EXECUTIVE BOARD
120th Session
Agenda item 4.14

EB120/INF.DOC./4
23 January 2007

Public health, innovation and intellectual property: towards a global strategy and plan of action

Report by the Secretariat

1. In order to assist discussion of the agenda item, the attached draft matrix sets out WHO's activities in some of the areas mentioned in the progress report.[1]

[1] See also document EB120/INF.DOC./1.

AREAS FOR EARLY IMPLEMENTATION PROPOSED BY THE INTERGOVERNMENTAL WORKING GROUP ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY
Current activities of WHO's Secretariat

Areas for early implementation (CIPIH recommendation)*	WHO programmes	Related activities	Estimated cost for additional activities	Sources of funding
Discovery				
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.	Health information, evidence and research policy UNICEF/UNDP/ World Bank/WHO Special Programme for Research and Training in Tropical Diseases	• WHO is promoting the strengthening of the ability of developing countries to take a broader role in research and development on tropical diseases. This activity is a core element of the new strategy of the Special Programme for Research and Training in Tropical Diseases. • Through ministerial forums, such as the High-level Ministerial Meeting 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.		
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.		[Country-led activity]		

* As listed in document CIPIH/2006/1.

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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.	UNICEF/UNDP/ World Bank/WHO Special Programme for Research and Training in Tropical Diseases Essential medicines	• WHO collaborates with industry in ensuring that compound libraries are available for screening for activity against parasitic diseases, particularly in countries where those diseases are endemic. 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 diagnostic tools and vaccine targets. A global screening platform for parasitic diseases using free computing power is under way. WHO continues to complement public–private collaboration in this domain, and provides support for open-source research through academic networks. • 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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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.	Health information, evidence and research policy Special Programme for Research and Training in Tropical Diseases Initiative for Vaccine Research Support to the secretariat for the Intergovernmental Working Group Stop Tuberculosis Initiative Essential medicines Communicable disease research (neglected tropical diseases)	• 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 the making and implementation of policies 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. • 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 has a mandate to reduce inequalities in health research and health research funding. • In collaboration with WHO, the Drugs for Neglected Diseases Initiative, set up in 2003 by research institutions from Brazil, France, India and Kenya, the Ministry of Health of Malaysia, and Médecins *sans Frontière*,supports 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.		

Areas for early implementation (CIPIH recommendation)*	WHO programmes	Related activities	Estimated cost for additional activities	Sources of funding
		• 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.		
2.7 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.	Essential medicines	• The WHO medicines strategy guides the provision of support to Member States in relation to intellectual property rights and trade agreements. • WHO has commissioned a study on patent claims for pharmaceutical products in order to assess the practices of patent offices and to generate lessons in order to improve the work of those offices. • WHO has issued guidelines on remuneration for the use of patents on medical technologies, and a guide on compulsory licensing.		
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.	Special Programme for Research and Training in Tropical Diseases Initiative for Vaccine Research Communicable disease research (neglected tropical diseases)	• 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 in order 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; information from the latter is shared for use in control of leishmaniasis. • WHO has launched an initiative to facilitate discovery of new drugs and diagnostic tools for helminth infections and has provided support for exploration of the patent-pool model for a vaccine against severe acute respiratory syndrome.		

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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.		[Country-led activity]		
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.		[Country-led activity]		
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 exclude support of health-related research which meets their industrial or export objectives and that could contribute to improved public health in other countries.		[Country-led activity]		
2.12 Public research institutions and universities in developed countries should seriously consider initiatives designed to ensure that access to research and development outputs relevant to the health concerns of developing countries and to products derived therefrom, are facilitated through appropriate licensing policies and practices.		[Country-led activity]		

