 diseases and tends to limit discussion about TRIPS and IP, with a temptation to drop” hot issues like utilisation of TRIPS flexibilities. It was agreed that open discussion is needed (and took place in Geneva) about priority setting for research and development but the question remains as to who will pay and how (existing incentives may not work for type 3 diseases and markets). The concept is that funding responsibility should be shared but an issue is how to ‘incentivise’ people to do vital research? There is a need for both push and pull mechanisms. It was suggested that using “prize” mechanisms might simply be a way of replacing high prices with prizes. The IGWG does offer opportunities to discuss patent pool development where the controversy is around patent pools for existing products. The patent pools concept looks at a collective way of approaching patent problems and can be pro-competitive.

Dr Venugopal stated that IP is necessary but what really matters is how innovatively you manage IP. He explained that the Indian patent law of 1970 was a stimulus for generic companies because it had recognised process patent but not substance patent and that it had been shown that in the case of Ibuprofen tablets the alternative processes developed had produced better quality products than the originator process. He said that in response to TRIPS some countries had changed patent law and as a result got lots of investment e.g. Brazil, however, it is not possible to achieve universal patent law because not all countries can comply and the best approach for countries is to have a system that is close to international view. On R&D he observed that R&D will only occur if there is a market and that in the case of small disease incidence R&D will only take place if it is in rich countries. He complemented US legislation that rewarded university research with royalties. Speaking about the DOHA declaration on TRIPS in relation to type 3 diseases he expressed a preference for agreeing voluntary licences over the use of compulsory licences and that partnerships should be established to use voluntary not compulsory licensing. His final plea was for innovation, innovation, innovation.

In follow-up discussion one speaker encouraged people to consider middle income countries (e.g. India and China) as significant users of medicines and not only as producers; noting that middle income countries as users have an impact on prices for other countries but that they are also very vulnerable to fluctuations in prices and are close to the poverty line and therefore totally dependent on generics.

Catherine Royce spoke in favour of bringing the best science to the most neglected diseases through partnering; by putting the needs of patients first; making products available and affordable in endemic countries; disseminating research; developing new products as public goods; acquiring patents on a case by case if necessary to assure public access. Tropical diseases, which are poverty-related, are responsible for 530,000 deaths per annum with a loss of 57 million DALYs. She spoke of the “unlucky 13” neglected tropical diseases of which five (filariasis, bilharzia, onchocerciasis, soil-transmitted helminths and dracunculiasis) are treatable, five are not so easy to treat (leprosy, buruli ulcer, dengue, cholera and trachoma) and three are difficult (trypanosomiasis, leishmaniasis and Chaga’s disease). DNDi uses robust science to develop new treatment for most neglected diseases. It is driven by patient needs not for profit and works through partnership with support from Pharma, DFID and other partners. They aim to develop, through R&D, 6-8 new treatments by 2013 and in endemic countries to raise awareness and advocate for increased responsibility.

She described two existing programmes, the Leishmaniasis East Africa Platform that is researching the use of paromycin, and the Malaria Fixed dose ACT project facilitating affordable, effective treatment for malaria. The challenges are to ensure sustainability of financing (a budget of 274 million Euro over 10 years) and momentum through advocacy (building awareness, political leadership, new financial mechanisms, involvement of NGOs and foundations) and building political momentum (through WHA resolutions and international activity). She emphasised the need for public leadership and collaboration in achieving the goals.

Sunil Shaunak began by reminding the seminar that medicines are becoming expensive and there is a need to use biotechnologies to make affordable medicines. He described how specific techniques had been developed, at Imperial College, to improve the qualities of the interferon molecule used in the treatment of hepatitis C; and the problems associated with the commercial development and marketing of the product. He described the model traditionally used to bring publicly/charitably funded innovations to the market that resulted in complete loss of public sector control over the technology and he would like to see a new business model for innovation enabling academics to contribute to major social problems by partnerships. He suggested that there is a need to structure the licence to ensure access for modest profit public health use to address neglected patient populations, to retain more control over health technologies, to avoid patent aggregators (middlemen) and introduce new and reduced fee structure for certain uses.

Tom Ellman began from the position that health and access to medicines is a human right and there needs to be a response to that need as a right and not as a market. He suggested that it was because of the inadequacy and failure of existing systems that a humanitarian organisation, like MSF, has had to be involved in financing R&D into new treatments. He explained that NGOs are looking for R&D systems that meet needs and produce new technologies (for both diagnosis and treatment), that are available and accessible, but that the current environment is frequently one with either no tools, inadequate tools or existing tools that are too expensive.

He pointed out that a market intensified system will not work in a situation of no tools and that philanthropic contributions are unsustainable; the need being for government commitment. He gave an example of TB as a situation where tools are poor yet there had been very little R&D taking place; the need is for incremental innovation to adapt basic innovations to the actual situation. In the third scenario, where tools exist but are unaffordable, the system is not working and patents are part of the problem. Not 'messing' with patents is not an option. He stated that "we are not beyond TRIPS" and that India (providing 50% of the worldwide market) has been and continues to be fundamental to the provision of ARVs. He reminded the audience that TRIPS arose because of the ARV situation and emphasised the need to ensure that TRIPS safeguards work in practice in relation to the treatment of other diseases.

Based on the silence of the expected support for the Government of Thailand in delivering compulsory licences for three ARV products in the face of strong opposition, he expressed concern about the lack of overt support that might follow the introduction of patent law in India. He welcomed DFID support in general and looked for specific support on implementation activities. He declared that without guarantees of sustainable funding all the discussion on ATM is theoretical; that there must be an openness to new ideas which includes 'messing' with systems that may be inadequate, that activism

needs to be wider and involve professionals, politicians and communities, that activism needs to be balanced by evidence and may need an impartial arbiter who can bring these problems together to make sense of the different priorities.

About 11 individuals made comments during the plenary session and they covered the following areas;

- The genuineness of industry's contribution to ATM was questioned but in response speakers suggested that it was not a smokescreen but a genuine response to the public pressure for them to be more compassionate
- The role of the beneficiary country governments in PPP's was very limited and there is a need for more involvement of recipient governments in PPP's
- In response to the suggestion of Universities being more involved in R&D and patenting innovation, an industrial representative suggested that the old model of licensing to make profit is no longer the case and many licenses are not exclusive. If we proceed in the direction of an academic role into innovation Universities are no longer behaving as academics but like a business. Patent registration may be wrong measure for success of academic institution
- In response to the possible extension of IGWG deadlines for responses to allow countries response time, it was clarified that no extension will be given though those issues requiring a lot of discussion may be dealt with differently
- One speaker from Tanzania expressed a concern that an impression was being conveyed that "if a country is small and poor then innovation is not an option" and the way forward is blocked because of developments in IPR, yet at some stage all countries worked without patents for products and processes but gradually developed.

