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## **Status of implementation of resolution WHA59.24**

### **Summary of public hearing**

1. Resolution WHA59.24 requested the Director-General to convene an intergovernmental working group, open to all interested Member States, to draw up a global strategy and plan of action aimed at, inter alia, securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries; and to submit them to the Sixty-first World Health Assembly through the Executive Board.

2. In order to obtain inputs for this process from as wide a group of stakeholders as possible, the Secretariat opened a web site as a forum for a public hearing from 1 to 15 November 2006. Contributors were invited to review the Commission's report,<sup>1</sup> resolution WHA59.24 and other relevant documents before making online submissions. Submissions were received from governments, academia, civil society, public-private partnerships, product development partnerships, and industry. The main elements and suggestions from the contributors are summarized below.

3. A number of submissions advocated the need to promote policies that encourage needs-driven research and access to innovation, with governments ensuring sustainable access. Redirecting present-day knowledge and scientific expertise to neglected needs might require a substantial change in the way essential health products are valued and made available, although it was acknowledged that this would require policies in which essential health research and the resulting products are considered as "global public goods"; it would also require political will to make such significant conceptual changes.

4. The need for an appropriate research and development agenda, and a clearer definition of neglected diseases was advocated by some contributors. It was argued that it is the poor themselves rather than the diseases that are neglected, and that policies regarding research on neglected diseases should include non-traditional partners in drug development.

5. The need to ensure that international public health concerns are adequately reflected in approved trade policies, was also advocated. Mention was made of the need for further studies on the impact of bilateral trade agreements on the flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and it was suggested that amendment to the Agreement might need to be considered regarding the export of products manufactured under compulsory licensing, and in other areas where dysfunctions occur. One contributor notes that the role of drug regulatory authorities would need to be clearly defined.

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<sup>1</sup> Public health, innovation and intellectual property rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health. April 2006.

6. There were several proposals for further legislative steps such as the adoption of a multilateral treaty on the regulation of the safety and cost-effectiveness of medicines and medical devices, funded by a tax on global financial transactions. Other proposals were for global funding mechanisms to support research and development, including the establishment of a global research and development treaty; a tropical disease fund; and a medical prize fund, to which governments would contribute financially, for inventions that improve health-care outcomes, limited to inventions that are voluntarily licensed to patent pools.

7. The debate on intellectual property rights produced a range of approaches, although contributors generally agreed that exclusive reliance on and recourse to market forces, as represented by intellectual property rights, do not constitute an ideal solution at present, either in relation to research and development or to access. It was suggested that an exclusive dependency on patents and intellectual property rights, particularly in poor countries, may sometimes hinder research and development and access to drugs. One contributor argued that currently, intellectual property protection works for “global diseases” where innovation is subsidized by rich countries; in addition, the need to reorientate the patent process towards “real innovation” was emphasized.

8. The question of equitable handling of intellectual property rights was also raised. The evolution of new patent regimes that align the interest of patent holders with those of patients and generic drug producers, and make neglected diseases “attractive profit opportunities” was advocated. One contributor argued that intellectual property rights were critical to innovation and the viability of the pharmaceutical industry, serving as an essential safety net to protect a company’s investment of time and money in bringing a drug to market; the risk inherent in such endeavours, should be recognized. It was submitted that for public development partnerships, an intellectual property right has been an effective tool for enhancing innovation, development and delivery of AIDS vaccine at appropriate prices. Some contributors noted that the TRIPS agreement struck a fair balance between providing intellectual property protection and allowing countries the flexibility to promote treatment for poor people in national emergencies.

9. Several submissions emphasized the barriers to access in poor countries, including high prices of medicines (arising from market-driven forces or from high taxes, tariffs and regulations) and the mismatch between areas of ongoing research and needs-based research on poverty. Other barriers mentioned were weak health systems, inadequate risk-pooling mechanisms, bureaucratic and burdensome registration procedures which depress demand and reduce investment in research and development for “diseases of poverty”. A university consensus statement referred to the Commission’s recommendation that “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”.

