

---

## **Draft global strategy and plan of action on public health, innovation and intellectual property**

### **Interagency work on the interface between trade, intellectual property and public health**

#### **Report by the Secretariat**

1. Over the past decade, the Health Assembly has adopted several resolutions that have governed WHO's work on the relations between public health, trade and intellectual property, the most recent of which are resolutions WHA59.24 (Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action), WHA59.26 (International trade and health) and WHA60.30 (Public health, innovation and intellectual property). For its part, the Secretariat continues to provide policy guidance and technical support to Member States in the area of public health, trade and intellectual property rights, and to respond to the specific requests to the Director-General.
2. In order to consolidate its policy guidance and technical support, WHO collaborates closely with other competent international organizations, in particular WTO and WIPO. Major interagency activities are summarized below.

#### **WHO'S MANDATE**

3. Several Health Assembly resolutions are concerned with the effects of trade agreements on policies on pharmaceuticals and health, including related technical cooperation. For instance, in resolution WHA56.27, adopted in 2003, the Health Assembly expressed itself as "mindful of concerns about the current patent protection system, especially as regards access to medicines in developing countries", and urged Member States "to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)". In resolution WHA57.14 the Health Assembly similarly urged Member States, but as a matter of priority, "to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights [and] to take into account in bilateral trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001)".

4. In May 2006, the Fifty-ninth World Health Assembly adopted two resolutions endorsing WHO's multiagency approach in technical cooperation. In resolution WHA59.26, it requested the Director-General "to respond to Member States' requests for support of their efforts to build the capacity to understand the implications of international trade and trade agreements for health and to address relevant issues through policies and legislation that take advantage of the potential opportunities, and address the potential challenges that trade and trade agreements may have for health". In resolution WHA59.24 it decided to establish an intergovernmental working group in order to draw up a global strategy and plan of action based on the recommendations of the report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health; the aim of that strategy and plan would be, inter alia, "securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries". Additionally, that resolution requested the Director-General "to continue to monitor, from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the Commission's report, on the development of, and access to, health care products, and to report thereon to the Health Assembly."

5. The Sixtieth World Health Assembly, in resolution WHA60.30, requested the Director-General "to provide as appropriate, upon request, in collaboration with other competent international organizations, technical and policy support to countries that intend to make use of the flexibilities contained in the agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements in order to promote access to pharmaceutical products, and to implement the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments" (with a footnote explaining the WTO General Council's meaning of "pharmaceutical product"). In addition, given the continuing discussions on sharing influenza viruses through the WHO-coordinated Global Influenza Surveillance Network and their potential use in the development of influenza-related pharmaceuticals, diagnostics and vaccines, the Health Assembly, in resolution WHA60.28, requested Director-General "to commission an expert report on the patent issues related to influenza viruses and their genes". This work is being done with WIPO.

## TECHNICAL COOPERATION

6. WHO's work with other international organizations focuses on four main areas, with varying degrees of participation: technical guidance to strengthen policy decisions; capacity building; direct country support; and monitoring and impact assessment.

### Technical guidance to inform policy decisions

7. Through consultation with various experts and relevant international organizations, the Secretariat continues to identify key issues related to implementation of the TRIPS agreement and the Doha Declaration on the TRIPS Agreement and Public Health, and to provide technical and policy guidance in the form of technical publications and briefing documents. Two recent examples follow:

- WHO and UNDP jointly issued *Remuneration guidelines for non-voluntary use of a patent on medical technologies*.<sup>1</sup> The Doha Declaration on the TRIPS Agreement and Public Health has confirmed the right of countries to grant compulsory licences and the freedom to determine

---

<sup>1</sup> Document WHO/TCM/2005.1.

the grounds upon which such licences are granted. However, the absence of an appropriate administrative/legal infrastructure and procedures to implement the compulsory licensing system may hinder its effective use. Because most developing countries do not have sufficient expertise or experience in this area, the publication is intended to provide them with a useful guide on a crucial requirement in the compulsory licensing regime.

- A collaborative project that is under way aims at designing an analytic and assessment tool, with an accompanying workbook being written to help policy-makers (1) to formulate better national policies and strategies related to trade and health and (2) to structure their requests for capacity building in issues related to trade and health. The project builds on other ongoing work in selected countries that focuses on better understanding of, and action on, trade and health issues. The project brings together senior trade and health officials from countries that have acquired these analytic skills, experts from WHO, WTO, the World Bank, UNCTAD, bilateral development agencies, academia, centres of excellence and civil society in order to review and assess completed national trade and health assessments, commissioned papers on current assessment methodologies and other tools in selected areas of trade and health besides the one being designed. The project's output, which will serve as the basis of a global initiative on trade and health, will be adapted for specific countries as necessary and to the needs of other stakeholders such as development partners, multilateral and regional development agencies, and technical bodies.

## **Capacity building**

8. WHO continues to adopt a multiagency approach to briefings and training sessions for health, trade and patent officials in order to enhance developing countries' capabilities for ensuring effective participation in trade negotiations and adequate consideration of public health interests in national policy and legislation. In 2005-2006, WHO organized and facilitated a series of regional and national training workshops for developing-country policy-makers and trade negotiators in order to increase their ability to understand and monitor the impact of trade agreements and to build negotiating skills. Three notable instances were the following:

- The WHO Intercountry Seminar on Intellectual Property Rights and Access to Medicines (Dhaka, March 2006), organized by the WHO Regional Office for South-East Asia, aimed to provide updates of developments related to intellectual property rights and trade agreements; examine how such developments would effect access to medicines (including oseltamivir and medicines for HIV/AIDS) at the national level; and recommend specific actions at the regional and national levels for deriving benefit from public health provisions in trade agreements. Participants included health, trade and patent officials from the Member States of the South-East Asia Region, in line with WHO's intersectoral approach to facilitate coherent policy-making.
- A WHO regional workshop on local production of essential medicines, including antiretroviral, (Brazzaville, February 2006) was organized by the Regional Office for Africa with the following main objectives: to review current capacities for the production of essential medicines in the African Region; to examine feasible strategies and policy options for strengthening production of essential medicines, including antiretrovirals; to prepare a strategic framework of activities for increasing capacities for local production of essential medicines, including antiretrovirals, for the period 2006–2010; and to formulate WHO's work plan for completing those activities. The resulting strategic framework covered such central

aspects as policy, including national medicines policies, intellectual property and trade-related issues.

