

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 is being 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 its final report is being prepared.³ 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 using 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, which will examine the main obstacles to transfer of pharmaceutical-related technology 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,⁴ 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 Innovation⁵ is being established with the goal to promote 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 For an executive summary, see document EB126/6 Add.1.

⁴ WHO Technical Report Series, No. 948, 2008.

⁵ See <http://apps.who.int/tdr/svc/publications/tdrnews/issue-81/african-network>.

With support from the Secretariat and in collaboration with several other organizations, notably the African Development Bank and the European Union, two consultative stakeholder meetings were held in 2009 and a business plan drawn up.

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 explore the establishment of 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 drugs 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. WHO has been working with the World Bank, WIPO, WTO, UNCTAD, international experts and trade and health policy-makers from several countries to develop a diagnostic workbook on trade and health that lists best practices, data sources, decision trees, and international norms and standards.

13. In 2009, with the support of the Government of the Netherlands and the WHO Secretariat, activities on training and technology transfer relative to vaccines by the Netherlands Vaccine Institute became fully operational. The Institute established a platform for the transfer of standard robust production technology for influenza vaccine and an on-site training programme for manufacturers in developing countries.

14. Through licensing agreements, WHO is providing developing countries with access to pandemic influenza (H1N1) 2009 vaccine manufacturing technology to produce vaccines for the public sector on a royalty-free basis. WHO has provided sub-licences on this technology to three vaccine manufacturers in China, India and Thailand, respectively, which are currently engaged in the development of vaccines against pandemic influenza A (H1N1) 2009 viruses.

15. The Secretariat has embarked on a new initiative aimed at making the benefits of core health technologies available at an affordable price, particularly in resource-limited settings. In this regard, WHO is preparing to examine the barriers to the use of innovative technologies by developing countries and proposed ways to overcome them. Additionally, WHO has launched a request for proposals for innovative technologies that may have a significant impact on public health for the business and scientific community in developing countries.

16. WHO is promoting transfer of technology for the production of a cocktail of monoclonal antibodies to replace rabies immunoglobulin for the post-exposure prophylaxis of severely exposed patients. Through a network of WHO Collaborating Centres for Rabies Reference and Research, the monoclonal antibodies have been selected. WHO identified an industrial partner for production and recently signed a material transfer agreement. WHO, in collaboration with the Program for Appropriate Technology in Health and the Infectious Disease Research Institute (both of Seattle, Washington, United States of America), is providing support for the initiation of ethical research projects on the suitability of new devices for intradermal application of rabies antigen for post-exposure prophylaxis.

17. The Secretariat provides support to Member States in which neglected tropical diseases are endemic in order to strengthen their procurement and distribution capacity for underserved populations and extend access to essential medicines for treatment and/or prevention of several neglected diseases. This work has included expansion of the distribution of praziquantel to treat schistosomiasis in eight

African countries and distribution of triclabendazole to treat fascioliasis in six countries in the Region of the Americas and in the Western Pacific Region.

18. With the support of two pharmaceutical companies, a new combination of eflornithine and nifurtimox was launched in September 2009 to treat human African trypanosomiasis. The project included the preparation of kits to improve logistics and administration (in collaboration with Médecins Sans Frontières and others) and training for proper administration of the combination is planned for all countries where the disease is endemic.

19. WHO is developing a framework for an agenda of priority noncommunicable diseases research to cover the public health needs of low- and middle-income countries. It focuses on research and development needs related to cardiovascular disease, diabetes, cancer, chronic respiratory disease, and associated risk factors. This work will also include a series of consultations with experts, researchers and other stakeholders. The framework is expected to be finalized in 2010.

20. Research on noncommunicable diseases in resource-poor settings is being conducted in collaboration with health ministries of eight low- and middle-income countries. The objective is to identify gaps in the delivery of essential noncommunicable disease interventions at primary care level and identify cost-effective and feasible solutions. Research is also under way on technologically appropriate products to address public health needs related to cardiovascular disease. As an example, a solar-powered non-mercury device to measure blood pressure for use by middle-level health workers has undergone technical and field validation.

