

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

WORLD HEALTH ORGANIZATION

Addendum

The following communication, dated 9 March 2004, has been received from the office of the Director for Government, Civil Society and Private Sector Relations of the WHO.

**TECHNICAL AND FINANCIAL COOPERATION PROGRAMMES CARRIED OUT BY
THE WORLD HEALTH ORGANIZATION (WHO) AND THAT ARE RELEVANT
TO TRIPS IMPLEMENTATION AND ACCESS TO DRUGS**

I. INTRODUCTION

Under the mandate of the WHO medicines strategy (resolution WHA54.11), the Revised Drug Strategy (resolution WHA52.19) and resolution WHA56.27 on Intellectual property rights, innovation and public health, the World Health Organization 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; (2) monitor, analyse, study and report on existing and future health implications of international trade agreements; and (3) 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.

II. WHO POLICY PERSPECTIVES ON ACCESS TO DRUGS

(See above-noted resolutions and *Globalization, TRIPS and access to pharmaceuticals*, WHO Policy Perspectives on Medicines, No. 3, March 2001)

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 the TRIPS Agreement and Public Health** (Doha Declaration), 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. 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.

2.1. Paragraph 6 of the Doha Declaration instructed the WTO Council for TRIPS to find an expeditious solution to the problem, faced by Members with insufficient or no manufacturing capacity in the pharmaceutical sector, of making effective use of the compulsory licensing provisions of the TRIPS Agreement. The Council for TRIPS failed to reach solution within the required time. A Decision was finally agreed by consensus on 30 August 2003, based on the 16 December 2002 draft, with an explanatory introduction by the Chair of the Council for TRIPS. This Decision covers all medicines and the WHO will work with the countries which could make use of the new arrangements to assist them to achieve the full public health benefit from the lower prices. The full impact of the Decision will depend on how effectively it can be implemented in countries.

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 reinvigorate efforts to develop innovations that add real therapeutic advantage in treating the world's major killer diseases, especially in developing countries. Resolution WHA56.27 expresses "concerns about the current patent protection system, especially as regards access to medicines in developing countries".

4. **Affordability of essential drugs is a public health priority** - WHO considers it a priority to assess the impact of trade agreements, the Doha Declaration and the recent Decision on paragraph 6 on the affordability of essential drugs, particularly those still on patent. Low-income populations, especially in developing countries, cannot afford to pay the same price for newer essential drugs as do the wealthy. Equity pricing is now recognized as a means through which prices can be adapted to the purchasing power of governments and households. Equity pricing can be achieved through a combination of factors, which may include market mechanisms, negotiation, bulk purchasing, voluntary licensing, compulsory licensing, and implementation of the paragraph 6 Decision. 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 re-affirmed by the Doha Declaration. Patents for pharmaceuticals should be managed in an impartial way, protecting the interests 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. These safeguards include setting standards of patentability which reflect public health concerns, legislative provision for compulsory licensing, parallel importation, exceptions to exclusive rights, implementation of the Decision on paragraph 6 and other measures which promote generic competition, as well as the full use of the possibility to extend the transitional periods in accordance with Article 66.1 of the TRIPS Agreement and Article 7 of the Doha Declaration. WHO recommends that countries assess the public health impacts of the TRIPS Agreement before introducing TRIPS-plus requirements in national legislation or as a part of subregional or bilateral trade agreements or extending TRIPS requirements to non-WTO Members. They should also ensure that the data

protection requirements of Article 39.3 of the TRIPS Agreement do not become a barrier to the registration and introduction of generic drugs and the use of compulsory licensing.

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, sub-regional and regional levels. WHO advises countries to monitor - carefully - the implementation of the TRIPS Agreement, the Doha Declaration and the paragraph 6 Decision. 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.

