

# The UK Government Response to the Report of the Commission on Intellectual Property Rights, Innovation and Public Health

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## INTRODUCTION

In 2001, the United Kingdom government sponsored an independent international Commission on Intellectual Property Rights to look at the ways that intellectual property rules needed to develop in the future in order to take greater account of the interests of developing countries and poor people. This responded to concerns that the extension of tighter intellectual property rules globally, as a result of the TRIPS<sup>1</sup> Agreement, could have adverse effects for developing countries, including on the price of medicines and access to them. The Commission's report, published in September 2002, stimulated considerable debate in the international community concerned with these issues. The report of the Commission, and the UK Government response to it, can be found at [www.iprcommission.org](http://www.iprcommission.org).

In May 2003, Member States of the World Health Organization (WHO) agreed at the World Health Assembly to set up a Commission to consider the relationship between intellectual property rights, innovation and public health. The objective of the Commission was to collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries.

The Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) was established by the Director-General of WHO in February 2004 and completed its report in April 2006. The UK Government, along with other funders, provided support for the work of the Commission. The Commission's report, and associated background documents, can be found at [www.who.int/intellectualproperty](http://www.who.int/intellectualproperty).

The UK Government believes that the Commission's report is an important contribution to an important subject. The report ranged far more widely than just the question of how intellectual property rights affect innovation in healthcare products relevant to the needs of poor people in developing countries. Importantly it recognised that the promotion of innovation could not be looked at in isolation from the issue of promoting access to both new and existing products. Moreover, the impact of intellectual property rights needed to be placed in the context of the political, institutional and technological factors that shape outcomes in respect of both innovation and access.

That the issue of intellectual property rights proved controversial within the Commission, with some members expressing reservations on parts of the report, should not detract from the importance of its overall message. In particular it focuses our attention on what more governments and other stakeholders need to do, in terms of funding and policies, if ways are to be found to develop and make accessible

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<sup>1</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights

diagnostics, vaccines and treatments required by poor people in developing countries.

It is this wider policy agenda, of which intellectual property rights policy is an important part, which the Intergovernmental Working Group (IGWG) set up by the World Health Assembly last year, has to address. This response by the UK government to the recommendations of the Commission is intended as a contribution to the work of the IGWG. The IGWG has encouraged member states to respond in this way.

Developing a government-wide response has been a useful process in developing coherence between government departments in this complex area – a step which other governments might emulate, as Switzerland, for instance, has already done. The UK government response to the recommendations and conclusions of each of the Report's chapters includes inputs from:

The Department for International Development (DFID)  
The Department of Health  
The United Kingdom Intellectual Property Office (formerly the Patent Office)  
The Department for Business, Enterprise & Regulatory Reform  
HM Treasury  
The Medical Research Council

The Wellcome Trust has also provided examples of its contributions and policies in relation to the recommendations of the Commission.

### **The UK Contribution**

The UK government, together with UK charitable foundations, make a major contribution to international health research relevant to developing countries. DFID's budget for research was £116 million in 2006/07, of which about £46 million was devoted to health research. DFID's overall research budget is due to rise to £220 million by 2010. This makes DFID one of the largest investors in international health research amongst bilateral donors. In addition, the UK is a major contributor to global efforts to eradicate disease. It recently pledged \$ 485 million towards the advanced market commitment for the pneumococcal vaccine, and it is exploring other areas such as malaria and tuberculosis. The UK is the largest bilateral contributor to the new public private partnerships for product development (PDPs). It is also a major funder of the GAVI Alliance and recently helped create the International Finance Facility for Immunisation (IFFIm) which will provide up to \$4 billion in new funding for vaccines. Spending on research needs to ensure that these discoveries reach poor people in poor countries. DFID has an integrated approach balancing basic research, operations research, but also policy actions supported through its bilateral and multilateral funding channels.

Apart from DFID, the UK Medical Research Council (MRC) spends about £30 million annually on relevant research from a total budget of about £450 million. DFID has provided MRC with a strategic contribution of £20 million over four years to support MRC work that meets DFID objectives. In addition to the above, DFID has committed a further £45 million to clinical trials run by MRC units in Africa concerning

microbicide development, and the delivery of antiretrovirals and antiretrovirals for children.

The Wellcome Trust, the largest health charitable foundation in the UK, spends about £500 million on medical research each year of which about £50 million supports research outside the UK, most of this in developing countries. As part of its new international strategy, it intends to increase its expenditure in developing countries. In 2005 the Trust committed a total of £102 million to researchers in the UK and abroad on HIV/AIDS, malaria, tuberculosis and neglected diseases.

Recently a UK Collaborative on Development Science has been established to bring together all UK funders of research relevant to developing countries, including the research funders mentioned above. The Bill and Melinda Gates Foundation will also act in an advisory capacity.

### **The UK Approach to the IGWG**

The IGWG is mandated to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission. The UK Government believes that it is an important process. Its outcome should include commitments by governments, both developed and developing, to particular courses of action. It should also provide, based on consultations with those involved, expectations for actions by other important stakeholders, including international organisations, the pharmaceutical industry, non-governmental organisations, and charitable foundations.

The UK Government believes that intellectual property rights are an important incentive for the development of new health-care products where there is an assured market demand for the products of research and development, as in developed countries. 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 the Government (and the Wellcome Trust) are significant investors in R&D directed at the needs of developing countries, including in product development partnerships. That is why also the UK has been a prominent supporter of new and innovative forms of financing and incentive mechanisms, including the IFFIm and advance market commitments. Moreover, the Government expects to increase its funding in these areas as part of its commitment to reach the UN aid target of 0.7% of gross national income by 2013. The Government believes that the plan of action developed by the IGWG should commit governments, both developed and developing, to greater funding of R&D on a more sustainable and predictable long term basis. It should also commit governments to the establishment of further innovative financing mechanisms to promote the development of, and access to, new health technologies.

Providing more funding is important but it also needs to be properly directed. There is a need for better priority setting for R&D in this field, and a better estimation of the financial needs of PDPs and other research institutions, particularly in developing countries. In parallel, if priority setting is to be more effective and resource allocation improved, it is important that performance indicators are developed and systematically monitored.

The UK Government agrees with the Commission that the development of new products for developing country markets cannot be divorced from the issue of making existing as well as new products accessible to those who need them. One important aspect of this is price which is determined by a host of policy and institutional factors including the cost of production, patent status, taxes and duties and the nature of the delivery chain. Where health-care products required in developing countries are patented (as for instance is the case with a number of antiretrovirals in many developing countries), this is a factor which may affect affordability for governments or patients themselves, depending, inter alia, on the outcomes of negotiations with right holders. At the same time, transparency and competition in the distribution chain are critical in determining prices paid by consumers.

The IGWG needs to pay particular attention to issues concerning the use of intellectual property in emerging economies, which are rapidly growing in global economic importance, but where also many poor people still live. Measures are therefore required to promote access to essential medicines in these countries, but not at the expense of damaging incentives to invest in R&D on which the development of new health-care products depends. Central to achieving this is agreement on appropriate differential pricing policies for countries at different stages of development.

