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INTERGOVERNMENTAL WORKING GROUP ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY
Second session
Provisional agenda item 2

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Report on developments since the first session of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property

Summary of second public hearing

1. In preparation for the second session of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, the Secretariat held a second web-based public hearing from 15 August to 30 September 2007. The aim was to obtain inputs from as wide a group of stakeholders as possible.[1]

2. The hearing was divided into two sections. Section 1 was dedicated to comments on, and inputs to, the draft global strategy and plan of action on public health, innovation and intellectual property,[2] and was based on the recommendations of the WHO Commission on Intellectual Property Rights, Innovation and Public Health,[3] relevant Health Assembly resolutions, outputs from the first session of the Working Group, and subsequent submissions from Member States. Section 2 responded to the specific request by the Health Assembly in resolution WHA60.30 to the Director-General "to encourage the development of proposals for health-needs driven research and development for discussion at the Intergovernmental Working Group that includes a range of incentive mechanisms including also addressing the linkage between the cost of research and development and the price of medicines, vaccines, diagnostic kits and other health-care products and a method for tailoring the optimal mix of incentives to a particular condition or product, with the objective of addressing diseases that disproportionately affect developing countries".

3. Member states, national institutions, academic and research bodies, civil society groups, the private sector, individuals and other interested parties submitted more than 70 contributions to the public hearing. The main issues and suggestions are summarized below.

[1] Full-length summaries and submissions in their original languages are available on the WHO web site (http://www.who.int/phi/public_hearings/second/contributions/en/index.html) and in hard copy on request.

[2] Document A/PHI/IGWG/2/2.

[3] Document CIPIH/2006/1.

SECTION 1

4. Some submissions highlighted the importance of prioritizing research and development needs (Element 1 of the draft global strategy), particularly on health products for neglected diseases and sharing of information on which parties are filling those needs. It was suggested that an inventory should be prepared of current research and development activities targeted at neglected tropical diseases so as to avoid duplication. Several contributors argued that any granting of access to compound libraries should be on a strictly voluntary basis.

5. With respect to promoting research and development (Element 2), concern was expressed about an open-source model for research and development of pharmaceutical products. In addition, one contributor recommended the establishment of a separate working group on promoting vital research and development on preventive and therapeutic vaccines.

6. On building and improving innovative capacity (Element 3), many contributors opposed a medical research and development treaty. Several proposals were made relating to human resources: appropriate training and retention of researchers and health professionals; systematic use of recent postgraduates and other junior professionals in order to accelerate research and development; and encouragement by the Working Group of public–private partnerships in order to synergize resources and assist in training developing country government officials in the formation of regulatory and intellectual property systems and enforcement practices. The importance of strengthening product regulatory capacity was emphasized, and it was suggested that countries in which product research and development was being undertaken should be required to provide stringent regulatory oversight of manufacturing processes.

7. Comments on transfer of technology (Element 4) stressed the need for concrete measures. New evidence could be collected on the desirability and feasibility of using a patent pool to reduce costs.

8. Contributions on the management of intellectual property (Element 5) noted the importance of assessing and enhancing new mechanisms of promoting innovation that respond to health needs, and stressed management of intellectual property generated with public funding so as to promote its application to developing countries' needs. Contributors supported the further formulation of proposals for advanced market commitments, specialized market-exclusivity mechanisms, for research and development, tax incentives and strategies and market-based incentives to promote research in underserved areas including "pooled advance-purchase commitments". Many comments called for the text to be revised in order to recognize the separation of function of patent offices and regulatory agencies.

9. Improving delivery and access (Element 6), in particular the importance of supporting access to medicines in the broader context of health policies and rational use of medicines, was highlighted in many submissions. It was noted that more targeted strategies are needed in order to improve disease management and treatment outcomes in underserved, high-risk populations and groups. For the regulatory approval process of medicines to be accelerated, advantage should be taken of scientific opinion developed by other jurisdictions or agencies. Some contributors recommended that the draft strategy should cover sustainable funding for product development, as well as coordination of, and increased funding for, the expansion of health-research capacity. The creation of a task force for collecting accurate information on the counterfeiting of pharmaceuticals was also suggested.

10. Among the responses to the question of whether any additional issues should be considered within the proposed global strategy and plan of action, it was suggested that gender-sensitive

provisions should be included; that special consideration should be devoted to preventive and therapeutic vaccines; that patients and patient groups should be given a central role in future discussions and provided with resources to educate their communities; and that rural residents should be given special consideration.

11. Several broad comments related to costing. Concern was expressed that the draft plan of action creates costly duplications of existing activities (such as those of the UNICEF/UNDP/World Bank/WHO Special Programme of Research and Training in Tropical Diseases) and therefore threatens to undermine other sources of investment into diseases of poverty, and that no cost estimate is provided for acting on the eight elements. Another concern was that the governance principles underlying WHO's extrabudgetary accounts rather than those applied to the regular budget control the management process. One contributor proposed a WHO-sponsored cost-benefit analysis of whether the plan of action, if implemented, would undermine local and foreign investment in the private pharmaceutical industry in sub-Saharan Africa.

12. Several contributors raised specific textual concerns, including: use of the terms "disease or conditions of significant public health importance" and "disproportionately affecting developing countries". Some requested definitions of the terms "exchange of information" and "dissemination of relevant information", and one recommended that the progress indicator under infrastructures should be changed to "number of developing countries that have increased investment in health delivery infrastructure as a share of total public budgets by 2015". It was also proposed that the future financial needs for research and development related to Type II and Type III diseases should be quantified.