III. WHO PROGRAMME OF WORK ON PHARMACEUTICALS AND TRADE

1. Policy guidance and information support

Critical among WHO policy guidance is the WHO medicines strategy (Resolutions WHA54.11, WHA52.19 and WHA 56.27). 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 through the WHO Department of Essential Drugs and Medicines Policy (EDM) documentation centre, include:

- *Cost-containment Mechanisms for Essential Medicines, including antiretrovirals, in China*, WHO/EDM/PAR/2003.6.
- *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.
- *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.
- *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, 2001.
- *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.
- *Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Implementation of TRIPS Safeguards in Relation to Pharmaceuticals in the WHO African Region*. Report of Workshop, Harare, 21-23 August 2001. AFR/EDP/02.1.
- 3 Statements by the Representative of WHO at the WTO Council for TRIPS (September 2001, March 2002 and September 2002). Available from URL: http://www.who.int/medicines/organization/ood/trips_med.shtml

2. Direct country support and regional awareness meetings

WHO provides direct country support on request, such as training or briefings on the TRIPS safeguards and advice on the revision of national pharmaceutical legislation. Recent examples include support to Brazil, Cambodia, China, Colombia, Indonesia 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 (SEARO) countries, the WHO African Region and Eastern European countries). Each country's strategy in regard to globalization in the field of 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:

- International Seminar on the impact of globalization on public health (Madrid, planned for 2004).
- Support to Asian, Caribbean and Pacific countries in the implementation of the TRIPS safeguards, including the recent Decision on paragraph 6 of the Doha Declaration (ongoing).
- Regional meeting on the follow-up to the WTO Declaration on the TRIPS Agreement and Public Health (Jakarta, May 2003).
- Briefing to Chinese Ministries of Health and Trade on mechanisms and safeguards for negotiations with the pharmaceutical industry for the reduction of prices of medicines (December 2002) and relevant national authorities related to the revision of pharmaceutical legislation in the light of the TRIPS Agreement (October 2002).
- 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, Indonesia, 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 previously mentioned World Health Assembly resolutions provide WHO with a mandate to study and report on existing and future health implications of international trade agreements.

3.1 Network for monitoring the impact 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. The annual meetings of the Network are attended by experts from four WHO Collaborating Centres (Brazil, Spain, Thailand and the United Kingdom of Great Britain and Northern Ireland) and other advisers.

Meeting in Beijing (February 2003)

The meeting reviewed data collected from 12 selected countries on the use of TRIPS safeguards in national legislation to protect public health and ensure access to drugs. The report of the meeting is in preparation.

Meeting in Brazil (February 2002)

The meeting reviewed and revised selected model indicators to offer important information regarding the following 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)

The meeting harmonized selected model indicators, to be adapted according to the particular characteristics of each region, in order to monitor and analyse the impact of trade agreements on access to drugs. Dr Supachai Panitchpakdi, then Director-General Designate of the World Trade Organization, made the opening remarks at the meeting.

3.2 Monitoring and analysing through four WHO Collaborating Centres (WHO CC) and other partners:

- **WHO CC for Health Economics, Thailand:** Transfer of technology and increase of research and development. *Study of the Implications of the WTO TRIPS Agreement for the Pharmaceutical Industry in Thailand* was published in October 1999.
- **WHO CC for Drug Policies, Brazil:** Evolution of drug prices, including AIDS-related drugs. *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 CC for Health Economics and Drug Policies, UK:** Evolution of the generic drug markets.
- **WHO CC 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 NGO Roundtable process:** Developing a methodology for comparative monitoring of essential drug prices.

3.3 Additional studies to support the activities of the four WHO CCs:

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)

Review of Public Health aspects of Intellectual Property Legislation of the People's Republic of China in the Light of the Doha Declaration on the TRIPS Agreement and Public Health. (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 occasions 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.
 - As a UNAIDS Cosponsor, 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. The UNAIDS Secretariat has observer status at the WTO ministerial conferences and has been granted ad hoc observer status by the WTO Council for TRIPS. WHO and the UNAIDS Secretariat collaborate closely on all trade issues relating to response to the AIDS epidemic.
 - Close collaboration with the South Centre, particularly in the review, publication, translation and dissemination of specific documents in the area of globalization and access to drugs, in coordination with the Rockefeller Foundation.
 - International organizations, including UNICEF, UNCTAD, UNDP, 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 NGOs.
 - Participation in WTO Ministerial Conferences in Doha, November 2001, and Cancún, September 2003.
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