Thus, the plan of action should include commitments to utilise the intellectual property system to promote both innovation and access. For instance, voluntarily established patent pools may have the potential to facilitate both objectives. And WHO, with other concerned international organisations, should monitor the impact of intellectual property provisions on innovation and access.

But, as the breadth of the Commission's report indicates, the promotion of innovation and access to diagnostics, vaccines and medicines is about much more than intellectual property. The driving force both for innovation and access is a functioning and adequately funded healthcare system which provides access to prevention and treatment services, including essential medicines. Such a healthcare system also provides the market-based incentive for the development of new products that meet the needs of patients. Thus the IGWG should accord priority to commitments by developing countries, supported by donors and other funders, to prioritise the financing of the healthcare delivery infrastructure. Donors and other funders should also commit to the use of country systems, and their strengthening.

A clear message from the Commission report is the parallel need to improve the financing and infrastructure for clinical trials, particularly in Africa, and to improve the regulatory infrastructure. Both are needed to speed the pace at which products can be developed and introduced. The IGWG should consider measures to address both these issues.

### **The UK Response to the CIPIH**

Provided below is the detailed response of the UK Government to the recommendations in the report of the Commission. The responses elaborate on the ways in which the UK is seeking to address the issues raised by the Commission,

provides pointers to the priorities that should be addressed by the IGWG and elaborates on UK policy positions on intellectual property, innovation and public health.

## CHAPTER 2

### THE DEEP WELL OF DISCOVERY: EARLY STAGE RESEARCH

**2.1 Governments of developed countries should reflect adequately this objective in their research policies. In particular, they should seek to define explicit strategies for R&D and devote a growing proportion of their total health R&D funding to the health needs of developing countries, with an emphasis on upstream and translational research**

The Government supports this recommendation. As noted in the introduction, DFID, the MRC and the Wellcome Trust together spend about £120 million annually on health research directed at the needs of developing countries. Moreover, this spending is projected to rise very significantly in the coming years, particularly given DFID's commitment to double its spending on research.

The type of research funded spans the whole range from basic through translational to applied research including socioeconomic research. For example, the twin strategic priorities of the MRC are, first, to improve our understanding of how cells, organs and organisms and populations behave in health and disease and, secondly, to place a major emphasis on translating this laboratory- and epidemiologically-based work into new and improved treatments, interventions and healthcare services. Similarly, the Wellcome Trust has as its first strategic aim "ensuring that the single biggest element of [its] total funding is used to support basic, curiosity-driven, investigator-led research and career initiatives – recognising that this underpins future discovery and application." A second strategic aim is to increase the opportunities for the development of products, devices and enabling technologies for health benefit including supporting translational research in neglected diseases in order to create new opportunities for product development by public-private partnerships in global health or other interested parties. In addition the Biotechnology and Biological Sciences Research Council is an important funder of basic biological research with application to health.

By contrast DFID tends to focus on operational and implementation research to improve the delivery and cost-effectiveness of healthcare interventions, and on the funding of public-private partnerships for product development.

**2.2 Developing countries should establish, implement or strengthen a national programme for health research including best practices for execution and management of research, with appropriate political support, and long-term funding.**

The Government agrees that national health research programmes are important in developing countries and that political support and long term funding are a prerequisite. Governments should develop national plans for research in health incorporating translational and operational research focusing on addressing key health issues in their own countries based on the burden of disease.

Moreover donors should support such initiatives to develop local health research capacity. For example, DFID, the Wellcome Trust, and the Canadian International Development Research Centre (IDRC) are working with Malawi and Kenya to develop national research plans. The Health Research Capacity Strengthening initiative aims to strengthen the capacity for the generation of new scientific knowledge within Kenya and Malawi, and improve its use in evidence-based decision making, policy formulation and implementation. The long-term vision is a framework for improving the quality of health care for Kenyans and Malawians, through the generation and use of health research evidence. This will require strengthening key academic research and health policy-making institutions and facilitating the collaborative engagement of national representatives. In both Malawi and Kenya the process of developing the project has been instrumental in bringing together institutions which have not traditionally collaborated. It has also highlighted the wealth of existing health research, often funded internationally, which is not well integrated with the rest of the health research infrastructure in the countries.

**2.3 Government and funder attention should be paid to upstream research that enables and supports the acquisition of new knowledge and technologies that will facilitate the development of new products, including drugs, vaccines and diagnostic tests to tackle the health problems of developing countries. Attention should also be paid to the current inadequacy of the research tools available in these fields of research. These include techniques to understand new pathways to discovery, better ways to use bioinformatics, more suitable animal models and other disease-specific technologies.**

As noted above, both the MRC and the Wellcome Trust, devote large resources to basic and upstream research. This discovery research provides the foundation for the development, evaluation and implementation of new healthcare products, technologies and policies. As an example, the Wellcome Trust Sanger Institute has made major contributions to the sequencing and annotation of pathogen genomes that are important to health in developing countries, including the causative agents of tuberculosis, leprosy, trachoma, dengue, falciparum malaria, leishmaniasis, and Chagas disease.

**2.4 When addressing the health needs of people in developing countries, it is important to seek innovative ways of combating Type I diseases, as well as Type II and Type III diseases. Governments and funders need to assign higher priority to combating the rapidly growing impact of Type I diseases in developing countries, and, through innovation, to finding affordable and technologically appropriate means for their diagnosis, prevention and treatment.**

The Government considers that efforts to combat diseases that affect poor countries and populations disproportionately, mainly Type II and III diseases, should remain the priority. But it recognises the rapidly growing burden of Type 1 diseases in developing countries. Much of the response to these diseases, as in developed countries, needs to focus on non-pharmaceutical preventative and lifestyle issues. However, consideration needs to be given to ways of making available cost-effective preventative treatments in resource-constrained contexts, particularly for high risk

patients. In some cases this will require innovation in either the products themselves or in delivery systems.

**2.5 Actions should be taken by WHO to find ways to make compound libraries more accessible to identify potential compounds to address diseases affecting developing countries.**

The Government agrees that the WHO should investigate ways in which compound libraries, held in the private and public sectors, can be made more accessible.

**2.6 WHO should bring together academics, small and large companies in pharmaceuticals and biotechnology, governments in the form of aid donors or medical research councils, foundations, public–private partnerships and patient and civil society groups for a standing forum to enable more organized sharing of information and greater coordination between the various players.**

The Government supports the view that more organised sharing of information, greater coordination and better priority setting in this field is desirable, and that WHO should have a role in bringing this about. Exactly how this should be achieved, through a standing forum or otherwise, is a matter which should be decided by the IGWG which is considering the follow up to the Commission's report.