5. SUMMING-UP BY THE HOSTS

Richard Horton;

- Whilst the global level is important what happens at country level is vital
- Disease issues include non-communicable diseases
- We need to understand the local context of irrational use and weak supply chains in an environment with a predominance of rural community
- A strengthening in the system to ensure use with an emphasis on primary health care in rural areas (Alma Ata declarations nearing 30th anniversary)
- Need to have greater commitment to health and health research including biomedical research and this should be included in the November ministerial conference to include discussions on health research
- The role of academia may be a neglected aspect but they are vital for discovery and local research capacity is essential for local growth, Gates and Wellcome Foundation are following similar tracks to fund capacity-building in the university sector through partnerships and links
- PPPs are essential to the participation of Pharma but there has been little evaluation to assess what makes them work and whether they are successful
- The pharmaceutical industry should be a partner of academia to encourage research capacity in low and middle income countries
- WHO has a crucial role to be an impartial arbiter and should retain and expand its mandate

- Funding agencies and foundations need more critical evaluation of projects to see what works and what does not work to ensure the cost effectiveness and cost benefit of programmes
- NGOs are a neglected group working through collaborative networks with an environment for action; they may not receive enough support but also what is the responsibility of northern NGOs to partner and help the development of “southern” NGOs?
- What is the role of media in advocating and disseminating and encouraging accountability?
- What is the role of the royal colleges and professional groups?
- Parastatals have a role and the next CHOGM health ministries meeting will address health systems and lifestyle procedures
- G8 countries have made statements but what have they achieved? They have a critical part to play in political support for global business plans being developed for specific diseases
- No access to secondary care, no access to medicines is the situation of 85% of people in low income settings and access to medicines is central but cannot be separated from much larger predicament that they face; ATM is not an answer to poverty and problems of poverty.

Gareth Thomas;

- It is not too late for the developing countries and DFID takes this seriously, especially for Africa
- Whilst many of the comments have been heard before, there has been much progress (63 new products are being developed) in the area of ATM but there is plenty yet to do
- Optimistic of total agreement on way forward but ...
 - TRIPS is still an important issue to contemplate along with issues of health systems development and strengthening
 - Issues are moving forward on ARVs and products and treatments for HIVAIDS
 - There are a number of donors looking together at what can be done
 - There are improvements in health system capacity in some situations
 - Transparency remains a serious issue and there is a need for more work in that area.

DFID Access to Medicines (ATM) Seminar**20th April 2007 10.00 am to 2pm****Technical Session 1 – Innovations and Intellectual Property and Public Health****6. BACKGROUND**

DFID's "Increasing Access to Essential Medicines in the Developing World: UK Policy and Plans" was launched in 2004. NGOs drove the resurgence of ATM in 2006, launching access and affordability campaigns (singling out intellectual property and UNITAID) in advance of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) meeting in December 2006 and Germany's 2007 G8 Presidency.

DFID and the Lancet co-hosted a two day Seminar in April 2007 as a means of promoting constructive dialogue on current ATM challenges. The two-day forum explored - with industry, civil society, and academic and donor expertise - the question "are we doing everything possible to promote access to medicines". A key aim was to help inform the kind of policy work and other action and support DFID and others should pursue in relation to ATM.

7. ARRANGEMENTS

Session organisers: Lynne Charles (DFID/International Trade) – facilitator morning; Michael Borowitz (DFID/ATM) – facilitator afternoon; Andrew Jenner (Intellectual Property Office).

Note-taker: Elizabeth Gardiner

8. OBJECTIVES

- To inform DFID/U.K. government's view on intellectual property including innovative mechanisms such as patent pooling;
- To explore how other mechanisms beyond IP can be used to achieve similar objectives to lower prices such as global pooled procurement (e.g. Global Drug Facility for TB, GAVI, etc.)
- To discuss IP arrangements under new hybrid models of innovation.

9. INTRODUCTION AND INTRODUCTIONS

After welcoming participants, Lynne Charles asked Michael Borowitz to say a few words. He explained that there is now an ATM hub at DFID's policy division aiming to enhance ATM strategy, re-engage on ATM issues, and discuss drugs together with health systems. Key issues for DFID are ways to draw on existing experience and continuous learning to improve the supply chain and make sure that drugs get to consumers. DFID is working to identify "the low-hanging fruit" and where the difficulties lie in ATM. He underscored that this is not simply an IP issue, and that DFID was open to new ideas.

Andrew Jenner noted that for the most part IP works in the developed world but is of limited effectiveness in developing countries. The key issue is therefore how to create incentives for pharmaceutical companies to develop medicines for diseases which affect developing countries, and especially what role Governments can play in this. He emphasised the need to pick "the low hanging fruit" now, i.e. operationalise incentives *now*.

A list of participants for the session can be found in the appendices.

10. PRESENTATIONS AND DISCUSSIONS

a. Presentation 1

Anthony So gave a presentation to provoke thoughts on IP issues and innovations. He suggested a framework with three broad options:

- Reshaping IP to align with public health priorities
- Diminishing reliance on IPR protection as an incentive
- Delinking IPR protection and innovation

To this end, he put on the table several proposals of what could be done by DFID and others for the group to discuss. These included:

- 1) *A drug patent database.* The status of patent filings and registrations, particularly in developing countries, is not easily discovered nor transparent to procurement agencies or public health stakeholders.
- 2) *Reduced or waived Patent Office fees for registration of inventions made available under specific humanitarian licensing approaches.* Certain circumstances might define what inventions might qualify (e.g., non-commercial purpose, dual market, or building block of knowledge).
- 3) *Changes in the drug regulatory process.* These might include requiring disclosure, but not regulatory linkage between patents and drug registration; rethinking data exclusivity; assessing the anti-competitive barriers standing in the way of fixed-dose drug combinations; mitigating the antitrust concerns over patent pools in biomedicine; and ensuring timely release upon drug registration of pharmacopoeia monograph information.
- 4) *Approaches to ensure continued process innovations.* Such steps might involve compensatory liability systems (use first, pay later) or patent pooling of critical building blocks.
- 5) *Support broad access to research tools.* Promising approaches include open access publishing and the development of public compound libraries for drug discovery.
- 6) *Regional pooled procurement and regional use of TRIPS flexibilities.* Such arrangements would take advantage of monopsony power, pooled expertise, and collective action of a bloc of countries where a single country might not be sufficiently emboldened to apply TRIPS flexibilities as needed;
- 7) *Metrics on fair returns on public investment in R&D and public-private partnerships.* Some evidence suggests that public-private partnerships for product development are performing as well, if not better, than private efforts alone, but sustainable funding for the growing number of these efforts is wanting.