- WHO continues to participate in WTO's regional training workshops on TRIPS issues, for instance providing resource persons at four regional workshops in 2006 on implementation of the TRIPS agreement and the Doha Declaration and giving training to health, trade and patent officials from a wide range of countries. WHO staff led a session on implementation of the TRIPS agreement and access to medicines, including medicines regulatory issues, at the WTO Seminar on Implementation of Paragraph 6 of the Doha Declaration (Geneva, September 2006).

9. In addition, WHO collaborated with WTO in preparing a module on the TRIPS agreement and access to medicines for a training course on health policy in a globalizing world (Geneva, June 2005) aimed at introducing current and emerging health policy issues to WHO staff and graduate students.

### **Direct country support**

10. WHO has provided, and will continue to provide, direct support to countries in order to facilitate review of their national policy and legal frameworks. Such support focuses on formulating domestic patent legislation that is sensitive to public health issues and incorporates the flexibilities in the TRIPS agreement. The approach was developed after close consultation with the country and regional offices. The provision of support responded to the Health Assembly's request in resolution WHA60.30 to the Director-General "to provide as appropriate, upon request, in collaboration with other competent international organizations, technical and policy support to countries that intend to make use of the flexibilities contained in the agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements in order to promote access to pharmaceutical products".

### **Monitoring and impact assessment**

11. The public health impact of intellectual property protection has yet to be fully assessed. There needs to be continual monitoring and analysis of the impact of trade agreements on public health and access to essential medicines. Further, data relevant to assessments of the implications of economic globalization and the TRIPS agreement on improving access to medicines need to be systematically collected and analysed. WHO will focus on monitoring and analysing the impact of trade agreements on public health and access to essential medicines, including emerging trends and developments. The priorities and related activities of this work are set out below:

- **determining the patent status of essential medicines.** WHO has embarked on a pilot project with several partners, including the European Patent Office, WIPO, and a selected number of national patent offices, to investigate and analyse the extent to which specified essential medicines are protected by patents in developing countries.
- **developing a public health perspective for the examination of pharmaceutical patents.** In order to respond to growing concerns about the increase in the number of patents that protect variants of existing medicines or processes while the number of patents on new molecular entities remains small and is declining, trends in pharmaceutical patenting need to be monitored and analysed. A study of the various categories of patent claims for pharmaceutical products, in order to assess the practice of some patent offices, indicated some mechanisms that might be adopted in order to incorporate public health perspectives in procedures for granting pharmaceutical patents. The study report proposed a set of general guidelines for the

assessment of some of the common modalities of pharmaceutical patent claims, and suggested elements of public health-sensitive guidelines for the evaluation and review of pharmaceuticals patents at the national level in developing countries. In carrying this activity forward, the Secretariat has collaborated with various Member States, WIPO, WTO, UNCTAD, the International Centre for Trade and Sustainable Development, and the South Centre. A working paper has been drafted and is currently undergoing further review through broad consultation.

- **impact assessment of trade agreements.** There is an increasing demand for clear analysis of bilateral and regional trade agreements from a public health perspective, including the implications for public health and access to medicines of provisions such as data exclusivity, patent-term extensions, restrictions on compulsory licensing and the link between patents and drug regulatory authorities. WHO, in partnership with the World Bank Institute and the International Centre for Trade and Sustainable Development, held an expert consultation on developing a methodology to assess the impact of TRIPS-plus provisions affecting the prices of medicines (Geneva, 31 July – 1 August 2006). The objective of the three organizations' joint project on impact assessment is to construct a common methodological framework to improve developing countries' capacity to evaluate the public health impact of TRIPS-plus standards. This framework is designed for application by governments, research institutes and civil society organizations. The availability of sound empirical evidence can, inter alia, strengthen governments' negotiating capabilities; identify where flexibilities in the negotiation of new standards for intellectual property rights may be warranted; and indicate where complementary policies may help to alleviate possible adverse public health implications of TRIPS-plus standards. By providing tools for empirical analysis and data for informed decision-making, the framework should contribute usefully to the debate on the implications of TRIPS-plus provisions.

## THE WAY FORWARD

12. The Secretariat's priorities remain as follows: to increase the capabilities of Member States at all levels, and to analyse, assess, and take action on the implications for public health of international trade, trade rules, and intellectual property rights. WHO seeks to foster outward-looking collaboration with a broad range of partners including the United Nations, regions and countries through three strategies:

- expand and disseminate knowledge on globalization, trade and health, including the development of clear policy perspectives and technical guidance on the implications of trade agreements and intellectual property rights for public health;
- develop and introduce tools and training materials, and provide technical support in order to build country capacity to analyse and act on the implications for public health of trade liberalization, trade rules, and intellectual property rights;
- promote coherence in WHO's policies on trade and health issues, and develop global partnerships in order to ensure that public health concerns are met in trade policy and trade rules.

= = =