**2.7 Countries should seek through patenting and licensing policies to maximize the availability of innovations, including research tools and platform technologies, for the development of products of relevance to public health, particularly to conditions prevalent in developing countries. Public funding bodies should introduce policies for sensible patenting and licensing practices for technologies arising from their funding to promote downstream innovation in health-care products.**

As regards patenting, the Government agrees that developing countries need to tailor their intellectual property system to meet their particular economic and social circumstances. Subject to meeting the standards laid down in TRIPS, which allows significant flexibility in interpretation (for example, in the precise definition of inventions or patentability criteria), some countries may benefit from a more restrictive approach to patentable subject matter, while others may benefit from a less restrictive approach. The Government also agrees that patent legislation and policy in this field should aim to facilitate the research and development of healthcare products relevant to their public health needs.

The Government believes that licensing policies should take into account the desirability of promoting innovation, particularly where widely applicable research tools or platform technologies are involved. This rule should apply in particular to technologies applicable to conditions prevalent in developing countries.

For example, the Wellcome Trust considers it important for funders in developed countries to ensure that inventions of relevance to developing countries that are developed in the course of funded activities are licensed under terms that allow the technology to be used for the benefit of neglected populations in developing countries. Depending on the situation, this may involve using exclusive licence

terms to reserve rights or require certain actions of licensees that would facilitate access to the technology for use by poor populations in developing countries. In many cases, grantee institutions rather than funders actually draft licence terms, so funders may need to require applicants for funding to demonstrate how they plan to make outputs accessible in developing countries. In order to ensure similar objectives, DFID research contracts provide for DFID to receive a non-exclusive irrevocable royalty-free world-wide licence to use, transfer or otherwise deal with any intellectual property produced in research.

**2.8 Patent pools of upstream technologies may be useful in some circumstances to promote innovation relevant to developing countries. WHO and WIPO should consider playing a bigger role in promoting such arrangements, particularly to address diseases that disproportionately affect developing countries.**

The Government supports the investigation of the possible use of patent pools to see whether they can simplify licensing arrangements, distribute risk, decrease the risk of patent infringement and encourage cooperation between pool members.

**2.9 Developing countries need to consider in their own legislation what form of research exemption might be appropriate in their own circumstances to foster health-related research and innovation.**

The Government agrees that developing countries should incorporate a research exemption within their legislation which is most appropriate for their needs and interests. In the UK the Government has accepted the recommendation of the recent Gowers review<sup>2</sup> that the patent law should be amended to clarify the circumstances where researchers may examine, learn from and improve upon inventions without fear of patent infringement. The Swiss Government has recently introduced an amendment to its patent law with the same objective.

**2.10 Countries should provide in their legislation powers to use compulsory licensing, in accordance with the TRIPS agreement, where this power might be useful as one of the means available to promote, *inter alia*, research that is directly relevant to the specific health problems of developing countries.**

The Government agrees that countries should consider putting in place compulsory licensing provisions, as exist in the UK, to deal, *inter alia*, with circumstances where an important technical advance of considerable economic significance is being prevented or hindered. For similar reasons, Switzerland introduced the right to a non-exclusive licence in its recent patent law amendment in order to avoid the monopolistic use of research tool patents.

**2.11 Developing countries should ensure that their universities and public research organizations maintain research priorities in line with their public health needs and public policy goals, in particular the need for innovative research of benefit to the health problems of their populations. This should not**

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<sup>2</sup> Gowers Review of Intellectual Property, HM Treasury, December 2006  
[http://www.hm-treasury.gov.uk/media/53F/C8/pbr06\\_gowers\\_report\\_755.pdf](http://www.hm-treasury.gov.uk/media/53F/C8/pbr06_gowers_report_755.pdf)

**exclude support of health-related research which meets their industrial or export objectives and that could contribute to improved public health in other countries.**

The Government agrees with this recommendation.

**2.12 Public research institutions and universities in developed countries should seriously consider initiatives designed to ensure that access to R&D outputs relevant to the health concerns of developing countries and to products derived therefrom, are facilitated through appropriate licensing policies and practices.**

The Government agrees with this recommendation. As noted above, DFID and the Wellcome Trust specifically address these concerns in their patenting and licensing policies. When involved in licensing R&D outcomes to commercial partners, the Wellcome Trust strives to include terms that preserve access to the technologies to address needs of developing countries, particularly if the primary licensee does not intend to serve those markets. The Trust encourages university technology transfer operations to approach licence agreements in a similar way.

Trust-funded researchers are obliged to publish their results in journals that either provide immediate open access or that permit open access within six months of the date of publication, with the aim of making findings accessible to the widest range of users in developing as well as developed countries.

In addition to appropriate licensing policies and practices, it is essential to support the communication of research outputs to policy makers in developing countries so that research outputs can be appropriately used in national ministries.

## **CHAPTER 3**

### **THE LONG ROAD FROM DISCOVERY TO DEVELOPMENT**

**3.1 Governments and the appropriate national authorities and funders should assign a higher priority to research on the development of new animal models, biomarkers, surrogate end-points and new models for assessing safety and efficacy, which would increase the efficiency of product development. They should also work with their counterparts in developing countries to formulate a mechanism to help identify research priorities in this area for Type II and Type III diseases particularly relevant to developing countries, and provide funding for this R&D.**

The Government agrees with this recommendation.

#### **3.2 To enhance the sustainability of public–private partnerships:**

- **Current donors should sustain and increase their funding for R&D to tackle the health problems of developing countries.**
- **More donors, particularly governments, should contribute to increase funding and to help protect public–private partnerships and other R&D sponsors from changes in policy by any major donor.**
- **Funders should commit funds over longer time frames.**
- **Public–private partnerships need to continue to demonstrate that they are using their money wisely, that they have transparent and efficient mechanisms for accountability, that they coordinate and collaborate, and that they continue regularly to monitor and evaluate their activities.**
- **The pharmaceutical industry should continue to cooperate with public–private partnerships and increase contributions to their activities.**
- **Research institutions in developing countries should be increasingly involved in executing research and trials.**

The Government agrees with this recommendation and is a major funder of public-private partnerships for product development (PDPs). To date the UK government has spent, or is committed to spend, over £125 million on PDPs. The UK was the first government to fund the International AIDS Vaccine Initiative (IAVI). It is also DFID's general policy to commit funds for longer time periods to provide more predictability to recipients of funding. Our current commitment to the Medicines for Malaria Venture (MMV) runs from 2005-2010.

In 2006, a number of developed country governments and foundations have acted on the Commission's recommendation to increase and broaden the funding base of drug and vaccine PDPs during 2006. However the response has been patchy and there is scope for other donors to increase their investment. The absence of diversified and

more predictable funding is a risk and as more products move into clinical trials, the financial requirement will grow correspondingly. The Government encourages others - particularly other bilateral donors, the World Bank and the European Commission - to provide more funding in a long term and predictable manner to PDPs.

The Government also agrees that, in spite of the difficulties of measuring performance inherent in the research and development process, PDPs need to demonstrate that their resources are being put to the best possible use. The Government therefore welcomes the work now under way to develop a set of metrics and performance indicators to allow better monitoring of the performance of the growing number of PDPs.