Dr. So also suggested ways in which DFID might potentially respond by:

1. Providing seed capital required for alternative models of innovation and IP;
2. Developing clear IP guidance as a funder of PDPs, GFATM, and multilateral institutions for fair return on public investment;
3. Mitigating the consequences of TRIPS-Plus FTAs by providing *independent* technical assistance and capacity building (e.g., Bolar provision, antitrust);
4. Ensuring measurable reciprocity of technology transfer under TRIPS;
5. Including transparency of IP as part of MeTA;
6. Encouraging humanitarian licensing at UK academic institutions and in public sector-funded research;

7. Developing white paper on boomerang effects of strengthened IP regime on long-term global health security.

In connection with this final point, he noted that we may soon enough face situations when the effects of blindly strengthening the IP regime may boomerang upon our own public health needs in industrialized countries. Consider the recent difficulties in securing continued access to samples necessary for the development of an avian flu vaccine from Indonesia without ensuring benefit-sharing over access to such a vaccine for those in Indonesia.

b. Discussion 1

An active discussion followed including the following points:

- 1) Databases of drug patents and drug registration would be strongly supported by WHO, but drug registration should not be linked to patent status as the competencies of drug regulatory authorities and patent offices are different. Drug regulatory authorities are sometimes called upon to enforce patents by denying registration to drugs submitted for approval, but they are not well positioned nor resourced to make such judgements on patent validity.
- 2) The representative from Jordan noted that as a consequence of the U.S.-Jordan Free Trade Agreement, Jordan's drug regulatory authority is now required to notify patent holders as part of the registration process for generic competitors. This is very difficult for Government as the infrastructure is not in place and there is no linkage between patent and registration offices. Why are developing countries being asked to follow the US approach when the EU has no such policy linking patent and registration?
- 3) BU noted that we have tended to ignore the role of the US and their objectives regarding the TRIPS and Doha agendas causing the rights of countries to exercise TRIPS flexibilities to be eroded and challenged. This ATM working group could express outrage at Abbott's efforts to withhold drug applications in Thailand.
- 4) Merck underscored the importance of having a specific discussion on identified needs focusing on what the PPPs and the private companies need.
- 5) MMV asked about the no disclosure, no enforcement policy
- 6) Imperial requested to hear from the pharmaceutical industry. Yesterday they said don't tamper with patents.
- 7) Johnson and Johnson (and MMV) noted that IP was important for a return on investment but that many companies are providing drugs at differential prices, offering voluntary licences and participating in PPPs. The area of challenge is the diseases only of the developing world which is why we have DNDI.
- 8) Novartis said it was looking at innovations that don't require a wholesale change or abandonment of the IP system. IP allows them to work with universities.
- 9) WHO pointed out that for chronic diseases developing countries do not have differential pricing, but rather higher prices. This problem is primarily at the country level not at pharmaceutical headquarters. Transparent prices would be a desirable development.
- 10) Novartis is looking at ways to use the current business model to do differential pricing across and within countries but the problem is that there are few regulations on pharmacists re pricing.
- 11) University of Delhi asked if there was a public domain of medicines and recommended that DFID help to develop one.
- 12) Stop AIDS wondered about the use of regional TRIPS flexibilities and how DFID could encourage that politically and technically.

Anthony So made the following summary comments:

- It is not clear that there is a significant correlation between a stronger IP regime as advanced by TRIPS and US foreign policy and the promised returns of increased foreign direct investment in most developing countries in the pharmaceutical sector. Of note, at the outset of the Uruguay Round negotiations, fifty countries did not recognise patents on pharmaceutical products, and the pharmaceutical industry's record of bringing new therapeutic innovations to market was innovative before TRIPS and ironically in decline over the past decade.
- There have been significant concerns over the pharmaceutical industry's influence and ties to the current U.S. Administration. This makes it difficult to imagine that a meeting like this one hosted by DFID would take place under the aegis of the Bush Administration.
- The short-term perspective on IP is a concern: we may one day be on the receiving end of the policies we are imposing on others (noting the sentinel warning over access to Indonesia's avian flu samples).
- Clearly if the status of a drug patent is not disclosed, it cannot and should not be enforced. How best to enforce this principle of "No disclosure, No enforcement" requires further development. A drug patent database would be a step in the right direction.
- Some universities have been less cognizant of humanitarian licensing approaches than industry and have exercised exclusive licensing where geographically limited approaches would have allowed more affordable access in developing countries.
- We need to be careful about segmenting markets *within* developing countries to capture profits. The value of all of sub-Saharan Africa as a percentage of the global pharmaceutical market is around 1.3%. Does it make sense to pursue the high-end market in developing countries? What burden does this impose on the health care delivery systems in those countries to maintain this segmented market?
- In support of examining the feasibility of regional pooled procurement, the South Centre has a useful paper on "Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks," and there is also important work to draw on planning for regional pooled procurement. There are advantages to the decisions for buying drugs to be locally owned, and at the same time, value in drawing on regional expertise and transparency among a group of countries in procuring drugs. The Global Fund could help bolster these regional pooled procurement efforts through the funding it provides for drug purchasing.

A final discussion followed for this session:

- 1) DFID noted that Dr. So had put forth a number of challenges on how DFID can support countries on TRIPS. She noted that the issue of IP and regional trade agreements was an important discussion in Europe too, and that we needed to keep an eye on how IP issues were being treated in the Economic Partnership Agreements, for example.
- 2) UNCTAD is carrying out some work on behalf of DFID on enabling developing countries to use TRIPS flexibilities to access affordable medicines. This pilot project could be expanded to consider regional approaches. There is a great need for awareness-building on TRIPS flexibilities.
- 3) WTO noted that regional approaches for TRIPS could be more widely used but that some convincing of the benefits is needed. For instance, these might apply in the Caribbean.

c. Discussion 1

Jamie Love spoke about patent pooling, defined as “the collective management of groups of patents.” Many different forms of patent pooling exist, with different management structures, royalties, etc., with the common theme of scaling up from one patent to many. People are interested because:

- Patent pools can create access to compounds for research and drug development
- Compulsory licensing is difficult (logistically and politically)
- Patent pools offer sustainability where donors are creating the market
- Patent pools can help companies to do well economically, which differential pricing based on marginal costs may not offer

Key issues are royalties, management of licenses and transparency. A pool approach supported by the UN can mitigate the political pressures as the country is simply following international norms. Incentives for getting patents into a pool are:

- Social norms: It’s the right thing to do
- Benefits to members: If you license your drug to the pool, you’ll have access to technologies acquired by the pool
- Financial incentives: Payment is based on the impact of their inventions – e.g. donors would set aside prize money to be divided among those who license
- Can improve the quality of the licensing process

We don’t want a for-profit to negotiate the pools, but we might have a for-profit management agency. The key role for DFID and other public sector partners would be policy.

d. Discussion 2

An active discussion followed:

- 1) Additional features of pooling:
 - incentivises entry of generics by aggregating markets (pool should include middle and lower income countries) which may also be a benefit to single countries
 - can set a standard for access terms (whereas compulsory licence negotiations are not transparent).
 - Patent pools vary because they are used for different purposes.
- 2) It is important that the patent pools provide technical expertise and leverage.
- 3) The pooling idea would be attractive to universities because the patent process is tedious. Universities want the pool in order to have the use of a patent in a particular field, i.e. treat these particular diseases. It would be important for information to go into an open access database. If we know what the revenue is at the end, it is easier to decide which route to take.
- 4) From a public health perspective, fixed dose combinations (FDCs) are important and patents are a barrier to FDCs.
- 5) Professional managers can help with TRIPS and WTO issues, as voluntary licenses should be the starting point.
- 6) The royalty structure should not relate to the cost of manufacture, but be tied to the GDP and how much the patient receiving the drug benefits.

