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## **Review of recommendations of the Commission on Intellectual Property Rights, Innovation and Public Health: WHO's response**

1. The Commission on Intellectual Property Rights, Innovation and Public Health in its final report presented a number of recommendations for the consideration of Member States.<sup>1</sup> The Commission also addressed a number of recommendations to WHO as an organization. Set out below is an overview of the response by the Secretariat as to the actions it has taken in compliance with its existing mandate in the areas covered by the recommendations of the Commission. Although not exhaustive, the information highlights the Secretariat's efforts to address the substance of the recommendations.

### **DISCOVERY**

2. The Commission concluded that it is in the interest of all countries to promote research that addresses the health needs of developing countries and to set specific and measurable targets in that regard. Specific recommendations on WHO's action are indicated below:

*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.*

3. WHO collaborates with industry in ensuring that compound libraries are available for screening against parasitic diseases, particularly in disease-endemic countries. A network of compound screening centres is being expanded to include more developing countries, and a drug-target portfolio will identify validated targets across parasite genomes; this network is being extended to diagnostics and vaccine targets. A global screening platform for parasitic diseases using free computer power is under way. WHO continues to complement public-private collaboration in this domain, and provides support for open source research through academic networks.

4. The Priority Medicines for Europe and the World Project has identified therapeutic gaps that require concerted research and development. In concluding agreements for drug discovery and product research and development, WHO generally seeks to obtain appropriate contractual commitments aimed at assuring that any resulting product (if deemed safe and effective) will be made widely available to the public, in particular to the public sector of developing countries on reasonable terms.

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<sup>1</sup> See document A/PHI/IGWG/1/2.

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.*

5. By convening high-level meetings, such as the series of conferences on health research for development, WHO promotes the use of health-research findings in policy-making and implementation as a partnership between policy-makers, civil society and researchers. It also promotes the Evidence-informed policy network. WHO has developed a drug discovery platform based on networks and partnerships between academia, industry and developing-country institutions to mobilize efforts and funding in this area. WHO promotes interaction between organizations and companies in order to bring about, or enhance, synergies in the development of innovative vaccines.

6. WHO also provides support for open access to scientific literature in developing countries, and for further development of a knowledge platform for neglected infectious diseases, to be initiated in 2007. It provides financial and technical support to the Global Forum for Health Research, which works to reduce inequalities in, and mobilize financing for, health research.

7. The Drugs for Neglected Diseases Initiative was set up in 2003 by research institutions from Brazil, France, India, Kenya, the Ministry of Health of Malaysia, and *Médecins sans Frontières*. In collaboration with WHO, the Initiative develops active regional networks of scientists involved in research on new drugs for neglected diseases. WHO also collaborates with the Global Alliance for TB Drug Development, a public-private partnership for better and affordable antituberculosis drugs, in moving suitable candidate drugs rapidly along the development pipeline to patients in need.

8. WHO continues to collaborate with the European Union Research Directorate on research and development initiatives in following up the Priority Medicines for Europe and the World Project.

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.*

9. WHO is planning to convene for developing countries a joint conference with WIPO on mechanisms for collaboration in such areas as research and development for natural products. It encourages pooling of publicly funded research to promote innovation for developing countries. Examples under the aegis of the Medicines for Malaria Venture, include the synthetic peroxide project and the project on 8-aminoquinolines for malaria, where information is shared for use in control of leishmaniasis.

10. WHO has launched an initiative to facilitate discovery of new drugs and diagnostics for helminth infections and has provided support for exploration of the patent-pool model for a SARS vaccine.

## DEVELOPMENT

11. Within the range of activities – from optimization of a lead compound to regulatory review of safety, efficacy and quality of a new product – several key issues require consideration. The Commission made the recommendation to WHO set out below.

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. ...*

12. WHO has provided support for establishment of public/private partnerships, such as the Foundation for Innovative New Diagnostics, which have developed several drugs for tropical diseases. It also provides support for the discovery, research and development of new drugs and diagnostics in collaboration with industry, and has published guidelines for diagnostics testing and evaluation.<sup>1</sup>

13. Through ministerial forums, such as that on Health Research for Disease Control and Development (Accra, 15-17 June 2006), WHO is encouraging governments, particularly in developing countries, to dedicate a percentage of their budget to health research.

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.*

14. Guidelines for clinical trials in developing countries have been issued.<sup>2</sup> WHO calls on scientists from disease-endemic countries to assist in monitoring studies. In August 2005 it set up the Secretariat of the International Clinical Trials Registry Platform, which started to identify and map clinical trial registers across the world, established a network of such registers and identified opportunities to develop new ones, such as a national register in India, an HIV/AIDS, tuberculosis and malaria register across sub-Saharan Africa, and the South African trials register. WHO/PAHO is promoting clinical trial registration in South America.

15. WHO contributes to the work of the European and Developing Countries Clinical Trials Partnership, continues to provide guidance on prequalification of medicines for developing countries, and works with regional groups to strengthen capacity for conducting clinical trials.

16. WHO is a member of a network funded by the European Commission, Networking for Ethics on Biomedical Research in Africa. Based on a survey conducted in 15 western and central African countries, a strategy is now suggested to the countries of the subregion, addressing the main needs identified, in particular strengthening capacity and harmonizing regulation of health research involving human participants. WHO participates in three projects funded by the European and Developing Countries Clinical Trials Partnership: two of them aim to strengthen research ethics committees in

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<sup>1</sup> See, for example *Diagnostics for tuberculosis: global demand and market potential*. Geneva, World Health Organization 2006.