The Government is also concerned about the absence of information to guide resource allocation decisions. There is not a clear understanding of where the main gaps in the research and development portfolio for Type II and III diseases lie, or data relating burden of disease and researchability which would enable better judgements on cost-effectiveness. There needs to be a more systematic approach to priority setting in the funding of the new PDPs for product development.

The in-kind support offered to PDPs by some pharmaceutical companies is to be welcomed. But it is important to foster strong commitments from more companies. WHO may be able to catalyse this through more engagement with the industry leaders and industry associations, and by convening pharmaceutical companies, funders and PDPs.

The Government welcomes the recommendation for closer involvement of developing country research institutions in research and trials. It is essential that developing countries participate fully in all steps to ensure R&D responds to specific needs and contributes to R&D capacity strengthening.

The Government hopes that the IGWG will address the above issues in the development of its Plan of Action.

**3.3 WHO should initiate a process to devise mechanisms that ensure the sustainability and effectiveness of public-private partnerships by attracting new donors, both from governments and the private sector, and also to promote wider participation of research institutions from developing countries. However, governments cannot passively rely on what these partnerships could eventually deliver; there is a need for a stronger commitment on their part for an articulated and sustainable effort to address the research gaps identified in this report.**

The Government believes that attracting more, and more diversified, funding from governmental donors and the private sector is a priority. Given the prominent role played in recent years by foundations in building up and financing public-private partnerships, there is a need for stronger commitment by governments to sustain this effort. It is also very important to engage developing country governments and research institutions fully in developing new products. The IGWG should make recommendations on the role WHO should play in pursuing these objectives.

**3.4 Further efforts should be made to strengthen the clinical trials and regulatory infrastructure in developing countries, in particular in sub-Saharan Africa, including the improvement of ethical review standards. WHO has a role to play, in collaboration with interested parties, in an exploration of new initiatives that might be undertaken to achieve this goal.**

The Government supports the recommendation that the clinical trials and regulatory infrastructure in developing countries should be strengthened. To deliver top quality clinical trials in developing countries, more training of individuals and more funding for developing country clinical trial sites is urgently needed. The Bill and Melinda Gates Foundation currently funds ten sites for malaria clinical trials, but more support is needed to provide training and infrastructure for clinical trials. There is a crucial need to provide career pathways for key individuals involved in clinical trials – including between trials – otherwise teams are lost and expertise dissipates.

The UK has long supported strengthening clinical trial capacity in low income countries through the MRC units in the Gambia and Uganda. We strongly support other countries doing more particularly to strengthen local institutions. The UK Government agrees that further, better co-ordinated and country-led efforts need to continue in this area and that WHO has an important brokering and facilitating role in strengthening regulation in this regard.

Where trials are designed with a view to the licensing of new healthcare products, or the addition of new indications to existing products, it is important to ensure that such trials meet internationally recognised standards for Good Clinical Practice and that the data from these trials are reliable enough for inclusion in applications for marketing authorisation such as those required in the EU or USA or as agreed by the International Conference on Harmonisation (ICH).

In the case of other clinical trials, which are not related to obtaining the approval of products for marketing, they should still abide by the highest possible standards, but these need not incorporate all the data which might be required for marketing authorisation. For example, the MRC has produced Good Clinical Practice Guidelines<sup>3</sup> to establish standards for research it funds in the UK and elsewhere. These recognise that the majority of trials it funds are not related to product approval, and that actual requirements will vary according to the nature of the trial, the type of intervention and whether or not medicinal products are involved.

As regards ethical issues, the MRC has issued two guidance notes on the conduct of trials in developing countries, one specifically addressing ethical values and standards of care in trials of HIV/AIDS treatments.<sup>4</sup> The Wellcome Trust has also issued a position statement and guidance notes on research in developing countries.<sup>5</sup>

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<sup>3</sup> <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002416>

<sup>4</sup> [http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/GlobalBioethics/index.htm#P12\\_703](http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/GlobalBioethics/index.htm#P12_703)

<sup>5</sup> [http://www.wellcome.ac.uk/doc\\_wtd015295.html](http://www.wellcome.ac.uk/doc_wtd015295.html)

The Government thinks the IGWG should accord a high priority to the question of what further practical steps could be taken to improve the clinical trial and regulatory infrastructure in developing countries.

**3.5 Governments should continue to develop forms of advance purchase schemes which may contribute to moving later stage vaccines, medicines and diagnostics as quickly as possible through development to delivery.**

The Government is one of the founder member countries and agencies actively supporting the \$1.5 billion pilot advanced market commitment for pneumococcal vaccine which the GAVI Alliance is managing. This seeks to accelerate the introduction of vaccines appropriate to developing countries. It is estimated that up to 5.4 million childhood deaths could be avoided by 2030. The Government agrees that advance purchase and market schemes offer significant potential as “pull” mechanisms for later stage vaccines, medicines and diagnostics and that more such schemes should be appraised and developed.

As also noted in the report, the Government, along with others, has promoted and now supports International Finance Facility for Immunisation (IFFIm) which will provide \$4 billion to the GAVI Alliance over the next decade for the purchase of vaccines. Providing money “up front” for vaccine purchase over an extended period sends a strong signal to the pharmaceutical and biotechnology industries that this will remain an area where continued investment in R&D will make commercial sense.

**3.6 Recognizing the need for an international mechanism to increase global coordination and funding of medical R&D, the sponsors of the medical R&D treaty proposal should undertake further work to develop these ideas so that governments and policy-makers may make an informed decision.**

The Government believes that new ideas to improve the coordination and funding of R&D should be encouraged, and it agrees with the Commission that further work needs to be done on the treaty proposal to elucidate its costs and benefits and how it might work in practice.

**3.7 Practical initiatives that would motivate more scientists to contribute to this field through “open source” methods should be supported.**

The Government agrees that the potential for doing research through electronic networks, and for mobilising scientists in collaborative ventures, should be further considered.

## CHAPTER 4

### DELIVERY: GETTING PRODUCTS TO PATIENTS

**4.1 Governments need to invest appropriately in the health delivery infrastructure, and in financing the purchase of medicines and vaccines through insurance or other means, if existing and new products are to be made available to those in need of them. Political commitment is a prerequisite for bringing about a sustained improvement in the delivery infrastructure and health outcomes. Health systems research to inform policy-making and improve delivery is also important. The integration of traditional medicine networks with formal health services should be encouraged.**

The Government agrees that sustainable improvement in the health of poor people will only be brought about through strengthening health systems to provide broad access to basic services. This requires increased investment by developing countries in their own systems and efforts to

- recruit, train and retain health workers
- expand and maintain physical infrastructure
- improve drug procurement and distribution systems
- build core management skills at central and peripheral levels.

DFID is committed in its new health strategy to deliver more resources and to help countries to expand access to basic health services by strengthening their health systems.

