

**Council for Trade-related Aspects
of Intellectual Property Rights**

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TECHNICAL COOPERATION ACTIVITIES: INFORMATION FROM OTHER INTERGOVERNMENTAL ORGANIZATIONS

WORLD HEALTH ORGANIZATION

Addendum

The present document reproduces the information which has been received from the World Health Organization (WHO) by means of a communication dated 2 September 2002. It was circulated as an advance copy at the TRIPS Council meeting held on 17 September 2002.

INFORMATION ON TECHNICAL AND FINANCIAL COOPERATION PROGRAMMES CARRIED OUT BY THE WORLD HEALTH ORGANIZATION AND THAT ARE RELEVANT TO TRIPS IMPLEMENTATION AND ACCESS TO DRUGS

Under the mandate of the WHO medicines strategy (resolution WHA54.11) and the Revised Drug Strategy (resolution WHA52.19), the World Health Organization (WHO) cooperates with its member States, at their request, and with relevant organizations to: (1) assist member States to develop pharmaceutical and health policies related to international agreements; and (2) monitor, analyze, study and report on existing and future health implications of international trade agreements. Furthermore, WHO will assess the public health implications of the Doha Declaration and will advise member States, upon their request, on the implementation of the Declaration into national legislation.

I. WHO POLICY PERSPECTIVES ON ACCESS TO DRUGS

1. **Basic principles and values** - The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being, as defined in the Constitution of the World Health Organization. Progressive realization of that right involves access to health facilities, prevention, care, treatment and support, including access to medicines. Access to essential drugs depends on: (1) rational selection and use of medicines; (2) sustainable adequate financing; (3) affordable prices; and (4) reliable health and supply systems.

2. **The Doha Declaration on TRIPS and Public Health**, adopted by the WTO Ministerial Conference, in November 2001, which affirms that the TRIPS Agreement should be interpreted and implemented so as to protect public health and promote access to medicines for all marks a watershed in international trade, demonstrating that a rules-based trading system is compatible with public health interests. The Declaration re-affirms 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. WHO expects that, as instructed by the Doha Ministerial Declaration, the WTO Council for TRIPS will find an expeditious solution for the use of compulsory licensing by WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector. WHO re-affirms its

commitment to support WTO Members and the TRIPS Council in whatever way they wish to find an expeditious solution to this problem. 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.

3. **Patent protection has been an effective incentive for research and development for new drugs** - Protection of intellectual property rights, including patent rights, has supported research and development for new pharmaceuticals. But questions remain as to whether the patent system is sufficient to ensure investment in medicines needed largely by the poor. Strong public involvement and investment is needed to ensure development of needed new drugs for priority health problems of the poor.

4. **Affordability of essential drugs is a public health priority** - Low-income populations in developing countries cannot afford to pay the same price for newer essential drugs as do the wealthy. Differential pricing is now recognised as a means through which prices can be adapted to the purchasing power of governments and households. An April 2001 WHO-WTO workshop observed that differential pricing could be achieved through a combination of factors, which may include market mechanisms, negotiation, bulk purchasing, voluntary licensing, compulsory licensing, and establishment of a flexible global differential pricing system. In addition, WHO supports other measures to improve access to essential drugs, including mechanisms to promote competition, such as: price information; generic policies; reduced duties, taxes, and mark ups; and the application of safeguards contained within the WTO/TRIPS Agreement.

5. **Essential drugs are not simply another commodity - TRIPS safeguards are crucial as affirmed by the Doha Declaration** - Patents for pharmaceuticals should be managed in an impartial way, protecting the interest of the patent holder and safeguarding the basic public health principles. Hence, WHO supports WTO/TRIPS-related safeguards, to be applied where justified in accordance with the provisions of TRIPS, to enhance affordability and availability of existing medicines, while not discouraging the development of needed new medicines. These safeguards include setting standards of patentability which reflect public health concerns, legislative provision for compulsory licensing, parallel importation, exceptions to exclusive rights and other measures which promote generic competition, as well as extension of the transitional period. WHO recommends that countries assess the public health impacts of the TRIPS Agreement before introducing TRIPS-plus requirements or extending TRIPS requirements to non-WTO Members.

