

**TECHNICAL COOPERATION ACTIVITIES: INFORMATION FROM
OTHER INTERGOVERNMENTAL ORGANIZATIONS**

WORLD HEALTH ORGANIZATION

Addendum

The present document reproduces the information on technical and financial cooperation activities relevant to the implementation of the TRIPS Agreement, which has been received from the World Health Organization (WHO) by means of a communication dated 20 September 2004. It was circulated as an advance copy for the Council's meeting on 21 September 2004.

I. INTRODUCTION

Since 1999, resolutions of the World Health Assembly have requested WHO to undertake work that ensures that its medicines strategy addresses the important issue of impact of international trade agreements on public health and access to medicines. Taken together, these resolutions have provided WHO a mandate that may be broadly summarized to include the following: (1) monitoring and analysis of the pharmaceutical and health implications of international trade agreements; and (2) assisting member States to assess and develop pharmaceutical and health policies and regulatory measures that maximize the positive and mitigate the negative impact of those agreements.

More recent resolutions have elaborated on the key focus of these broad objectives. Resolution WHA56.27, in May 2003, expressed "concerns about the current patent protection system, especially as regards access to medicines in developing countries," and urged member States to adapt "national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)." It further established a time-limited body to collect data and proposals from the different actors involved, and produce an analysis of intellectual property rights, innovation and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries. In addition, Resolution WHA57.14 of 22 May 2004 urged member States to "encourage that bilateral trade agreements take into account the flexibilities contained in the WTO TRIPS Agreement and recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health."

II. WHO POLICY PERSPECTIVES AND APPROACHES

1. Doha Declaration on the TRIPS Agreement and Public Health

Consistent with the above mandate, WHO seeks to provide appropriate technical assistance and country support to member States to promote implementation of the TRIPS Agreement that is consistent with the protection of public health and promotion of access to medicines. This work is guided by WHO's policy perspectives, which place public health and access to medicines as priorities, consistent with the basic tenets of the **Doha Ministerial Declaration on the TRIPS Agreement and Public Health** (hereinafter "the Doha Declaration").

The Doha Declaration affirmed that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." In this regard, the Doha Declaration enshrines the principles WHO has publicly advocated and advanced over the years, namely, the re-affirmation of the right of WTO Members to make full use of the safeguard provisions of the TRIPS Agreement in order to protect public health and promote access to medicines.

A WHO publication, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (WHO/EDM/PAR/2002.3) maps out some of the options and their implications for public health.

2. Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health

Paragraph 6 of the Doha Declaration instructed the WTO Council for TRIPS to find an expeditious solution to the problem faced by WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector, of making effective use of the compulsory licensing provisions of the TRIPS Agreement. On 30 August 2003, the **Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health** (hereinafter "the August Decision") was finally adopted after lengthy negotiations. The full impact of the August Decision will depend on how effectively it can be implemented in countries.

During the negotiations for an "expeditious solution" to the Paragraph 6 problem, WHO's view was, and continues to be, that the guiding principle must be that patients in a country without or lacking domestic pharmaceutical production capacity should be no less protected by compulsory licensing provisions (or indeed other TRIPS safeguards) than those in countries capable of producing the product, nor should they face any greater procedural hurdles.¹

In line with this principle, WHO has enunciated the key features of effective implementation of the August Decision, as follows: a rapid and effective response to public health needs; equality of opportunities for countries in need, irrespective of the patent status of a drug in the importing country, and without regard to its membership in the WTO; the sustainability of quality supply at affordable prices; the facilitation of a multiplicity of potential suppliers, both from developed and developing countries, which can compete to drive prices down; and provision of a wide range of pharmaceutical products to meet an array of health problems. All these elements should ideally be incorporated within a stable international legal framework, which would ensure legal certainty and security. Within this framework, WHO is fully committed to assisting its member States to make the most effective use of the August Decision.

¹ Statement by the representative of the World Health Organization at the WTO TRIPS Council, 17 September 2002, Geneva.

3. Informed country approaches to health and trade

WHO will continue to provide independent data and technical assistance to countries to help them develop informed approaches to addressing the health implications of trade issues at the national, subregional and regional levels. Countries with the least capacity for implementing international trade agreements are most at risk in terms of access to medicines. It is therefore crucial that countries are informed of all available options in the implementation of the TRIPS Agreement, the Doha Declaration and the August Decision. In this regard, WHO's focus in technical cooperation will be:

- (1) awareness raising and capacity building of policy makers and negotiations of the health impacts of international trade agreements, so as to ensure effective participation in international and regional negotiations, and that developing country needs and interests are adequately taken into account;
- (2) review of national health, pharmaceutical and intellectual property policies, legislation and practices, with a view to promoting the development and incorporation of TRIPS safeguards within the national policy and legal framework; and
- (3) continued monitoring and analysis of the impact of trade agreements on public health and access to essential medicines, including the impact of new trends and developments at the regional and bilateral levels.

III. WHO TECHNICAL ASSISTANCE AND COOPERATION

WHO's programme on technical assistance and cooperation can be described as follows:

1. Policy and technical guidance

Critical to WHO's technical cooperation programme is policy and technical guidance. WHO provides policy guidance and technical advice through its publications and related documents, which are made available to member States. Such policy and technical documents undergo a review process, including consultations with other international organizations and independent experts. The most recent publications in the Health Economics and Drugs Series of the Department of Essential Drugs and Medicines Policy - a WHO series of analysis papers looking at the implications of the new trade and economic context on health and drug policies - include the following:

- *IPR, Innovation, Human Rights and Access to Drugs - An Annotated Bibliography*, Health Economics and Drugs, EDM Series No.14
- *IPR in China: The Doha Declaration and the Protection of Public Health - A Review of Chinese Legislation*, Health Economics and Drugs, EDM Series No.15
- *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, Health Economics and Drugs, EDM Series No.16 (forthcoming).