13. Broader concerns included the idea that the text should focus only on Type II and Type III diseases, and that the draft strategy oversteps WHO's mandate by trespassing on the jurisdictions of WTO and WIPO.

SECTION 2

14. Contributors to this section were invited to consider the following in drawing up proposals: focus on diseases that disproportionately affect developing countries; feasibility; and likely contribution to fostering innovation, building capacity and improving access.

15. Several contributors expressed concern about the development of alternatives to the current private-sector model of innovation. Some argued that private firms are generally better informed than governments about the potential value of innovations to patients and providers, and that governments would aim to reduce costs in areas of research valuable to consumers; and that the incentives created through the current intellectual property system must be protected in order to ensure the development of new medicines for life-threatening diseases. A strong business community, improved economies and funding mechanisms such as micro-financing were proposed as alternatives to changes to the current model. Public and private initiatives that increase overall incentives for research and development were well supported.

16. New proposals for health-needs research and development that should be considered by the Working Group are summarized below.

17. It was proposed that WHO should mediate the coordination of research, innovation and equitable access to antiretroviral medicines in underserved markets through facilitation of a multipronged strategy that was based on incentives and the principle of voluntary licensing. Such an

approach, under WHO management, might expand equitable and sustainable access of resource-limited populations to appropriate antiretroviral treatment, while boosting know-how, technology transfer, innovation, research and development, and national industry capacities and market penetration by generic manufacturers of pharmaceuticals.

18. Another proposal posited a comprehensive advance market commitment, whereby pharmaceutical innovators may openly license their technologies in exchange for payments based on the improvement in health resulting from their innovation. Because payments under the commitment would be conditional on measurable effects, the scheme would align incentives with health needs, offering firms an incentive to develop and promote products to improve health, to work with public health agencies in order to promote their product and ensure its rational use. The approach could be used to create new incentives for research and development into drugs for use in developing countries because it is not restricted to research and development on diseases of industrialized countries.

19. Another suggestion was to supplement the current patent system with a second-track system that rewards innovators, in so far as they relinquish exclusivity on any pharmaceutical innovation or aspect thereof, in proportion to the global health impact of the innovation they place in the public domain. By allowing the open manufacture, distribution and sale of a new medicine, a firm would be entitled to second-track rewards, backed by any treaty that may be negotiated for the medicine's success in reducing the global burden of disease in the early years after its introduction.

20. The proposed "green intellectual property" scheme would call for unimpeded access to necessary technologies (typically including essential medicines) while maintaining patent protection, consequently stimulating incentives. The scheme would work by imposing costs on patent owners ("insurance" to guarantee early investments and reasonable rewards), from which proceeds would be used to create a trust fund so that financial assistance could be offered to technology users who have little or no access to a patented technology. The system would increase inventors' incentives to develop new technologies.

21. Another submission discussed the idea of a consortium for drug discovery research for infectious diseases affecting the poor, which would focus on the early phases of drug research and the development of lead compounds, and bring together major players such as the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases, academia (in developed and developing countries), the pharmaceutical industry and product development partnerships. This approach could make better use of financial contributions from governments and private foundations that fund research and development on drugs for infectious diseases that affect developing countries.

22. The use of monetary prizes as an alternative mechanism to stimulate private investments in research and development was recommended. Specifically, donors and governments could consider prizes instead of marketing monopolies as the reward for successful investments. Proposals for patent buy-outs or advanced marketing commitments work in a similar way and should also be considered.

23. A further suggestion was for practical and constructive initiatives to increase and strengthen research and development on diseases that disproportionately affect developing countries. These initiatives could include increasing resources for the Special Programme for Research and Training in Tropical Diseases; strengthening existing public–private partnerships that focus on Type II and Type III diseases; identifying gaps in research on Type II and Type III diseases and proposing constructive, market-based incentives (such as advance market commitments) to fill those gaps; and incentives to promote research and development on Type II and Type III diseases by researchers and companies in developing countries and collaboration between the latter.

24. It was noted that possible areas for patent pools include essential medical technologies developed by Essential Inventions (a non-profit corporation) and technologies related to HIV/AIDS currently being discussed by the UNITAID board. A broader proposal was for an essential medical inventions licensing agency.

25. The following management strategies were suggested: include in exclusive technology-transfer agreements licensing terms that ensure low-cost access to health-related innovations in the developing world; develop a transparent, case-by-case global access strategy to ensure access to health-related technologies; and carve out an exemption for research on Type III diseases for any patents held or licences executed by a university.

26. One contributor noted that the strategy should explore innovative and sustainable mechanisms for financing research and development, such as the excise tax on cross-border currency transactions (Tobin Tax) and other incentives that do not depend on intellectual property ownership. A model of sustainable funding for the development of new medicines (specifically small molecules) for diseases where the market mechanisms of the more affluent countries do not function was proposed.

27. Other contributors suggested that WHO should create a virtual advisory institute for research on HIV vaccines, new diagnostic methods and viral inhibitor technologies by facilitating information-sharing on the existing technologies and available tools declared to be free for use. WHO should also provide an international professional service for the elaboration of integrated national or regional plans to set priorities in health policies. WHO was urged to undertake a comprehensive study of possible initiatives, particularly public–private partnerships, in order to improve access for those with infectious diseases.

28. Further, several contributors urged WHO to consider recent market initiatives, including in the United States of America, the recent provision of the Food and Drug Administration Amendments Act of 2007 which creates a new incentive for companies to invest in new treatments for neglected tropical diseases: the transferable “priority review voucher” awarded to any company that obtains approval for a treatment for a neglected tropical disease.

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