- 7) Rewards should be based on registration of a new product, which is a substitution for the exclusivity provided by patents. The pool has an interest in having expensive drugs licensed into the pool so paying an incentive would help to bring more expensive drugs in. A reward system requires a simple model using quality-adjusted life years so if the more health benefits the product creates, the more the creator would get paid.
- 8) A large number of countries have supported patent pools in both upstream and downstream phase.
- 9) Industry representatives noted that they are not against patent pooling, but suggested that discussions about pools should be based around specific drugs as there are some circumstances where pools would be useful and beneficial and others where they would not be. It would be easier to take forward a pooling idea if the specifics of the proposal were clear.

e. Presentation 3

Dr. P.V. Venogopal presented what could be done and what has been done under the Medicines for Malaria Venture (MMV) as part of the discussion on IP under new global partnerships.

- Combination drugs can be compared with the complexity of building a building on three separate plots of land. This complexity underscores the need for companies to collaborate.
- Pricing of drugs can be compared to airline pricing in complexity. The consumer and government are the two parties that can intervene to change pricing, though insurance companies also influence price. If price is too low, customers will consider it to be a fake. MMV has set it up that they dictate prices in developing countries, while companies can charge what they want in developed markets.
- IP is not patent alone but also logo, trademarks etc.

In the interest of time, discussion was withheld until after lunch and the next presentation. The afternoon sessions were chaired by Michael Borowitz.

f. Presentation 4

Brenda Waning from Boston University presented her findings from analysis of ARV pricing data on the web. The research aimed to identify where and why price variation occurs and use information to inform donors and programs. The data set included 5,219 procurements between 2002 and 2006 in 90 countries valued at \$231 million.

- The idea of pooled procurement by the Global Fund was challenged. Why is it necessary? The Global Fund could instead use the information on the web as a mechanism to monitor.
- There was very high variability in procurement prices, equating to high variability of number of people treated. For first line treatments, generics were less expensive. For second line, generics were more expensive.
- Procurement estimates are poor, but very little relationship between volume and price was found. Companies held true to advertised prices.
- Waning proposed
 - Creating a list of prices paid as a benchmark for countries as a way to reduce prices
 - Encouraging the Global Fund to use the existing data to help countries secure lower prices

g. Discussion 3

An active discussion followed:

- 1) Pooled procurement would be a solution for the Global Fund as the idea of direct payment from the Global Fund was appealing to industry. Waning countered that direct payment to the suppliers might be a solution but that this did not make an argument for pooled procurement.
- 2) UNITAID analysis has found savings through pooled procurement.
- 3) The market for generics was not yet established and that volume was low partially because of patents. For this reason the price of second line drugs would be expected to be higher but dynamic.
- 4) Pharma mentioned the challenges of getting the distributors to maintain the lower prices.
- 5) The Clinton Foundation is a powerful price negotiator, but not an agency conducting pooled procurement.
- 6) Supply Chain Management System (SCMS) is coming on board to conduct procurement. Several people expressed concern that a separate agency will do procurement on behalf of the countries. The Global Fund approach was to build capacity for procurement and hold people accountable.

h. Presentation 5

Richard Laing gave a presentation on IP from a public health perspective. He asked the question, "If there were substantial public funds available, how should they be spent from a public health perspective?" He recommended reading "Priority Medicines for Europe and the World."

- Drug innovations are declining: The US Food and Drug Administration registered 32-33 innovations in 2006, so now there are more drugs coming off patent than new drugs. The generic market may become better than innovator. How many drugs actually need compulsory licenses?
- Burden of disease: low actual burden now, but very high potential. Growing interest in chronic disease medicines in developing countries.
- There are still several neglected diseases on which little research is being done for diagnosis and/or treatment. The growth of resistance is particularly worrying alongside the decline in innovation, to a point where MRSA (methicillin resistant *Staphylococcus aureus*) is almost like an orphan disease.
- Data exclusivity and product registration keeps the polypill for cardiovascular disease and stroke out of European markets (potentially 60 million people)
- Pricing should be linked with value of the products where GDP per capita reflects the value. The industry is urged to move toward a transparent pricing model that would be predictable.
- Discussion should be on Fixed Dosed Combinations (FDC) driven by health need
- Registers should have more transparency so it will be clearer why some drugs take longer to register than others.

Discussion was withheld until after the final presentation.

i. Presentation 6

Peter Evans made a presentation on global procurement, meaning not just the order but the relationship between customer and supplier.

- We need to make sure we are protecting industry partners. Novartis promised a factory and production and we promised a market, but we aren't delivering.
- Pooled procurement can allow the pool to allocate the drugs.
- Standardising can improve prices. (See UNICEF and PAHO example).

- Quality and perceptions of quality can be a barrier. (See Indian vaccine example).
- Forecasts can be very poor, as we saw with Coartem
- It is necessary to solve low end availability at point of use for both existing and new products.

j. Discussion 4

- 1) Coartem: Projections in 2004: 4 million, 2005: 120 million, actual produced 30 million (with great effort), actual sales: 9 million. In 2006 30 million treatments delivered. In 2007, discussion on incentivising generics. A lesson of Coartem was not to change treatment guidelines overnight.
- 2) Pooled procurement must be done professionally with plenty of time.
- 3) Guaranteed payments or advance payments are crucial to keep suppliers from pulling out.
- 4) Concern about pooled procurement being perceived as a magic bullet and about separate payment mechanisms for each drug. Instead in-country capacity must be built by conducting actual procurement (not workshops).
- 5) The Global Fund is a financing organisation not a procurement agency, which appears to be collecting data but completely ignoring them. Before developing a pooled system, the Global Fund should use its power to demand accountability for any payment above median. Local Fund Agents don't do more than look at receipts. Others thought that the Global Fund has fragmented the market and should standardise treatments.
- 6) Procurement accountability is very difficult as it is not possible to take money away because then treatment doesn't get to patients.
- 7) Both generics and big pharma need a profit, and that we should give more accolades for those who give a good price.

11. Conclusion and Summary of Meeting Points

Michael Borowitz thanked everyone for coming and promised that DFID would be following up on the day's discussions.

Open source access to patent and registration data is desirable for transparency and lowering prices, but the financial and human resources of governments should be taken into account.

- 1) **Patent pooling** represents an interesting new idea with potential to overcome certain patent issues. For the countries patent pooling can improve quality of licensing and access to patents, economies of scale if several countries joining together, political acceptability, etc. For pharma and other producers patent pooling can create financial incentives to participate, provide opportunity for access to other patents in the pool.
- 2) Financial rewards, such as **prize mechanisms**, can be based on registration of a new product, which is a substitution for the exclusivity provided by patents. A reward system requires a simple model using quality-adjusted life years so if the more health benefits the product creates, the more the creator would get paid.
- 3) Drug pricing could be linked with value of the drug which should be reflected in per capita GDP per capita. The industry is urged to move toward such a **transparent pricing model** that would be predictable.
- 4) **Countries need assistance** with interpreting TRIPS and with drug demand forecasting.
- 5) The need for **fixed dose combinations** from a public health perspective should drive demand for overcoming IP challenges.
- 6) **Pooled procurement** is not a magic bullet and donors should exercise caution before establishing separate payment mechanisms for each drug (such as Supply Chain Management System (SCMS)). Building in-country capacity by conducting actual procurements and holding countries accountable for them is essential for long-term sustainability. The Global Fund and others may want to consider using existing procurement pricing data to lower procurement costs before adopting other procurement mechanisms.

