

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

Report by the Secretariat

1. The Sixty-first World Health Assembly adopted resolution WHA61.21 on a global strategy and plan of action on public health, innovation and intellectual property, which, inter alia, requested the Director-General to monitor performance and progress of its implementation and to report to the Sixty-third World Health Assembly, through the Executive Board.
2. The global strategy and plan of action outline more than 100 specific actions across eight elements.¹ In order to implement those actions, the plan of action identifies stakeholders in four categories: governments, WHO, other international intergovernmental organizations and other relevant stakeholders (including development partners).
3. A monitoring and reporting framework based on the progress indicators that were accepted by Member States in resolution WHA62.16 has been created. Where those indicators are quantitative, the Secretariat will provide additional complementary information on the implementation of the specific actions.
4. For those specific actions that fall under the responsibility of the Secretariat, implementation of the global strategy and plan of action is being entrusted to departments with the appropriate technical capacity and managerial responsibility. This document provides an overview of activities that have been initiated by the Secretariat and other stakeholders to implement the global strategy and plan of action.

IMPLEMENTATION LED BY WHO

5. In addition to the activities described here and in line with resolution WHA61.21, WHO undertook a Quick Start Programme to begin immediate implementation of a number of specific

¹ The elements are: (1) prioritizing research and development needs; (2) promoting research and development; (3) building and improving innovative capacity; (4) transfer of technology; (5) application and management of intellectual property to contribute to innovation and promote public health; (6) improving delivery and access; (7) promoting sustainable financing mechanisms; and (8) establishing and monitoring reporting systems.

actions that fall under its responsibility.¹ The report on the Quick Start Programme is available on the WHO web site.²

6. In November 2008, in accordance with paragraph 4(7) of resolution WHA61.21, the Director-General established a results-oriented and time-bound Expert Working Group to examine current financing and coordination of research and development, including proposals for new and innovative sources of funding. The Expert Group, composed of internationally-recognized policy-makers and technical experts, held three meetings in 2009, and finalized the English version of its report in December. The work of the Group was supported through two web-based public hearings, one on proposals for new and innovative sources of funding to stimulate research and development and the other on the evaluation process. Proposals were evaluated with tools that were specifically designed for this purpose, including an evaluation framework and criteria. An inventory of the financing proposals under consideration was drawn up and shared with relevant groups as part of the consultation process.

7. Within the context of element 4 of the global strategy and plan of action, the Secretariat has initiated a European Commission-supported project in partnership with UNCTAD and the International Centre for Trade and Sustainable Development that will examine the main obstacles to transfer of pharmaceutical-related technology to, and local production in, developing countries. Work includes a survey of relevant stakeholders; a screening process of existing initiatives and support schemes; and a text on trends in health-related technology transfer and local production. Additionally, the project scope has been expanded to include vaccines and diagnostics.

8. In line with the recommendations of the Expert Committee on Specifications of Pharmaceutical Preparations,³ the Secretariat is developing guidelines to support technology transfer. The guidelines outline key elements needed for technology transfer, from a quality perspective. These elements include transfer of analytical methods for quality assurance and control; skills assessment and training; and organization and management of the transfer.

9. In the area of intellectual property, activities are undertaken in collaboration with other competent international organizations and have focused on capacity building and training. Interagency collaboration has been expanded through cooperation with WIPO and WTO. The work is a follow-up to the high-level meetings of the Directors-General of these organizations and provides a basis for the joint planning of activities and projects.

10. Regional and national networks for innovation are vital components in ensuring the implementation of the global strategy and plan of action, notably to promote research and development and to build capacity. The African Network for Drugs and Diagnostics Innovation is being established with the goal of promoting African-led product research and development innovation through the discovery, production and delivery of affordable new tools, including those based on traditional medicines, and will aim to provide support to infrastructural and capacity development.

¹ Resolution WHA61.21 requested the Director-General, *inter alia*, "to prepare a quick start programme with adequate budget provision and begin immediately to implement the elements of the global strategy and plan of action on public health, innovation and intellectual property that fall under the responsibility of WHO".

² http://www.who.int/phi/Q_Sprogramme/en/index.html and click on the Quick Start Activities option.

³ WHO Technical Report Series, No. 948, 2008.

11. Preliminary discussions are under way in the South-East Asia Region and the Region of the Americas for the establishment of regional networks. Discussions have been initiated by PAHO and the Secretariat to establish a Latin American network, with a first meeting held in Panama City in September 2009. At a meeting in Shanghai, China, in October 2009 an initiative to establish a Chinese network for medicines and diagnostics innovation was launched, with the participation of scientists from academia and industry and with representation from the ministries of science and technology and of health.

12. The global strategy calls for the strengthening of WHO's Prequalification Programme. Work in that direction has included an expansion of the scope of the prequalification of medicines to include products for neglected tropical diseases, pandemic influenza and reproductive health. More specifically, since January 2009:

- 44 products have been prequalified, including the following for paediatric use: eight for the treatment of HIV/AIDS, three antituberculosis agents, one to treat malaria, and seven to treat influenza – the total number of products prequalified by WHO is now 236;
- four quality-control laboratories were prequalified, bringing the total number to 12;
- the prequalification of diagnostics is operational, and has four components: dossier review; inspection of the manufacturing site; laboratory evaluation; and the building of regulatory capacity, including post-market surveillance. So far, 99 applications have been received, of which 23 have been identified as a priority and invited to proceed to the dossier review stage. At the same time, the product range of diagnostics procured through WHO has expanded in collaboration with other organizations in the United Nations system. Pilot projects to strengthen national capacity in regulation and post-market surveillance of diagnostics have been initiated in three African countries (Burkina Faso, Côte d'Ivoire and United Republic of Tanzania). Preparations are in hand to add two more countries, China and South Africa, to the pilot scheme.

13. The Council on Health Research for Development, in partnership with the African Union, the New Partnership for Africa's Development, and the George Institute for International Health has produced an innovative framework to support countries in implementing the global strategy and plan of action, particularly in the African Region. The framework is designed to support countries in assessing their needs for innovation and local medicines production. Furthermore, it gives countries a practical tool to select those elements of the global strategy and plan of action that are most relevant to their needs and to monitor their implementation through a web-based information platform.

14. The fifth session of the High-Level Task Force on the Implementation of the Rights to Development, in April 2009,¹ commissioned a desk review of the work of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property and the global strategy and plan of action from the perspective of the right to development. The Task Force's report² documents the process leading to the adoption of the global strategy and plan of action and maps the Task Force's work on criteria based on the right to the enjoyment of the highest attainable standard of health against

¹ The High-Level Task Force on the Implementation of the Right to Development was set up in pursuance of the Commission on Human Rights resolution 2004/7, within the framework of the working group on the right to development.

² WHO. *Research and development coordination and financing: report of the expert working group*. Geneva, World Health Organization, 2010. (http://www.who.int/phi/documents/ewg_report/en/index.html) §

the global strategy. Additionally, it identifies lessons learnt from the intergovernmental process that can aid efforts to refine and develop right-to-development criteria in relation to Millennium Development Goal 8 (Develop a global partnership for development).

15. In January 2010, the Executive Board at its 126th session considered this report and an extensive executive summary of the report of the Expert Working Group on Research and Development Financing. The Board agreed that the full report should be made available in all official languages a few weeks later and that a web-based consultation would be held, followed by a day-long consultation with Member States the week before the Health Assembly.¹

ACTION BY THE HEALTH ASSEMBLY

16. The Health Assembly is invited to note the report.

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¹ Document EB126/2010/REC/2, summary record of the second (section 2), third (section 2) and fourth meetings.