2. Country support and capacity building

Direct country support and regional meetings over the past years have contributed to heightened awareness of the relevant issues and more importantly, increased capacity for effective participation in international and regional negotiations. WHO has adopted a multi-agency approach in conducting briefings and training sessions for health, trade and patent officials from more than 80 countries, and will continue to do so. In response to individual country requests, WHO has also provided policy guidance and technical advice.

Through the review of national policies and legislation, WHO experts have assisted individual developing countries in their efforts to review and amend their national laws so as to incorporate public health safeguards within their national policy and legal frameworks. A network of legal experts who have specialized knowledge and understanding of the public health and pharmaceutical impact of international trade agreements is being developed as a resource for these purposes.

Recent meetings and briefings include the following:

- Informal technical briefing and discussion on the TRIPS Agreement and the Doha Declaration implementation (Kuala Lumpur, February 2004)
- Technical briefing on TRIPS, intellectual property rights issues and cost containment measures, Joint Ministry of Health/WHO/UNAIDS Mission (China, February-March 2004)
- Technical briefing to ANDEAN Ministers of Health on bilateral and regional trade agreements, intellectual property rights and implications for public health (Venezuela, March 2004). This briefing resulted in the request for individual briefings to the Ministries of Health of Colombia and Peru on the impact of intellectual property rights and patents on the health of their population, which took place in May and July 2004 respectively.
- Informal technical discussion on the Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Jakarta, May-June 2004)
- Technical briefing on globalization, trade, intellectual property rights and health to the 9th Meeting of Health Secretaries of the Countries of South-East Asia (New Delhi, July 2004)

Other planned country and regional support activities include:

- Technical assistance and country support to Asian, Caribbean and Pacific (ACP) countries in the implementation of the TRIPS safeguards, including the August Decision
- Technical briefing on TRIPS implementation and review of national legislation (Nigeria, October 2004)
- Regional workshop on TRIPS implementation - post-Doha and August Decision (Ghana, November 2004)

3. Monitoring and analysing the effects of globalization on access to medicines

The public health impact of the TRIPS requirements for intellectual property protection has yet to be fully assessed. The **WHO Network for Monitoring the Impact of Globalization and TRIPS on Access to Medicines** (TRIPS Network) was initiated with a view to systematically collecting and analysing data relevant to assessing how the processes of economic globalization and the TRIPS Agreement are related to the challenge of improving access to medicines. The TRIPS Network has been refining standard monitoring tools, methods and selected indicators to be used for monitoring and analysis of the impact of the TRIPS Agreement on access to medicines. In this regard, the TRIPS Network has been coordinating its work with that of the WHO/Health Action International Project on Medicine Prices, in order to ensure coherent and systematic data collection.

The meetings of the TRIPS Network are attended by experts from four WHO Collaborating Centres (Brazil, Spain, Thailand and the United Kingdom of Great Britain and Northern Ireland), as well as other invited experts, advisers and researchers. Recent meetings and developments include the following:

- Regional Meeting of the TRIPS Network in April 2004, organized by the Centre for Health Economics, Chulalongkorn University (Bangkok Collaborating Centre). The meeting brought together researchers from countries in the Asian Region to exchange information on drug and other related policies. Researchers from China, Indonesia and Thailand, who were involved in the field testing of the Template of indicators developed by the TRIPS Network, reviewed the Template and provided suggestions for improvements and revision. The meeting also resulted in the proposed TRIPS surveys in China and Pakistan, due to be undertaken by the end of 2004.
- The annual meeting of TRIPS Network (Bangkok, July 2004) was convened to address the following issues: revision of the Template of indicators so as to incorporate the WHO/HAI pricing surveys and the future use of Template as a monitoring tool; and to coordinate the future work programme of the TRIPS Network and its proposed outputs. The final revised Template is expected in September 2004.

4. Technical cooperation with international organizations

Cooperation with international organizations remains an essential component of WHO's programme on technical cooperation and assistance.

WTO: As an observer on an *ad hoc* basis at the WTO Council for TRIPS, WHO is now able to monitor all relevant issues under discussion at WTO that may have implications for the health sector and to provide informal support to member States at their request. In addition, WHO has now been invited to participate in the WTO Secretariat's programme of technical assistance on TRIPS implementation. WHO has participated in three of the seven regional workshops in the WTO plan for 2004; namely in Malaysia, South Africa and Cameroon. WHO will continue to participate in these activities, as an active participant to promote an adequate public health focus in trade technical assistance programmes.

UNAIDS: As a UNAIDS co-sponsor, WHO serves as the lead agency within UNAIDS with responsibility for HIV/AIDS care and treatment, including the area of international trade rules and access to HIV medicines. WHO and the UNAIDS Secretariat will continue their collaboration on all trade issues, in particular intellectual property rights issues, relating to the response to the AIDS epidemic.

Other international organizations, including **UNCTAD, UNDP, UNICEF, WIPO** and **WTO**, are systematically invited to WHO meetings on issues relating to trade, globalization and access to medicines. These include expert consultations and reviews of WHO policy and technical guidance documents relating to TRIPS implementation. One such example was the WHO Expert Consultation (New York, March 2004) convened to review the draft paper, "*Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*", hosted by the Ford Foundation. The one-day consultation included participants from international organizations (UNAIDS, UNDP, WIPO and WTO), government and nongovernmental organizations, as well as academic trade, intellectual property and public health experts.