12. Technical Session 2 – Push And Pull Mechanisms

(innovative financing and NTDIs -push/pull, priority setting for PDPs, R&D, AMCs)

a. Arrangements

Session organisers: Chris Collinson (DFID/ATM) - facilitator; Owen Barder (DFID/Development effectiveness);

Note-taker: Paul Spivey

b. Objectives

- To inform DFID/UK government's approach to innovation;
- DFID believes that pull mechanisms are relatively neglected and should be prioritised. To consult on this in the broader ATM community.
- To understand mechanisms for prioritising funding for new product development.

c. Introduction and Introductions

After welcoming participants the facilitator explained that the DFID/ATM agenda has been developing since 2003 and this meeting is one of three concurrent DFID consultations on ATM-related subjects with the purpose of informing policy and implementation on various areas of ATM. The objective of this group is to suggest how "push" and "pull" mechanisms can be used in optimal ways in relation to innovation of products needed to improve access to medicines and treatment in developing countries.

Participants then introduced themselves. A list of participants can be found in the annexes.

The first part of the meeting was focused on information with presentations from DFID and OHE around the factors that could influence decision making towards either mechanism. The second part of the meeting was intended to be focused around discussion of some of the issues arising from these presentations, but in reality a lot of discussion took place during the above presentations in response to the material presented.

d. Presentations

Owen Barder (DFID) gave a presentation which looked at an abstract model for push and pull mechanisms, the real world differences for each, before concluding that;

- In abstract models it can be demonstrated that push and pull mechanisms are equivalent in their net return for the investor.
- In real situations the decision in favour of push or pull will be influenced by circumstances, more so by the probability of success and rewards than by the cost factors.
- Push mechanisms may be more appropriate where basic research and development is involved, whereas pull mechanisms may be more effective for late stage involvement for testing and marketing specific products.

Martina Garau (OHE) presented work done for the Gates Foundation which involved modelling the relative efficiency of the push and pull mechanisms.

Both presentations stimulated debate during the course of the presentations. The discussions based on the OHE presentations centred mainly on the assumptions that were made in reaching the conclusions of the work. In particular assumptions that suggested that:

- Push is a more efficient way to get global health discovery done than pull (Push funding can be spread across a range of approaches, companies and researchers, with the PPP making the strategic choices as to what to try and what to kill)
- Push funding (via ADIPs) probably more efficient to prepare markets on behalf of a range of companies (Companies alone will achieve slower up-take rates)
- Companies have a higher cost of capital than donor (Push is cheaper in cash terms)
- Pull approach leads to higher “out-of-pocket” development costs
- Pull driven clinical trial efforts are likely to have higher success rates than push (Pull provides strong incentives for companies to seek to kill “problematic” projects early in an effort to raise success rates for the later stages)
- pull achieves shorter timelines (companies do not get a commercial reward until they have got a product to market and there are significant “first mover” advantages)
- pull achieves higher quality of product than push because of competition, although given the uncertainty about the amount of competition that will emerge this effect may vary by disease area

Participants expressed a desire to discuss the options for, and experience with, “real-world” and specific push and pull mechanisms, rather than a discussion about the nature of the complementarity between generic push and pull funding. However, DFID pointed out that high level decisions on what to fund, and in what circumstances have to be made by donors, and so the questions raised in the generic debate are highly relevant and “real world”.

e. Discussion

It was suggested by the representative of the industry that for vaccines which operate a different business model where the vast majority of the volume is already going to the developing world, pull mechanisms, such as Advance Market Commitments (AMC), which provide the promise of a viable market and the confidence to invest in larger production facilities, have an important role to play.

Andrew Jones (GAVI) described the planning and current stage of implementation involved with the pneumococcal vaccine using the AMC model of pull mechanism. There was discussion around the concept of the subsidised price for a particular volume of sales and the subsequent tail price. It was explained that the AMC was tied to purchase volume and this in turn influenced the length of time (dependant on the rate of uptake) and of the contracted tail price.

It was suggested that mechanisms that seek to ensure a profit on medicines to treat malaria developed in PPP’s could help “incentivise” companies. The Mary Moran study showed that large pharmaceutical companies tend to be engaged in PPP’s because it is the right thing to do and are driven by image and reputation imperatives, whereas for SME’s and biotechs they see more of a commercial opportunity from working on diseases of the developing world. In response a representative from the industry said that it was important to understand the motivations of companies. Therefore for larger companies, such as GSK, who are already active in this area but operating on a not-for-profit basis, mechanisms designed to ‘create’ a profit are unlikely to be a major incentive. However, pull mechanisms that could assist in scaling up production and ensure access to patients would be useful. For smaller companies the situation may be different.

In response to the question of ongoing motivation for the company to continue production, under an AMC, based on marginal cost recovery, one alternative suggestion to a tail price period was the option of buying out the intellectual property rights at the conclusion of the advance purchase period, with a view to keeping the price low through subsequent generic competition and with the possibility of lowering the price further. It was suggested that whilst this might be applicable for other medicinal products there might not be a sufficient range of generic manufacturers for biological products to make it an option.

This was followed by a discussion of “prize” incentives as an alternative pull mechanism to stimulate innovation, especially where procurement is largely dependent on large donors (e.g. items largely purchased with Global Fund grants). The prize mechanism (as described by Jamie Love) is seen as an alternative to tying R&D incentives to the eventual price, which is the effect of the PDP and AMC mechanisms. “Prize” incentives would reward the marketing and supply of the product in a country (by distributing amongst companies who register a product a % of the total GF spending on the products) but allowing the pooling of patents to stimulate competition to establish the lowest price. Such a scheme would therefore enable producers without R&D facilities to participate in the prize reward as well as the innovator industry and regardless of product price.

It became clear that there are different experiences with push and pull mechanisms, that there are different models, that the case of vaccines may be different to other products and essential medicines. Unfortunately time did not permit this discussion to take place.

f. Summary of Meeting Points

- In an abstract economic model “push” and “pull” mechanisms appear to be equivalent;
- In reality there are factors which may influence the choice of one mechanism over another, and these may include the different motivation of and implications for, various stakeholders and actors;
- Current research may be using assumptions based on anecdotal or theoretical information rather than evidence and experience, which may be leading to false conclusions;
- There is a need to document and publish the findings and experiences of existing programmes for both mechanisms in order to provide evidence to inform evaluation, research and future ventures;
- There may be other funding approaches (e.g. prize funding) to motivating innovation that need to be fully researched, clearly explained and documented for consideration.

13. Technical Session 3 – Health Systems and Access to Medicines

a. Arrangements

Session organiser: Danny Graymore (DFID/MeTA)

Facilitator: Lorraine Hawkins (DFID Consultant)

Note-taker: Bruce Mackay (HLSP)

b. Objectives

- To inform participants of DFID's broader approach to health systems including health financing and human resources;
- To update participants on the Medicines Transparency Alliance;
- To explore issues on the intersection between health systems and access to medicines

c. Introduction

Lorraine Hawkins (Consultant to DFID on MeTA) explained the purpose of the meeting, and introduced Danny Graymore of DFID.

d. Presentations

Danny Graymore of DFID made a presentation on MeTA, describing its current programme, including the seven pilot countries. As this is covered elsewhere in this report, MeTA is not summarised here.