**4.2 Developing countries should create incentives designed to train and retain health-care workers in employment.**

The Government supports this recommendation which will greatly assist in the administration of medicines and enable patients to receive treatment in the most appropriate manner. Responding to the crisis in health workers will require building capacity within government to plan, monitor and evaluate human resource policy; and a review of the best mix of skills to deliver optimal outcomes in a limited resource setting. The UK is committing £1 million over two years to help the Global Health Workforce Alliance tackle the urgent need to find solutions to the lack of health workers in poor countries across the world. The Alliance is an international partnership set up in May 2006 to raise awareness, bring together and maximise current efforts of governments, donors and agencies to tackle staff shortages. It has already started work in 8 countries, including 5 in the most severely affected region of sub-Saharan Africa, helping to train and support a new generation of local leaders who will develop and put in place health workforce plans for their countries.

DFID has also provided £55 million over six years to Malawi to fund a programme to support the training, recruitment and retention of health workers. The programme covers initiatives such as salary top ups, improvements in housing and training, the filling of short-term gaps with international volunteers and incentives for retired health professionals to return to work. Early indications indicate some success in

recruitment and increased enrolment of doctors and nurses in training but more time is needed to judge the sustainable impact of these interventions.

**4.3 Developed countries should support developing countries' efforts to improve health delivery systems, inter alia, by increasing the supply of their own trained health-care workers.**

The Government believes that while changes to international recruitment practice may help manage the flow of outward migration, there are more serious domestic issues to be addressed around recruitment, training and retention, skill mix, performance management and productivity, staff distribution and planning, and the conditions under which most health staff work (see above).

In 2001 the UK introduced a code of practice for international recruitment with the objective of stopping active recruitment from developing countries unless there was a government to government agreement. In the last few years the UK has rapidly reduced its recruitment of staff from developing countries as it has expanded its own training and introduced robust human resource policies to attract and retain staff. With the expansion of the European Union (EU), the UK is one of the few developed countries which now have little need to recruit new health workers from developing countries.

**4.4 Governments have an important responsibility to put in place mechanisms to regulate the quality, safety and efficacy of medicines and other products. As a starting point, adherence to good manufacturing practices and effective supply chain management can ensure product quality and will also curb the circulation of counterfeit products.**

The Government agrees with this recommendation.

**4.5 Policies for biomedical innovation must take account of the fact that health systems in many developing countries remain resource-constrained. Policies must emphasize affordable innovations adapted to the realities of healthcare delivery in developing countries, and covering appropriate technologies for the diagnosis, prevention and treatment of both communicable and noncommunicable diseases. Mechanisms for promoting such adaptive research in a systematic way must be improved.**

The adaptation of innovation to low resource contexts is essential. Simplified delivery, long-use, increased stability and cheaper and user-friendly diagnostics could make a substantial contribution to improved health. In particular, diagnostics suitable for use in developing country settings are a particular priority. This is an area where WHO could play a greater role, particularly in advocacy. The IGWG should consider this as part of its agenda.

**4.6 All companies should adopt transparent and consistent pricing policies, and should work towards reducing prices on a more consistent basis for low and lower middle income developing countries. Products, whether originator's or generic, should be priced equitably, not just in sub-Saharan Africa and least**

**developed countries, but also in low and lower middle income countries where there are a vast number of poor patients.**

The Government agrees that pricing policies for all companies in pharmaceuticals should be transparent and consistent, and that they should apply differential pricing as a means to make products as accessible as possible in low and middle income countries. This recommendation holds not only for the multinational pharmaceutical industry but also for domestic manufacturers.

In order to encourage more transparent and consistent pricing policies, DFID is working with others - including the WHO and Health Action International – on developing a project called the Medical Transparency Alliance (MeTA). This would bring together developing country governments, the pharmaceutical industry and civil society organisations and other stakeholders – to facilitate international support for, and commitments to, transparent working practices on the part of all stakeholders engaged in medicines registration, procurement, distribution and sales. The principal objective is to support national efforts to enhance transparency and build capacity in medicines policy, procurement and supply chain management. The added value of this initiative would entail explicit commitments from international actors in support of national efforts, coupled with focused technical and financial support to strengthen transparency and accountability. Such national efforts would seek to improve access to information about medicine quality, availability and pricing, with strong civil society and consumer involvement in scrutiny and debate.

**4.7 For non-communicable diseases, governments and companies should consider how treatments, which are widely available in developed countries, can be made more accessible for patients in developing countries.**

The burden of non-communicable disease is increasing rapidly, especially in middle-income countries linked to lifestyle risk factors, especially tobacco and obesity, adverse environmental impact and an ageing population. The economic impact of this shift will be massive. Appropriate preventative interventions need to be encouraged and implemented – particularly, tackling smoking, poor diet, inadequate physical activity promoting a healthier environment. The Government will focus on supporting partner countries to take early preventive action against the spread of these diseases.

The IGWG needs to give consideration to ways of making available cost-effective preventative treatments in resource-constrained contexts, particularly for high risk patients. In some cases this will require innovation in either the products themselves or in delivery systems. The Government notes that, for the first time, a cholesterol reducing drug, simvastatin, has been added to the latest WHO Model List of Essential Medicines for use in high risk patients.

**4.8 Continuing consideration needs to be given to the prices of treatments for communicable diseases, particularly of second-line drugs for HIV/AIDS treatment.**

The DFID 2006 White Paper committed the Government to support international efforts to achieve the goal of universal access to comprehensive HIV prevention

programmes, treatment, care and support by 2010 and there is a need to ensure that new medicines are made available as soon as, and as cheaply as, possible. Price is important, although it is only one factor in determining the availability of treatment for resistance to first line antiretroviral (ARV) therapy.

Prices of treatments can be lowered in a number of ways. Pooled procurement has an important role to play in bringing down prices. With more predictable demand, and a more stable market, prices are likely to fall. The effectiveness of the global market for ARVs needs to be improved by putting in place better demand forecasting and more transparency. Under the MeTA project, mentioned above, the UK is exploring greater transparency in global procurement with key partners. The Government also backs current efforts to implement a high-level subsidy for artemisinin-based combination therapies (ACTs) to encourage their use in preference to older drugs which have encountered widespread resistance.

A good example of what can be done is provided by the Clinton Foundation which recently negotiated to lower the price of 16 second line ARV formulations in 66 low and middle income countries with two Indian generic manufacturers. This was achieved partly by offering technical support to help lower production costs. UNITAID, the international drug purchase facility established in 2006 by France, Brazil, Chile, Norway and the UK, has helped to provide a guaranteed market by agreeing to provide over \$100 million to support purchases by the Clinton Foundation on behalf of these countries.

The Government also supports the right of developing countries to utilise the flexibilities allowed under TRIPS to ensure affordable access to medicines to meet public health needs, including the use of compulsory licensing provisions included in the TRIPS agreement.