6. **Informed country approaches to health and trade** - Countries with the least capacity for implementing international trade agreements are most at risk in terms of access to medicines. 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 national, subregional and regional levels. WHO advises countries to monitor - carefully - the implementation of the TRIPS Agreement. 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 developing countries.

II. WHO PROGRAMME OF WORK ON PHARMACEUTICALS AND TRADE

1. Policy guidance and information support

Critical among WHO policy guidance is the WHO medicines strategy (World Health Assembly resolutions WHA54.11 and WHA52.19). The Director-General's speeches, WHO publications and related documents provide other WHO policy guidance and information support for Member States. The following examples, available upon request through the WHO Department of Essential Drugs and Medicines Policy documentation centre, include:

- *WTO Agreements & Public Health*, A joint study by the WHO and the WTO Secretariat, 2002
- *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, (Published in collaboration with the South Centre), 2002
- *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, WHO/EDM/PAR/2002.3
- *Trends in Drug Patenting: Case Studies*, a study conducted by the University of Buenos Aires for the WHO Department of Essential Drugs and Medicines Policy.
- *Network for Monitoring the Impact of Globalization and TRIPS on Access to Medicines*, Report of a meeting, February 2001, Bangkok, Thailand, WHO/EDM/PAR/2002.1
- *Globalization, TRIPS and Access to Pharmaceuticals. WHO Policy Perspectives on Medicines*. No. 3, March 2001.
- *TRIPS, CBD and Traditional Medicines: Concepts and Questions. Report of an ASEAN Workshop in the TRIPS Agreement and Traditional Medicine. Jakarta, 13-15 February 2001.*
- *Globalization, Patents and Drugs. An Annotated Bibliography, Second Edition.* EDM/PAR/2001.1.
- *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, South Centre, 2000 (cosponsored by The Rockefeller Foundation, the South Centre and WHO/EDM).
- *The TRIPS Agreement and Pharmaceuticals*. Report of an ASEAN Workshop on the TRIPS Agreement and its impact on Pharmaceuticals. Jakarta, 2-4 May 2000.
- *Mission conjointe MSF/OMS/ONUSIDA. Revue de la Politique pharmaceutique au Cameroun. Les Brevets de Médicaments dans les Pays d'Afrique francophone.* February 2000, World Health Organization.
- *Essential drugs in the new international economic environment*, Bulletin of the World Health Organization, Volume 77, Number 3, 1999.
- *Globalization and Access to Drugs - Perspectives on the WTO/TRIPS Agreement*, WHO/DAP/98.9, Revised, January 1999.

2. Direct country support and regional awareness meetings

WHO provides direct country support on request, such as briefings on the TRIPS safeguards and advice on the revision of national pharmaceutical legislation. Recent examples include support to Brazil, Brunei Darussalam, the People's Republic of China, Colombia, the Islamic Republic of Iran, South Africa and Thailand. WHO also sponsors or participates in interregional, regional and national awareness meetings (e.g. Association of South-East Asian Nations (ASEAN), Southern African Development Community (SADC) countries, the WHO South-East Asia Region countries and the WHO Region for Africa). Each country's strategy with regard to the production, distribution and use

of drugs will need to be incorporated into its National Pharmaceutical Policy, a component of the National Health Policy.

Examples of planned and completed country and regional support include:

- Meeting for OAPI countries on the TRIPS Agreement in the context of the Doha Declaration and the Revised Bangui Agreement, (Yaoundé, May 2002)
- Intercountry meeting on the TRIPS Agreement and its impact on access and prices of pharmaceuticals in Eastern Europe (Warsaw, September 2001).
- Workshop on TRIPS and the implementation of its safeguards in relation to pharmaceuticals in the WHO African Region (Harare, August 2001).
- Briefing on WHO policy perspectives on globalization and access to medicines for the drug regulatory authorities of Ibero-America (Costa Rica, September 2000).
- Briefing on TRIPS to Ministers of Health of the Member States of the Southern African Development Community (South Africa, June 2000).
- Meeting on the impact of globalization and trade agreements on access to pharmaceuticals, organized by the Directorate General of Drug and Food Control, Ministry of Health, Indonesia, with EDM support (Jakarta, May 2000).
- Joint WHO/UNAIDS mission to Thailand to provide technical backup to the continuing debate in Thailand on HIV/AIDS-related drugs that are under patent protection (February 2000).
- Joint WHO/UNAIDS-MSF assessment of the patent situation of AIDS-related drugs in francophone African countries (February 2000).
- At the request of the Chinese Government, WHO mission to provide briefing to Ministry of Health and Ministry of Trade officials on TRIPS (January 2000).
- Continuation of ongoing WHO support to national comprehensive drug programmes (e.g. Bolivia, Brazil, South Africa).