10. Several specific suggestions were made for reducing existing barriers to access in developing countries, such as improving disease-management programmes, education and service infrastructure to ensure effective delivery of new medicines and other tools to patients; granting rights to generic companies to manufacture and export university innovations to developing countries; price reductions; non-patenting requirements, and participation in patent pools; separation of financing of research and development needs (including translation research), end costs of producing and cost for delivering products; and promoting agreements among research partners at the outset to permit flexibility in manufacturing practices and pricing.

11. Several submissions highlighted the growth and importance of public-private partnerships and public development partnerships in mobilizing and channelling resources towards research and

development efforts directed at diseases of poverty, to purchase medicines and develop health-system infrastructure. It was noted that public-private partnerships combine elements of public-sector activity, such as coordination of basic research with private-based activity, such as discovery and development of new molecules. It was therefore considered useful to support public-private partnerships and/or public development partnerships and recognize them as part of the overall systems for improving health outcomes. The need for additional funding and the creation of regulatory environments that nurture public-private partnerships and the private-sector development of drugs was stressed. It was submitted that the intergovernmental working group should examine economic incentives to promote innovations in this area and identify ways of providing incentives to the private sector with appropriate protection of intellectual property rights (e.g. advance purchase commitments/dedicated advance purchase funds, licensing agreements that encourage distribution of products to low-income countries, differential pricing, roaming patent extensions, streamlined approval procedures, grants, tax credits).

12. One submission noted that research success, including research on neglected diseases, should be measured by the impact on human welfare rather than by a count of patents or licensing revenue. A free-market approach to innovation might not be sufficient: the advantages of a needs-driven priority setting for research and development should be explored further. The importance of strengthening public leadership and civil society in determining priorities in research and development (with opportunities for inputs and dialogue on issues and implementation) and supporting non-profit initiatives was raised in some submissions.

13. Enhanced support for basic research on biological mechanisms, including molecular targets, and epidemiological studies was suggested by one contributor. Research and development would require the engagement of non-traditional partners (public-private partnerships), the recruitment of a faculty conducting research on neglected diseases, and the priority ranking of neglected-disease research. It was advocated that special attention should be given to disease areas, such as human trypanosomiasis, Chagas disease, and dengue, in which there are few available tools or research and development pipelines. The importance of developing countries increasingly being recognized as significant partners in development and innovation, including clinical trials (which should be supported by strong regulatory institutions and ethical processes) was also noted. There was therefore an urgent need to develop such capacities in the developing countries.

14. The role of the WHO Secretariat and the intergovernmental working group was seen as one of coordination; some contributors were in favour of giving direct responsibility to the intergovernmental working group in that regard. Several submissions encouraged the intergovernmental working group to view its mandate more broadly, covering not only neglected diseases but also major diseases, such as HIV/AIDS and tuberculosis, and noncommunicable diseases. The specific requirements of vaccine development should be given due consideration, bearing in mind that: (a) the issues involved go beyond patenting and licensing to include trade secret data, manufacturing know-how, materials transfer and other rights; (b) there is a need to expand the researcher's freedom to use intellectual properties in developing candidate vaccines; (c) adequate compensation must be determined for ownership of information or technology. One submission urged the intergovernmental working group to extend its mandate to include injuries; the political and social determinants of health (e.g. trade policies, impact of conflict and environmental practices, as well as violence); and traditional medicine.

15. It was suggested that the WHO Secretariat should support Member States in implementing the Commission's recommendations and in reporting to the intergovernmental working group. A technical expertise group might also be set up to assist Member States in dealing with intellectual property/public health issues and their harmonization.

16. It was proposed that WHO, through the intergovernmental working group, should define the conditions by which essential health innovation can be promoted and the research and development outcome accessed; formulate plans for the implementation of the Commission's recommendations; investigate alternative methods of funding, based on health outcomes rather than intellectual property rights or return on investment; and identify the resources required to cover unmet needs for essential medical research and development.

17. Full-length summaries and submissions in their original languages (English, French and Spanish) are available on the web site<sup>1</sup> and in hard copy on request.

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<sup>1</sup> [http://www.who.int/public\\_hearing\\_phi/en/](http://www.who.int/public_hearing_phi/en/).