21. The success of the global strategy and plan of action depends on the strengthening of research capacity for development. An independent ethics committee that meets minimum standards must exercise an oversight role in respect of research. To enhance guidance and standards relative to the ethical dimensions of research, the Secretariat organized a meeting in November 2009 to discuss the creation of norms and standards for research ethics committees, attended by about 30 stakeholders from the six WHO regions including representatives from health ministries, international bilateral organizations, ethics organizations, and others. The meeting recommended that Member States should establish research ethics committees to review all human research conducted in their countries and that WHO should promote ethical research.

22. 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:

- the following paediatric formulations were prequalified: four fixed-dose combinations for treatment of HIV/AIDS, two new antituberculosis products, and five oseltamivir products and one zanamivir product to treat influenza
- three more quality-control laboratories were prequalified, bringing the total number to 11
- 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, 79 applications have been received. At the same time, the product range of diagnostics procured through WHO has expanded in collaboration with other organizations in the United Nations system.

23. WHO, in partnership with the New Partnership for Africa's Development and the Pan-African Parliament, and with the support of the Department for International Development, (United Kingdom of Great Britain and Northern Ireland), the Bill & Melinda Gates Foundation and the Clinton Foundation have formed a consortium to improve access to medicines through regulatory harmonization and collaboration in Africa. In 2009, the consortium invited regional economic communities to submit project proposals on regional harmonization and medicines registration. Proposals have been submitted, reviewed and are now being further enhanced through technical and financial support from the New Partnership for Africa's Development and WHO.

24. WHO has designed a capacity-building model in the area of vaccines that has proved to be cost effective. It has targeted capacity building from both an individual and an institutional point of view. The model consists of five principal steps and tools, as well as approaches that can be used as a generic model for several purposes including the implementation of the global strategy and plan of action. An analysis, produced in 2009, documenting 12 years' experience is useful for boosting capacity building in different areas including support for countries to strengthen their regulatory capacity. The model is also used for supporting countries to expand their vaccine production capacity and meet emerging demand in the global supply of vaccines.

IMPLEMENTATION ACTIVITIES LED BY PARTNERS AND OTHER STAKEHOLDERS

25. Capacity-building initiatives have been explored as partnerships between product development partners and national regulatory authorities, one recent example in Africa involving the Drugs for Neglected Diseases Initiative and regulators from African countries.

26. The Council on Health Research for Development, in partnership with the New Partnership for Africa's Development and the George Institute for International Health, Sydney, Australia, 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.

27. The Global Forum for Health Research undertook a study between August and October 2009 on the extent of financed research on communicable and noncommunicable diseases. By drawing on publicly available information on research and development financing, the study provides an overview of the largest research funders including government, private sector and not-for-profit organizations during 2008, across these disease areas. Additionally, the study proposes a globally coordinated approach to research and development for communicable and noncommunicable diseases.

28. Health Action International Africa and IQsensato (Geneva, Switzerland) in partnership with the Regional Office for Africa, have designed a tool for monitoring implementation of the global strategy and plan of action on public health, innovation and intellectual property. The tool has been piloted in Ghana, Kenya, Rwanda, Uganda and Zimbabwe.

29. The international drug purchase facility UNITAID is working on the establishment of a voluntary patent pool for medicines, with specific reference to a pool for HIV/AIDS medicines. WHO has contributed to activities linked to the patent pool, including identification of missing essential medicines based on clinical need, and also to meet the needs and challenges of resource-limited settings. At the regional level, WHO has supported stakeholder consultations on patent pools, including one in India.

30. The fifth session of the High-Level Task Force on the Implementation of the Right 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 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).

ACTION BY THE EXECUTIVE BOARD

31. The Executive Board is invited to note the report.

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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 Document A/HRC/12/WG.2/TF/2 and Corr.1.