#### **4.9 Governments of low and middle income countries where there are both rich and poor patients should formulate their funding and price regulation with a view to providing access to poor people.**

The Government believes that this objective should be pursued through public funding directed particularly at poor people. Removing user fees can dramatically increase access to health services. In Uganda, abolishing fees doubled the number of people going to clinics, and more than doubled immunisation rates for children. It has been estimated that more than 230,000 children's lives could be saved each year if fees were abolished in twenty African countries. Social insurance schemes also have a role to play. Measures in the fields of competition policy, price regulation and pro-competitive intellectual property policy can also promote lower prices.

#### **4.10 Governments need to prioritize health care in their national agendas and, given the leverage to determine prices that patents confer, should adopt measures to promote competition and ensure that pricing of medicines is consistent with their public health policies. Access to drugs cannot depend on the decisions of private companies but is also a government responsibility.**

We agree that governments should give a high priority to healthcare in their national planning and budgeting. They are encouraged to achieve the target set in the 2001 Abuja Declaration that all African countries should devote 15% of all public spending to health services. Many countries are still far short of this goal. As noted above,

they should also adopt measures to promote competition and lower prices. One example is to utilise policies to promote the early entry of generics on patent expiry, including through the use of an “early working” exception to patent rights. Reimbursement rules and price regulation schemes can be used to relate decisions on funding and pricing to public health benefits, taking account of the need to provide appropriate incentives for research and development. Developing countries could also consider systems to look at the relative effectiveness of different interventions. In England and Wales, the National Institute for Health and Clinical Excellence (NICE) issues evidence-based guidance to the National Health Service on the cost-effectiveness in relation to health benefits of technologies referred to it.

**4.11 Corporate donation programmes can be of great value in a number of fields in collaboration with the actions of governments and nongovernmental organizations. However, addressing health needs in developing countries requires more structured and sustainable actions by governments and other parties that stimulate accessibility to products, while generating new treatments and products adapted to the needs of developing countries.**

Donations can work well in disease eradication programmes and when undertaken responsibly can have a role in emergencies. But the Government agrees that for routine healthcare delivery sustainability in the provision of essential medicines depends on government investments in the healthcare system.

**4.12 Governments should remove any tariffs and taxes on health-care products, where appropriate, in the context of policies to enhance access to medicines. They should also monitor carefully the supply and distribution chain to minimize costs that could adversely influence the prices of medicines.**

The Government is proposing through the Medicines Transparency Alliance (MeTA) to improve transparency around the selection, procurement, sale and distribution of medicines in developing countries, thereby strengthening governance and encouraging responsible business practices. This builds on work already undertaken by WHO and Health Action International. The overall goal is, in co-operation with pharmaceutical companies and other stakeholders, to improve access to affordable essential drugs in developing countries. The Government supports the examination of supply chain issues, including the abolition of indirect taxes and tariffs in the pharmaceutical sector.

**4.13 The Doha Declaration clarifies the right of governments to use compulsory licensing as a means of resolving tensions that may arise between public health and intellectual property, and to determine the grounds for using it. Developing countries should provide in their legislation for the use of compulsory licensing provisions, consistent with the TRIPS agreement, as one means to facilitate access to cheaper medicines through import or local production.**

The Government supports the right of developing countries to use compulsory licensing provisions in order to facilitate access to medicines. The Government agrees that legislation and procedures should be established by developing countries to allow the effective use of compulsory licensing and government use, as provided

for in TRIPS and the amendment to TRIPS agreed in December 2005. 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.

**4.14 Developed countries, and other countries, with manufacturing and export capacity should take the necessary legislative steps to allow compulsory licensing for export consistent with the TRIPS agreement.**

The Government agrees with this recommendation which concurs with the recommendation of the Gowers review of intellectual property. An EU Regulation which implements the 2005 TRIPS amendment came into force on 9 June 2006. This enables European generic manufacturers to export medicines under a compulsory licence to developing countries in accordance with the TRIPS amendment.

**4.15 The WTO decision agreed on 30 August 2003, for countries with inadequate manufacturing capacity, has not yet been used by any importing country. Its effectiveness needs to be kept under review and appropriate changes considered to achieve a workable solution, if necessary.**

The World Trade Organization (WTO) Decision has now been fully implemented by the 2005 TRIPS amendment and therefore it is important to keep under review how this new system is working. The World Health Assembly in Resolution 59.24 requested WHO “to continue to monitor, from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the Commission’s report, on the development of, and access to, health care products, and to report thereon to the Health Assembly.” If any changes are contemplated, it would be for the WTO to undertake any review and propose revisions.

**4.16 Companies should adopt patent and enforcement policies that facilitate greater access to medicines needed in developing countries. In low income developing countries, they should avoid filing patents, or enforcing them in ways that might inhibit access. Companies are also encouraged to grant voluntary licences in developing countries, where this will facilitate greater access to medicines, and to accompany this with technology transfer activities.**

The Government agrees that companies' patenting, licensing and enforcement policies should take full account of the need to facilitate access to medicines in developing countries. The Government notes that some companies have adopted explicit policies on the lines proposed by the Commission on patenting, licensing and technology transfer in developing countries, and encourages other companies to do the same.

**4.17 Developing country governments should make available full and reliable information on patents granted. WHO, in cooperation with WIPO and others, should continue to pursue the establishment of a database of information about patents, in order to remove potential barriers to availability and access**

**resulting from uncertainty about the patent status in a country of a given product.**

The Government agrees that it would be useful for WHO and the World Intellectual Property Organization (WIPO) to compile a patents database which provides developing countries, and purchasers of medicines on their behalf, relevant patent information. DFID proposes to offer support to this initiative in conjunction with other interested parties.

**4.18 Developed countries and the WTO should take action to ensure compliance with the provisions of Article 66.2 of the TRIPS agreement, and to operationalize the transfer of technology for pharmaceutical production in accordance with paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health.**

The Government supports the developed country obligation as defined in Article 66.2 of the TRIPS Agreement and in this vein the UK files annual returns to the WTO on the UK technology transfer activities which often include a public health dimension.

**4.19 The restriction of parallel imports by developed countries is likely to be beneficial for affordability in developing countries. Developing countries should retain the possibilities to benefit from differential pricing, and the ability to seek and parallel import lower priced medicines.**

The import of cheaper patented drugs from outside the EU (“parallel imports”) is prohibited. The Government, along with the European Commission and other EU member states, is working to strengthen further border measures to prevent differentially priced pharmaceuticals (i.e. parallel imports of medicines specifically priced at a lower rate for developing countries) from entering the EU. This is important as it will help keep pharmaceutical products priced for poor people in the developing world in the intended market and thus support the wider differential pricing framework. However, if middle income developing countries were to resort to parallel importation on a significant scale to benefit from lower prices offered by companies to the poorest developing countries, this might threaten the ability of companies to continue to offer such prices.