<sup>2</sup> Document TDR/PRD/GCP/02.1b.

Nigeria and Gabon, the third will provide distance-learning tools for members of research ethics committees and other stakeholders in health research focusing on the African context.

17. WHO has also contributed to a number of training activities, regional consultations and conferences in order to strengthen ethical review of research. It participates in the steering committee of the Global Forum on Bioethics in Research and contributes to organization of annual forums that give an opportunity to more than 100 participants from developing countries to discuss ethical issues related to the globalization of health research. WHO also serves as secretariat for the Global Summit of National Bioethics Commissions.

## DELIVERY

18. The Commission examined the factors affecting the introduction of new and existing products into developing countries, including health delivery systems, regulation, pricing, intellectual property and policies to promote competition. The following actions were recommended for WHO:

*4.17 ... 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.*

19. WHO's medicines strategy guides the support provided to Member States related to intellectual property rights and trade agreements.<sup>1</sup> WHO has issued remuneration guidelines for the use of patents on medical technologies;<sup>2</sup> a guide on compulsory licensing and authorization of government use of medical patents is in preparation. It has set up training and capacity-enhancing workshops, such as those on intellectual property rights and public health (Buenos Aires, March 2006); intellectual property rights and access to medicines (Dhaka, March 2006) and the local production of essential medicines, including antiretrovirals (Brazzaville, February 2006). WHO continues to participate actively in WTO regional workshops on issues related to the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), and has collaborated with WTO in a training module on the Agreement and access to medicines.

20. WHO provides direct support to countries in order to facilitate the review of national policy and legal frameworks, focused on patent legislation related to public health and incorporation in domestic legislation of flexibilities provided for in TRIPS.

21. Once products are developed, WHO provides evidence to inform policy (the case, for example, of artemisinin combination therapy). Through active participation in the work of bodies such as Global Fund to fight Aids, Tuberculosis and Malaria, the Global Alliance for Vaccines and Immunization, and UNAIDS, WHO helps to develop mechanisms that facilitate the purchase of, and access to, medicines.

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<sup>1</sup> Document WHO/EDM/2004.2.

<sup>2</sup> Document WHO/TCM/2005.1.

## FOSTERING INNOVATION IN DEVELOPING COUNTRIES

22. The Commission addressed the subject of capacity building in developing countries in science and technology, regulation, clinical trials, transfer of technology, and traditional medicine, as well as intellectual property. Actions recommended for WHO are noted below.

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.*

23. Management of intellectual property was one of the themes of a workshop on innovation organized by WHO (Yaoundé, November 2005). WHO also initiated discussion with WIPO on ways to handle training on, and management of, intellectual property related to natural products. It will continue to further networks and partnerships in order to promote effective action, and to adopt a multi-organization approach in conducting briefings and training sessions for health, trade and patent officials. WHO and other organizations also cooperate in capacity-building initiatives.

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.*

24. WHO has helped publish ethical review guidelines,<sup>1</sup> and maintains an in-house ethical review committee. It fosters North/South collaboration in the areas of product discovery, development and access. WHO also actively participates with the European and Developing Countries Clinical Trials Partnership to help build capacity to conduct clinical trials in Africa. Courses are also organized in Eastern Europe.

## SUSTAINABLE GLOBAL EFFORT

25. The Commission agreed on the urgent need for action to generate more and sustainable financing for research and development in order to address the health needs of developing countries, and to increase government engagement in this endeavour. WHO, as the lead international agency for public health, should play a major role in pursuing this objective.

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.*

26. Resolution WHA59.24 requested the Director-General to convene an intergovernmental working group to prepare a global strategy and plan of action. This process is now under way.

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<sup>1</sup> *Handbook for good clinical research practice (GCP): guidance for implementation*. Geneva, World Health Organization, 2005.

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

27. Monitoring and analysis activities include the following:

- determining the patent status of essential medicines: pilot project under way with WIPO, the European Patent Office and national patent offices to analyse the extent of patent protection for essential medicines in developing countries
- determining a public-health perspective for examination of pharmaceutical patents: WHO has commissioned a study on patent claims for pharmaceutical products with a view to assessing the practices of patent offices
- assessing the impact of trade agreements: in partnership with the World Bank Institute and the International Centre for Trade and Sustainable Development, WHO organized an expert consultation (Geneva, 2006) on developing a methodology to assess the impact of TRIPS-plus provisions affecting the prices of medicines.

28. After organizing a technical workshop (Geneva, April 2004) that dealt with the relationship between vaccines and intellectual property rights in developing countries, WHO is conducting field studies to assess the impact of intellectual property rights on the development of innovative vaccines by local manufacturers in Brazil and India. Capacity-building projects are under way in Africa, Asia and Latin America.

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

29. The report of the Commission and resolution WHA59.24 were considered by all WHO regional committees in 2006. The regional committees for South-East Asia and for The Americas adopted resolutions calling on Member States and the Regional Directors to promote action at regional level.<sup>1</sup> A regional consultation was to be held in the South-East Asia Region before the session of the Intergovernmental Working Group. The Regional Office for Europe is following up this recommendation with the European Union and some of its Member States.

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<sup>1</sup> See document A/PHI/IGWG/1/3.