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

The public health impact of TRIPS requirements has yet to be fully assessed. Therefore, the WHO medicines strategy (resolution WHA54.11) provides WHO with a mandate to study and report on existing and future health implications of international trade agreements.

3.1 Network for monitoring the implications of globalization and TRIPS on access to medicines: To define standard monitoring tools, methods and selected indicators to be used periodically over the next five years.

Meeting in Brazil (February 2002)

Experts from four WHO collaborating centres (Brazil, Spain, Thailand and the United Kingdom of Great Britain and Northern Ireland) and other members of the Expert Group met in Brazil in February, 2002.

- Review and revision of selected model indicators.

- The WHO collaborating centres' plans of action and the selected model indicators used in monitoring the impact of the TRIPS Agreement on access to essential drugs are guided by four questions:
 1. What is the impact, if any, on the prices of essential drugs under the new IPR regime?
 2. Has there been any impact on the speed with which generic drugs are being introduced?
 3. Are more new drugs for neglected diseases being developed?
 4. Are transfer of technology and direct foreign investment in developing countries increasing or decreasing?

Meeting in Thailand (February 2001)

- Dr Supachai Panitchpakdi, then Director-General Designate of the World Trade Organization, made the opening remarks.
- Harmonization of selected model indicators to be adapted according to the particular characteristics of each region.

3.2 Monitoring and analysing through four WHO collaborating centres and other partners:

- **WHO Collaborating Centre for Health Economics, Thailand:** Transfer of technology and increase of research and development. A Study of the Implications of the WTO TRIPS Agreement for the Pharmaceutical Industry in Thailand was published in October 1999.
- **WHO Collaborating Centre for Drug Policies, Brazil:** Evolution of drug prices, including AIDS-related drugs. The publication The WTO TRIPS Agreement and Patent Protection in Brazil: recent changes and implications for local production and access to medicines was published in April 2000.
- **WHO Collaborating Centre for Health Economics and Drug Policies, LSE, UK:** Evolution of the generic drug markets.
- **WHO Collaborating Centre for Research and Training in Pharmacoepidemiology, Spain:** Developing a list of indicator drugs for monitoring the impact of TRIPS on access to essential drugs.
- **WHO/Public Interest Nongovernmental Organizations Roundtable process:** Developing a methodology for comparative monitoring of essential drug prices.

3.3 Additional study to support the activities of the three WHO Collaborating Centres:

Globalization, Patents and Drugs. An Annotated Bibliography, Third Edition. (Forthcoming)

Study on the implications of "TRIPS-plus" measures on access to medicines. (Forthcoming)

A framework for setting compensation guidelines for compulsory licensing. (Forthcoming)

4. Cooperation with international organizations

- In June 2000, WHO was awarded observer status on an ad hoc basis by 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.
 - WHO and WTO on occasion organize joint briefings and workshops. Examples include a joint briefing on trade and health during the Fifty-third World Health Assembly in May 2000, a joint workshop on Differential Pricing and Financing of Essential Drugs in April 2001 in Høsbjør, Norway and a joint study on the WTO Agreements & Public Health. WTO Director-General Dr Supachai Panitchpakdi is a member of the WHO Commission on Macroeconomics and Health. In addition, he opened the first meeting of the WHO monitoring network on TRIPS and globalization.
 - International organizations, including UNAIDS, UNCTAD, WIPO and WTO, are systematically invited to WHO meetings on issues relating to trade, globalization and access to medicines.
 - Matters related to trade agreements and access to essential drugs are addressed in WHO collaboration with public-interest and industry Nongovernmental Organizations, particularly through the Director-General's roundtable process.
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