**4.20 Developing countries need to decide in the light of their own circumstances, what provisions, consistent with the TRIPS agreement, would benefit public health, weighing the positive effects against the negative effects. A public health justification should be required for data protection rules going beyond what is required by the TRIPS agreement. There is unlikely to be such a justification in markets with a limited ability to pay and little innovative capacity. Thus, developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS.**

TRIPS does not define a length of time pharmaceutical data should be protected from being used or relied on by third parties. Countries are therefore free to determine in accordance with their own national needs and requirements how to

implement TRIPS provisions requiring countries to 'protect data against unfair commercial use'.<sup>6</sup> However, some countries may consider it in their interest to introduce data exclusivity laws which prescribe a certain period during which health regulatory authorities may not rely on data provided by the originator company to grant approval to an equivalent generic product.

**4.21 In bilateral trade negotiations, it is important that governments ensure that ministries of health be properly represented in the negotiation, and that the provisions in the texts respect the principles of the Doha Declaration. Partners should consider carefully any trade-offs they may make in negotiation.**

The Government agrees that 'joined up Government' produces the most appropriate results as it enables the individual needs and requirements all key stakeholders, including health ministries, to be fully taken into account before reaching a negotiating position. The Government does not believe that bilateral agreements should, as a matter of course, oblige countries to adopt intellectual property standards that go beyond TRIPS and will seek to ensure that EU agreements with developing countries avoid imposing obligations beyond TRIPS.

**4.22 Governments and concerned international organizations should promote new purchasing mechanisms to stimulate the supply of affordable new products and to enhance the number of suppliers in order to provide a more competitive environment.**

The Government fully supports this recommendation. As noted above, the UK is one of the founder member countries actively supporting the advanced market commitment for a vaccine for pneumococcal disease which the GAVI Secretariat will manage as well as the IFFIm to support vaccine purchase. The UK also supports the investigation of new procurement mechanisms (for example, by UNITAID – the International Drug Purchase Facility) which would have the effect of making demand more predictable, encouraging competition between suppliers and thereby promoting lower prices.

**4.23 Developing countries should adopt or effectively implement competition policies and apply the pro-competitive measures allowed under the TRIPS Agreement in order to prevent or remedy anti-competitive practices related to the use of medicinal patents.**

The Government fully supports this recommendation and urges developing countries to adopt these provisions if they have not done already. Since mid-2000 the UK Government has been active in encouraging countries to adopt competition laws appropriate to their needs and situation, or to improve existing laws. For example, DFID funding provided for preparation of a new competition law for Tanzania and a peer review of South Africa's competition law.

**4.24 Countries should provide in national legislation for measures to encourage generic entry on patent expiry, such as the "early working" exception, and more generally policies that support greater competition**

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<sup>6</sup> Article 39(3) WTO TRIPS Agreement

**between generics, whether branded or not, as an effective way to enhance access by improving affordability. Restrictions should not be placed on the use of generic names.**

The Government agrees that 'early working' exceptions are useful in enabling generic medicines to receive marketing approval in order for the generic medicines to enter the market after patent expiry. The EU has adopted an 'early working' exception as part of the Medicines Directive which applies to both human and veterinary medicines. Countries should consider how their policies can encourage greater use of generic medicines. In the UK this is done through encouraging practitioners to prescribe generically.

**4.25 Developing countries should adopt or effectively implement competition policies in order to prevent or remedy anti-competitive practices related to the use of medicinal patents, including the use of pro-competitive measures available under intellectual property law.**

The Government fully supports the right of developing countries to implement the competition provisions as defined in the TRIPS Agreement (see response to recommendation 4.23 above).

**4.26 Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries.**

The Government agrees that bilateral and other agreements should not, as a matter of course, oblige countries to adopt intellectual property standards or timetables that go beyond TRIPS. For our part, the Government will seek to ensure that EU agreements with developing countries avoid imposing obligations beyond TRIPS.

The Government also supports the right of developing countries to make use of the transition periods provided by the TRIPS Agreement. Developing countries should decide for themselves if accelerated compliance would be beneficial for their economies. The Government also supports the right of developing countries to adopt standards beyond TRIPS if they consider it is in their interests to do so.

**4.27 Governments should take action to avoid barriers to legitimate competition by considering developing guidelines for patent examiners on how properly to implement patentability criteria and, if appropriate, consider changes to national patent legislation.**

The Government agrees that barriers to legitimate competition should be removed. It is important that appropriate training be given to patent examiners in order to ensure that granted patents are both novel and inventive and have utility or industrial applicability.

## CHAPTER 5

### FOSTERING INNOVATION IN DEVELOPING COUNTRIES

**5.1 A prerequisite for developing innovative capacity is investment in the human resources and the knowledge base, especially the development of tertiary education. Governments must make this investment, and donors should support them.**

The Government supports this recommendation. DFID is committed to the doubling of its spending on education to £1 billion annually by 2010 and is committed to provide new support for higher education and vocational skills including training the professional staff needed by health and education services.

**5.2 The formation of effective networks, nationally and internationally, between institutions in developing countries and developed countries, both formal and informal, are an important element in building innovative capacity. Developed and developing countries should seek to intensify collaborations which will help build capacity in developing countries.**

The Government agrees that in today's world innovation systems are increasingly global in scope - involving networks of individuals and institutions from around the world. The challenge for developing countries is how to access these global innovation systems. They need to understand the innovation processes at work, what is being produced and whether it is appropriate, or can be adapted, for their needs. Often, simple adaptation will not be enough and countries will have to foster indigenous innovation. In effect, for countries to access global innovation systems they have to develop their own national innovation systems. In the modern world, simply working with advanced technologies is not enough, advanced understanding of the scientific underpinnings of technologies is essential. Only in this way can countries effectively break into international networks.

**5.3 WHO, WIPO and other concerned organizations should work together to strengthen education and training on the management of intellectual property in the biomedical field, fully taking into account the needs of recipient countries and their public health policies.**

The Government supports this recommendation as a means of increasing awareness and understanding of intellectual property which helps to ensure that developing countries can make fully informed public health care policies suitable for their national needs and circumstances. The Government welcomes the adoption at WIPO of a Development Agenda which, inter alia, will strengthen the provision of technical assistance adapted to the needs of particular developing countries.

**5.4 Developed countries, and pharmaceutical companies (including generic producers), should take measures to promote the transfer of technology and local production of pharmaceuticals in developing countries, wherever this**

**makes economic sense and promotes the availability, accessibility, affordability and security of supply of needed products.**

The Government supports this recommendation and encourages other developed countries and pharmaceutical companies to do the same, where such actions are of benefit to public health.

**5.5 Developed countries should comply with their obligations under article 66.2 of the TRIPS Agreement and paragraph 7 of the Doha Declaration.**

The Government continues to fully support the developed country obligation to provide incentives to enable the transfer of technology as defined under Article 66.2, and we continue to make annual notifications to the WTO TRIPS Council in this regard.