Julia Watson of DFID presented on *'How does MeTA fit into DFID's approach to health systems?' A reliable supply of essential medicines is one of the critical building blocks of an effective health system. Given that pharmaceuticals can constitute 50-90% of out-of-pocket spending on health for poor households, improving the availability and affordability of essential medicines of assured quality is key to improving health outcomes for poor people. She described some of the DFID-funded initiatives at country level, but suggested that MeTA fits in better at the global level, as 'DFID believes that WHO and the World Bank are best mandated to lead the international architecture on health systems.'* She concluded with four questions - how country-led will MeTA be? What kind of global governance will it have? Will it be system-wide or disease-specific? And how will it be monitored?

e. Discussion

About twenty of the participants spoke, making the following points:

Most of the attention paid to essential drugs over the past 30 years had missed the significance of the private sector.

The centrality of the transaction between the buyer and seller was stressed - MeTA (and other well-meaning interventions) risk missing these transactions by the poorest people, and could end up favouring the more formal sector transactions made by the better-off.

For all the prominence of 'access' in health strategies, there has traditionally been little focus on the drugs purchased by the poorest third of the population. This was why MSH had focused its Gates-funded SEAM project in Tanzania and Ghana on the lowest level drug shops.

The problem is that the quality of a medicine cannot be judged simply by observation at the point-of-sale, so action on fakes has to be taken further upstream in the distribution chain. Fake and sub-standard drugs are a priority – in Kenya, 67 types of SP were examined and only 5 met the proper standard.

MeTA was 'incredibly ambitious', as the medicine market is much more complex than the extractive industries, for which EITI has been such a success. It was pointed out that even in Western Europe there is no satisfactory system for tracking medicines from manufacturer to consumer. It was suggested that MeTA develop a logframe, and set some priorities and focus on the top ones, which for now should be those where change was most needed and which were most feasible. On the other hand, ambition was no bad thing, and DFID's interest in the topic presented an opportunity to drive it up the agenda.

It was suggested that one way to reduce the scope might be to look at international, national and local levels, and to consider public procurement and commercial distribution separately. There was criticism of the assumption that high mark-ups were necessarily 'excessive' – margins are a fundamental part of any successful business. Inappropriate public procurement would be a good place to start, as it is clearly wrong and clearly open to change.

Clarification was sought on MeTA's objectives over the next 3-5 years. If MeTA's goal is to improve 'access', then it needs to include factors other than just the price, as distance and opportunity-cost and poor distribution all work against the poor getting access to the medicines they need.

Access is a reflection of market structure, and that the market itself is distorted by the promotional activities of drug companies - providers are 'brain-washed' by the pharmaceutical industry. Regulation of the product may be more effective than regulation of the personnel. It is difficult to engage private doctors because they are so fragmented, and even their own trade association is dominated by big city specialists.

It was noted that existing schemes to improve access do not always work – for example, in Peru they have found that exemptions for drugs for certain diseases such as HIV/AIDS are not reaching the patient, and certainly not reaching the poor.

HAI may itself have a bias toward the formal retail sector, but noted that in Uganda they are currently doing a survey on anti-malarials which includes the informal sector of small shops and drug peddlers. HAI is also doing mystery-client surveys.

Several speakers stressed the importance of government in all aspects of access to medicines, from its role as buyer and procurer of medicines for its own services, as regulator of their quality and of all players in the distribution chain, and as the protector of its citizens from fake and sub-standard drugs and from inappropriate prescribing and selling of drugs. Government is central, but it was noted that in many

countries the whole health system is weak, and that without more and better staff, change would not take place. Governments need to have more of the right people, with the right skills – many governments have lost good people over recent years and there is a need to strengthen the capacity of government.

It was suggested that as well a need for new information such as household-based health-seeking behaviour surveys, there was a lot of existing information which could be pulled together and discussed at a planning meeting of all stakeholders.

Context is all-important, and this is why the pilots will be important. Lessons learned from comparable projects are also useful, for example from PPS for HIV drugs.

For many people the word ‘transparency’ evokes ‘corruption’, and this association would divert attention from MeTA’s focus on access. MeTA should focus on information for the purchaser. The poorest, sickest people do not have a voice; and nor do the people who sell them medicines, since they too are outside the system. In Cambodia the only approach to ARVs which worked was to address the patient’s decision to purchase; in Thailand MSF has supported ‘ARV buyers clubs’; and likewise in Nepal, educating mothers on what they should buy and how much they should pay for children’s medicine.

Before the meeting broke for lunch, Loraine Hawkins (DFID Consultant) suggested that key themes and questions which had emerged so far included the importance of the grass-roots demand-side, and the informal sector which sell medicines to the poor; the need to set priorities, and for DFID to decide what is important and ‘what we can live with for the time being’; the importance of having the right people at the MeTA table, and the reality of the vested interests of the private sector. She concluded by asking ‘how will MeTA be different? She acknowledged that seemingly high mark-ups and prices are not necessarily unfair, and suggested that the majority of people in the ‘public health’ business ignore the reality and importance of the commercial distribution of medicines. She suggested that we need to work out how to make it uneconomic for people to sell fake drugs. She also explained the idea of the ‘MeTA Observatory’, based on the European Health Reform Observatory, a network of country studies using common methodology, plus cross-country studies of key themes.

Danny Graymore of DFID started the afternoon session by highlighting the importance of the pilots – the evidence in favour of transparency is already so good, MeTA needs to take this forward at country level and below. And in each pilot country we can expect the stakeholders to take forward different issues, depending on the context. EITI was certainly ambitious, exceedingly so, but it succeeded, so must not let caution blind our ambition. The key is ‘learning by doing’ – in EITI, they decided to focus first on tracking the revenue side, and leave expenditure for later. He said that MeTA is just one intervention, there are other things going on. A lot has happened already, there is information out there, and it is being shared, so we are building on a more general movement towards greater transparency and stakeholder engagement. In Ghana the new health insurance scheme is accrediting pharmacists, in Kyrgyzstan the whole system is rapidly improving, so MeTA is not starting from scratch. MeTA will follow the example of EITI and include advocacy and training for journalists to ensure that the information gets out and that the analysis is understood.

In the discussion which followed, the assumption that civil society actually speaks for the poor and vulnerable was questioned - much of civil society in sub-Saharan Africa is a western-based 'packaging of the poor', not an indigenous voice of the poor.

Patient groups are not all the same - some diseases (such as HIV) lend themselves to patients organising themselves, while others (such as malaria) do not. There is a risk that the former come to dominate the civil society stakeholders.

There is a risk that MeTA could be 'captured' by vested interests, and core issues such as drug promotion by pharmaceutical companies might be dropped.

There was a reference to MSF's publication 'Untangling the Web', which sought to explain the chain of pharmaceutical distribution - the evidence from this was that despite numerous mark-ups down the chain, the manufacturer's starting price was the key one.

It was suggested that the Demographic and Health Surveys had become so valuable thanks to 30 years of investment, mostly by USAID. Such long-term commitment in standardised data collection and analysis yields all sorts of benefits, not least that country comparisons and 20-year trends become clear.