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Development				
3.2 To enhance the sustainability of public–private partnerships: • current donors should sustain and increase their funding for research and development to tackle the health problems of developing countries; • more donors, particularly governments, should contribute to increase funding and to help to protect public–private partnerships and other research and development 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.	Special Programme for Research and Training in Tropical Diseases Stop Tuberculosis Initiative HIV/AIDS Global Malaria Programme Essential medicines	• Some of the available medicines for tropical diseases have been developed through public–private partnerships involving or established by WHO. • WHO has provided support for the establishment of existing public–private partnerships for product development, such as the Medicines for Malaria Venture and the Foundation for Innovative New Diagnostics. • Through the Special Programme for Research and Training in Tropical Diseases, WHO is supporting the discovery of new drug and diagnostic leads for the development of the portfolios of public-private partnerships. • WHO is providing guidance on the prequalification of medicines for developing countries. • Through the special Programme for Research and Training in Tropical Diseases, and relevant areas of work, WHO is providing the evidence to inform policy once products are developed (for example evidence that led to adoption to artemisinin–combination therapy). • WHO is providing support to public–private partnerships and industrial entities that are investing in research into tropical diseases by developing mechanisms that enhance purchase and access (the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Global Alliance for Vaccines and Immunization, and the International Drug Purchasing Facility (UNITAID)) in order to achieve the Millennium Development Goals.		

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		• WHO, through, for example, the Special Programme for Research and Training in Tropical Diseases and with the Foundation for Innovative New Diagnostics, has supported the publication of several guidelines for diagnostic testing and evaluation, and has recently issued an analysis of the market for diagnostics tools for tuberculosis. • WHO is supporting the Global Fund to Fight AIDS, Tuberculosis and Malaria and working with companies to ensure access to medicines.		
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.	UNICEF/UNDP/ World Bank/WHO Special Programme for Research and Training in Tropical Diseases UNDP/UNFPA/ WHO/World Bank Special Programme of Research, Development and Research Initiative for Vaccine Research Policy-making for health in development	• Guidelines for clinical trials in developing countries have been issued.[1] 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.		

[1] Document TDR/PRD/GCP/02.1b.

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	Essential medicines Health information, evidence and research policy	• 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. • 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 Gabon and Nigeria, the third one will provide distance-learning tools for members of research ethics committees and other stakeholders in health research focusing on the African context. • 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.		

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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.		[Country-led activity]		
3.7 Practical initiatives that would motivate more scientists to contribute to this field through "open source" methods should be supported.		[Country-led activity]		
Delivery				
4.2 Developing countries should create incentives designed to train and retain health-care workers in employment.		[Country-led activity]		
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.		[Country-led activity]		
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.		[Private-sector-led activity]		
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.		[Country-led activity]		

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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.		[Country-led activity]		
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.		[Country-led activity]		
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.		[Private-sector-led activity]		
4.18 Developed countries and 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.		[Country-led activity]		

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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.		[Country-led activity]		
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.		[Country-led activity]		
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.		[Country-led activity]		
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 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.		[Country-led activity]		

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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.		[Country-led activity]		
4.26 Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries.		[Country-led activity]		
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.		[Country-led activity]		
Fostering innovations				
5.2 The formation of effective networks, nationally and internationally, between institutions in developing countries and developed countries, both formal and informal, is an important element in building innovative capacity. Developed and developing countries should seek to intensify collaboration which will help build capacity in 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.		[Country-led activity]		

Areas for early implementation (CIPIH recommendation)*	WHO programmes	Related activities	Estimated cost for additional activities	Sources of funding
5.5 Developed countries should comply with their obligations under Article 66.2 of the TRIPS agreement and paragraph 7 of the Doha Declaration.		[Country-led activity]		
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 way forward				
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.	Essential medicines Support to the secretariat of the Intergovenmental Working Group	• Monitoring and analysis activities include the following: - determining the patent status of essential medicines: a pilot project is under way with WIPO, the European Patent Office and national patent offices in order 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;		

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		- 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. 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 in order 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.		
Other recommendations				
Member States could consider voluntary reporting on their implementation.		[Country-led activity]		