**5.6 Developing countries need to assign a higher priority to improving the regulation of medical products. Developed countries, and their regulatory institutions, should provide greater financial and technical assistance to help attain the minimum set of regulatory standards needed to ensure that good quality products are available for use. This assistance should also support infrastructure developments within a country, to ensure that good manufacturing practice and supply chain management standards are implemented and sustained.**

**5.7 The process of the International Conference on Harmonisation currently lacks immediate relevance to the needs of many developing countries, but those countries should maintain their participation in the process. In the meantime, developing country governments and regulatory institutions should give support to regional initiatives, tailored to the current capacities of their member countries, which offer more scope for lifting standards over time, exploiting comparative advantages, avoiding duplication, sharing information and facilities, and promoting appropriate standardization without erecting barriers to competition.**

The Government supports the recommendations aimed at improving quality in the manufacture of medicines. Even if developing countries cannot yet aspire to meeting ICH standards, it is important that they should continue to develop standards - especially internationally agreed standards of GMP - that increase public health protection.

The Government supports initiatives to strengthen this infrastructure and will explore this through MeTA. There is also a need for greater regulatory authority and greater harmonisation within regions. The Government supports WHO initiatives to share regulatory capacity across countries in Southern Africa. This shift could be deepened and replicated across other regions. WHO has a role in commissioning research to develop evidence on best practice on regulatory harmonisation. These regional initiatives should be monitored closely for emerging recommendations.

**5.8 WHO has an important role to play, in collaboration with interested parties, in helping to strengthen the clinical trials and regulatory infrastructure in**

**developing countries, in particular in sub-Saharan Africa, including the improvement of ethical review standards.**

**5.9 Apart from the European & Developing Countries Clinical Trial Partnership, donors together with medical research councils, foundations and nongovernmental organizations, need to offer more help to developing countries in strengthening clinical trials and regulatory infrastructure.**

The Government agrees with these recommendations and refers to the response to Recommendation 3.4 above.

**5.10 Digital libraries of traditional medical knowledge should be incorporated into the minimum search documentation lists of patent offices to ensure that the data contained within them will be considered during the processing of patent applications. Holders of the traditional knowledge should play a crucial role in deciding whether such knowledge is included in any databases and should also benefit from any commercial exploitation of the information.**

The Government agrees that these libraries will play a valuable role in helping to ensure that patents are granted on the basis of a full knowledge of extant prior art. The information in such libraries should only be included with the consent of those who lay claim to that knowledge. The UK is working with other members of WIPO in the Intergovernmental Committee on Genetic Resources, Traditional Knowledge, and Folklore on the setting up of an appropriate databases and it is envisaged that traditional medicines will be included. Preliminary work has been based on databases provided by India and China, amongst others, and the UK Intellectual Property Office is reviewing these to identify those that provide useful search tools.

**5.11 All countries should consider how best to fulfil the objectives of the Convention on Biological Diversity. This could be, for instance, through the establishment of appropriate national regimes for prospecting for genetic resources and for their subsequent utilization and commercialisation; contractual agreements; the disclosure of information in the patent application of the geographical source of genetic resources from which the invention is derived and other means.**

The Government agrees that countries should consider how best to fulfil the objectives of the Convention on Biological Diversity and work in this regard is being taken forward within the appropriate fora.

## CHAPTER 6

### TOWARDS A SUSTAINABLE PLAN TO PROMOTE INNOVATION AND ACCESS

#### **6.1 WHO should develop a Global Plan of Action to secure enhanced and sustainable funding for developing and making accessible products to address diseases that disproportionately affect developing countries.**

The Government fully supports this recommendation and underlined its commitment in agreeing to the WHO resolution<sup>7</sup> of May 2006 which established the IGWG to draw up a global strategy and plan of action in order to provide a medium-term framework to achieve this objective. This response to the CIPIH report is part of the UK Government contribution to the work of the IGWG.

The UK proposes that the plan be built around the following pillars:

- Better priority setting for R&D in this field and estimation of financial needs of the PDPs and other research institutions, particularly in developing countries
- Firm commitments by developing countries to prioritise health financing at national level and strengthen systems, including accountability
- Firm commitments by OECD donors to sustainable funding mechanisms for PDPs
- Commitments by PDPs to establish performance indicators and more systematic monitoring
- Monitoring the impact of TRIPS on innovation and access by WHO and other international organisations
- Firm commitments by OECD donors to develop further innovative financing mechanisms to promote the development of, and access to, new health technologies
- Investigations of new intellectual property mechanisms to promote innovation and access e.g. patent pools
- A plan to improve the clinical trials and regulatory infrastructure at national, regional and international level to facilitate product introduction
- WHO should put in place the institutional capacity to monitor on an ongoing basis the progress being made in the implementation of the plan and to highlight required actions.

The Government believes that the Plan should examine further the potential benefits of pooled funding, on the lines used to finance international agricultural research, as a means of providing finance on a sustainable basis to R&D for the benefit of developing countries.

#### **6.2 WHO should continue to monitor, from a public health perspective, the impact of intellectual property rights, and other factors, on the development of**

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<sup>7</sup> WHA59.24

**new products as well as access to medicines and other health-care products in developing countries.**

The Government agrees that WHO should continue its monitoring activities in this area. It endorsed World Health Assembly resolution (A59.24) which requested the Director-General:

*(4) to continue to issue public health-based research and development reports, identifying from a public health perspective gaps and needs related to pharmaceuticals, and to report on them periodically;*

*(5) to continue to monitor, from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the Commission's report, on the development of, and access to, health care products, and to report thereon to the Health Assembly.*

**6.3 WHO, including its regional offices, should consider the recommendations of our report, in consultation with others, and recommend how these should be taken forward in each region and country.**

The Government agrees with this recommendation.

## List of Acronyms

ACTs	Artemisinin-based combination therapies
AIDS	Acquired immunodeficiency syndrome
ARV	Antiretroviral
CIPHI	Commission on Intellectual Property Rights, Innovation and Public Health
CMH	Commission on Macroeconomics and Health
DFID	Department for International Development (DFID)
EDCTP	European and Developing Countries Clinical Trials Partnership
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration (United States)
GAVI	Global Alliance for Vaccines and Immunization
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
GFATM	Global Fund to fight AIDS, Tuberculosis and Malaria
HIV	Human immunodeficiency virus
IAVI	International AIDS Vaccine Initiative
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDRC	International Development Research Centre
IFFIm	International Finance Facility for Immunisation
IGWG	Intergovernmental Working Group on Public Health, Innovation and Intellectual Property
IP	Intellectual property
IPM	International Partnership for Microbicides
IPRs	Intellectual property rights

LDCs	Least developed countries
MDGs	Millennium Development Goals
MeTA	Medical Transparency Alliance
MMV	Medicines for Malaria Venture
MRC	Medical Research Council
MSF	Médecins sans Frontières
MVI	Malaria Vaccine Initiative
NICE	National Institute for Health and Clinical Excellence
NITD	Novartis Institute for Tropical Diseases
OECD	Organisation for Economic Co-operation and Development
PATH	Program for Appropriate Technology in Health
PDPs	Public–private partnerships for product development
R&D	Research and development
TB Alliance	Global Alliance for TB Drug Development
TDR	Special Programme for Research and Training in Tropical Diseases
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom of Great Britain and Northern Ireland
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
UNITAID	International Drug Purchase Facility
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization



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