Misuse of drugs was such a major problem already that many of the drugs MeTA was considering risked being ineffective within 10 years. It is the 'patient of the future' we should be worrying about.

The informal sector often has its own, informal mechanisms of self-regulation, which could be utilised if the incentives were clear. In Ghana and Tanzania SEAM tried to legitimise the illegal market - 'you do not want to stop the illegal market, you want to improve it'. It would be hard to promote transparency when 80% of the prescription drugs sold in sub-Saharan Africa are sold illegally, by people who are not officially allowed to sell them.

Danny Graymore of DFID was asked if all the pilots included both public and private sectors, and he explained that if the pilot countries wanted to focus on one or other, that is their decision. The Philippines is likely to cover both.

The experience of Kyrgyzstan suggests that if the problem is high prices, everyone would benefit if they fell, and the poor would benefit most simply because the price is a bigger hit on their pocket. But it is not enough to know that prices are high, we need to understand why they are so high.

With so much donor funding now going into budget support, governments were much more in the driving seat. 'MeTA relies on NGOs but NGOs do not have a seat at the SWAp's table'. If DFID is funding through budget support or a SWAp, the recipient is the government, so how will DFID fund MeTA where there is a SWAp?

Danny Graymore explained that some of the DFID funding would go to government and some to civil society, and some to international work by agencies such as HAI. This was the pattern in the EITI.

MeTA was urged to harness the existing pharmacists and their knowledge, though pharmacists are often in a weak position to question what doctors or health officials do.

A participant who had been a retail pharmacist himself noted that their peer network is strong and should be mobilised. It is they who are most likely to raise the issue of fake and sub-standard medicines. It is implementation of regulation on the ground which is key to this, if the existing regulations are not enforced that is the first place to start. Politics and timing are crucial ingredients of any change such as those proposed by MeTA – in Zambia one lesson would be ‘get the bishops on your side first’, and make sure the key communications are by word-of-mouth, not written reports.

Government leadership is a key to success. For transparency the MeTA process needs both government and NGOs working together – but the government will be in the lead, as it can give a 5-year commitment under the SWAp.

It was argued that some characteristics of the medicines market are quite deliberately designed to restrict access, so MeTA will face obstacles from vested interests. The public sector is also important, it is not an ‘either-or’ choice,

Danny Graymore of DFID was asked ‘what is new in MeTA?’, and what role DFID envisaged for WHO in the MeTA process. He replied saying that DFID was anxious that there should be no new architecture; MeTA would have to fit into the existing structures and processes.

Julia Watson of DFID thanked the participants, and closed the meeting.

f. Summary

1. Consumers

Must keep the focus on the consumers, on the demand side. They are the beneficiaries, and we need to understand what medicines they buy and why. Those consumer purchases are the core transactions.

2. Sellers

How do the peddlers and shop-keepers in those transactions get their products? We need to understand the incentives, disincentives and risks for them. The ‘informal’ supply chain to the drug peddlers and village shops is as or more important than the formal chain to large urban pharmacies - we need to know how both of them work.

3. Complexity

The medicines business is much more complex than the extractive industries ones. The medicines business has government as both regulator and purchaser; doctors who prescribe and pharmacists who dispense often have jobs in both public and private sectors; there are international as well as national markets; and the supply chain may cover several jurisdictions.

4. Accountability

It is all very well to talk about ‘partnerships’ and ‘stakeholders’, but there are vested interests in the drugs business, just as there are in any business, and potential conflicts of interest in the MeTA process. And who does civil society really represent? Where is its accountability?

5. Information

Better information and transparency are clearly benefits, but there are still choices to be made about what information is collected, how it is presented, and how it is disseminated. For example, margins are what makes the whole supply chain work, so what is or is not an 'acceptable' mark-up? And who says so?

6. Governments

Government's role as purchaser of medicines for its own facilities is different to its role as regulator of what is bought and sold in private drug transactions. National governments are the sovereign power, what is their place in this? It is not just Ministry of Health, but also Trade & Industry, and Finance decides tariffs.

7. Scope

Is MeTA too ambitious? Trade-off between what is desirable and what is feasible, not clear what the choices are, and how priorities are decided.

8. Governance

What is MeTA's own governance structure? What are its decision-making processes? What is DFID spending and what is its commitment for the future?

9. Architecture

How does MeTA fit into the wider architecture – of health policy, of foreign aid, of drug marketing and regulation? WHO already covers some of the MeTA issues, so how will MeTA fit in with what they do?

ANNEX 1: LIST OF PARTICIPANTS

Surname	First Name	Organisation	Apr-19	April 20, Session 1	April 20, Session 2	April 20, Session 3
Adachi	Kiyoshi	UNCTAD	X	X		
Amoako Johnson	Fiifi	University of Southampton	X			
Alcorn	Keith	NAM	X			
Alvarez de Toledo	Lucia	London Translations	X			
Anil	Soni	Clinton Foundation	X			
Aslanyan	Garry					
Arhinful	Daniel	Noguchi Memorial Institute for Medical Research (NMIMR)	X			X
Ashworth	Nick	UKIPO	X			X
Atkins	Dominic	Novartis	X	X		
Azais	Boris	MSD UK	X	X		
Back	Emma	Consultant - DFID	X			
Baghdadi-Sabeti	Guitelle	WHO	X			
Baker	Prof. Brook	Northeastern University, School of Law	X	X		
Bale	Harvey Bale	International Federation of Pharmaceutical Manufacturers Associations (IFPMA)	X			
Bannenberg	Wilber	Campaign for Access to Essential Medicines	X			X
Banerjee	Jaya	MMV	X		X	
Bard	Ellie	DFID	X			
Barder	Owen	DFID			X	
Barker	Dr Richard	Association of the British Pharmaceutical Industry (ABPI)	X			
Barrington	Robert	F&C Investments	X			
Barrow	Michael	Boehringer-Ingelheim	X			
Blanco	Francisco	UNICEF Supply Division	X			
Bluestone	Ken	STOP AIDS Campaign				
Boateng	Samuel	Ministry of Health, Ghana	X			

Surname	First Name	Organisation	Apr-19	April 20, Session 1	April 20, Session 2	April 20, Session 3
Borowitz	Michael	DFID	X	X		
Brickwood	Dr David	Johnson & Johnson	X	X		
Brown	Kathy Ann	Commonwealth Secretariat	X	X		
Brewster	Amanda	Wellcome Trust	X	X		
Bryce	Gavin	TB Alert	X			
Buckle	Dr. Gilbert	National Catholic Health Services	X			
Calland	Richard	IDASA	X			
Cameron	Ali	WHO	X			
Cockburn	Steve	STOP AIDS Campaign		X		
Campos	Edgar	World Bank	X			
Cat	Oriol	Consultant -DFID	X			
Chalker	John	MSH	X			X
Chapman	Alison	DFID	X			
Charles	Lynne	DFID	X	X		
Charlesworth	Frances	AstraZeneca	X			
Chetley	Andy	Healthlink	X			
Childs	Michelle	Knowledge Ecology International	X		X	
Colatrella	Brenda	Global Health Partnerships Merck	X			
Collinson	Chris	DFID			X	
Deschamps-Smith	Natacha	Association of the British Pharmaceutical Industry (ABPI)	X			X
Djankorozova	Mariam	Ministry of Health, Kyrgyzstan	X			X
Djusupova	Dr. Djanyl	Pharmacopoeian Committee of the Ministry of Health, Kyrgyzstan	X			X
Dodoo	Dr Alex	University of Ghana Medical School	X			
Druce	Nel	Consultant - DFID	X	X		
Dukes	Graham	Eurohealth Group	X			
Edele	Andreas	GTZ	X	X		
Eden	Kate	Boehringer-Ingelheim	X			
Elhmoud	Dr. Lama	Ministry of Health, Jordan	X			
Elbotrova	Zuzana	VP IFMSA	X			X

Surname	First Name	Organisation	Apr-19	April 20, Session 1	April 20, Session 2	April 20, Session 3
Ellman	Tom	MSF	X			X
Evans	Peter	Consultant - DFID	X	X		
Ewen	Marg	Health Action International (HAI) Europe	X			X
Falkingham	Jane	University of Southampton	X			
Fife	Paul	NORAD	X			
Forrest	David	Abbott	X			
Foucher	Matilde	AXA	X			
Frere	Dr. Jean Jacques	World Bank	X			
Fundafunda	Boniface	Ministry of Health Zambia	X			X
Garau	Martina	Office of Health Economics			X	
Glinkowski	Jakub	DFID HRC	X	X		
Goldstein	Clara	TB Alliance	X		X	
Gomez	Jose Pablo	WHO	X			
Gordon	Matt	DFID	X			X
Graymore	Danny	DFID				X
Green	Carolyn	International HIV/AIDS Alliance	X			
Gyansa-Lutterodt	Martha	Ghana National Drugs Programme	X			X
Hall	Peter	Concept Foundation	X			X
Hanson	Kara	LSHTM	X			X
Hawavitarne	Dashanta	DFID	X			
Hawkins	Loraine	Consultant - DFID	X			X
Haxane	Myriam	Tibotec Buba			X	
Hillman	David	Stamp Out Poverty	X		X	
Hunt	Mary	DFID	X			
Ireland	Elaine	Aids Alliance	X			
Jamieson	David	Partnership for Supply Chain Management	X			X
Jenner	Andrew	Patent Office	X	X		
Jones	Andrew	GAVI Alliance	X		X	
Kadyrova	Ninell	Health Insurance Fund, Kyrgyzstan	X			X
Kamal-Yanni	Mogha	Oxfam	X	X		

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Kampf	Roger	WHO/Intellectual Property	X	X		
Katz	Jennifer	Drugs for Neglected Diseases Initiative (DNDI)	X		X	
Kennedy Martin	Matthew	Pfizer	X			
Khanna	Ritu	SustainAbility	X			
Kingsmill	William	DFID	X			
Knight	Madeleine	LSE	X	X		
Kotwani	Anita	Delhi University	X			
Laing	Richard	WHO	X	X		
Laux	Dr Petra	Novartis	X			
Leereveld	Wim	Access to Medicine Index	X			
Leftwich	Adrian	University of York	X			
Levy	Brian	World Bank	X			
Lewis	Maureen	World Bank	X			
Lopez	Roberto	Health Action International (HAI) Peru	X			
Louck	Christian	PATH Malaria Vaccine Initiative	X		X	
Love	Jamie	Knowledge Ecology International	X	X	X	
MacArthur	Tessa	DFID	X			
MacKay	Bruce	HSLP				X
Marcus	Rachel	DFID	X			
Mbiindyo	Regina	WHO NPO	X			X
Meza-Cornejo	Edson	Health Action International, Peru (AISLAC)	X			
Mikkola	Heli	Ministry of Foreign Affairs, Finland	X	X		
Mills	Anne	LSHTM	X			X
Mestre-Fernandiz	Jorge	Office of Health Economics	X		X	
Mockler	Chris	APG	X			X
Mulligan	Jo	DFID		X		
Mubangizi	Patrick	Health Action International, Uganda	X			
Mutambi	Rosette	HEPS Uganda	X			

Surname	First Name	Organisation	Apr-19	April 20, Session 1	April 20, Session 2	April 20, Session 3
Mwape	Esnat	Pharmaceutical Regulatory Authority Zambia	X			
Mwiindi	Jonathan	Ecumenical Pharmaceutical Network	X			X
Mwoga	Joseph	WHO NPO	X			X
Nazzaro	Susan	The Bill and Melinda Gates Foundation	X			
Nusseirat	Adi	Jordan Food and Drug Administration (JFDA) Rational Drug Unit	X			
Oatham	Jeff	One World Trust	X			
Obeidat	Dr. Mohammed	National Society for Consumer Protection in Jordan	X	X		
Olive	Dr Jean-Marc	WHO	X			X
Ombaka	Eva	Ecumenical Pharmaceutical Network	X			
Owusu-Agyei	Samuel	Ministry of Health, Ghana	X			
Palikadavath	Saseendran	University of Southampton	X			
Patel	Vaishalee	International HIV/AIDS Alliance	X			
Pender	Jon	GSK	X		X	
Peters	David	Johns Hopkins	X			
Quiambao	Dr Dennis	Ministry of Health, Philippines	X			X
Reed	Tim	Health Action International (HAI)	X			X
Rifat	Atun	Imperial College	X	X		
Rogerson	Andrew	DFID	X			
Rosenberg	David	GSK		X		
Ross Degan	Dennis	Harvard University	X			
Rowley	Jane	Consultant IPM			X	
Royce	Catherine	DNDi	X		X	
Saad	Samia	Consultant - DFID	X			
Sabot	Oliver	Clinton Foundation	X	X		

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Santerre	Frederique	International Federation of Pharmaceutical Manufacturers Associations (IFPMA)	X			
Saunders	Philippa	Consultant - DFID	X		X	
Samuels	Jill	Pfizer	X			X
Sboul	Dr Hanan	Jordanian Association for Manufacturers of Pharmaceuticals and Medical Appliances (JAPM)	X			
Seeley	Elizabeth	London School of Economics (LSE)	X			
Sekhri	Neelam	WHO India	X			
Shah	Dilip	Indian Pharmaceutical Alliance	X			
So	Anthony	Duke University	X	X		
Sharma	Aditi	ActionAid	X			
Spivey	Paul	Consultant - DFID	X		X	
Stephens	Peter	IMS	X			
Stern	Tim	Treasury, UK	X			
Suscenko	Elizabeth	London Translations	X			
Tate	Jody	DFID HRC	X			
Thompson	Peter	World Press Centre	X		X	
Tickell	Sophia	SustainAbility	X			
Valera	Madeleine	Philippine Health Insurance Corporation	X			X
Vasquez	Susana	Ministry of Health, Peru	X			X
Vaughn	Hillary	Crown Agents	X	X		
Venugopal	P.V.	MMV	X	X		
Vykes	Susan	APPMG MMV	X		X	
Watson	Julia	DFID				X
Waning	Brenda	Boston University	X	X		
Wells	Lee	Novartis	X			
Woods	Paul	Department of Health, UK	X			
Worley	John	DFID	X		X	
Wuliji	Tana	International Pharmaceutical Federation	X			X

