Pharmaceuticals in the Trade Related Aspects of the Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO)

A BRIEFING ON TRIPS

WORLD HEALTH ORGANIZATION
Regional Office for the Western Pacific
Manila
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Preface

A longstanding aim of the World Health Organization is to support Member States to ensure the accessibility of quality essential drugs and their rational use. Access to essential drugs is a key priority for WHO and, in collaboration with Member States and relevant partners, the Organization will keep working to improve access to essential drugs. Current trends towards trade globalization will have a potential impact on access to essential drugs in many countries, and it is WHO's view that particular attention needs to be paid to ensuring that access to these drugs is as good as possible.

In line with its Revised Drug Strategy, WHO, in close cooperation with Member States and with relevant partner organizations, will analyse and monitor the public health implications of international agreements, including the Trade Related Aspects of the Intellectual Property Rights Agreement (TRIPS). This includes informing Member States on provisions relating to the public health safeguards included as part of the TRIPS Agreement.

The publication of this booklet is to provide brief and practical information about the TRIPS Agreement, especially those related to pharmaceuticals, to relevant parties who are involved in policy-making and in the

provision and implementation of health and pharmaceutical services. This booklet does not cover all provisions in the agreement in great detail, but only those most relevant to pharmaceuticals.

I hope that this publication will help readers to understand various issues related to the TRIPS agreement, especially regarding those measures designed to safeguard public health.

Dr Shigeru Omi
Regional Director

Introduction

Equitable and appropriate health care is universally considered as a basic human right, and pharmaceuticals are an integral part of the modern health care system. Essential medicines save human lives and reduce suffering. Access to essential drugs is, therefore, a critical part of this fundamental human right. Essential drugs are not ordinary commodities. Every effort should be aimed at improving access to essential medicines for those who need them. With the current globalization of trade, access to drugs becomes a critical issue, which needs particular attention.

Member States of the World Trade Organization (WTO) have to abide by several multilateral agreements, of which Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement probably has the greatest effect on access to medicines. TRIPS Agreement deals with patent law and sets some minimum standards, such as 20-year patent protection for pharmaceuticals. In certain instances, such as a public health emergency, TRIPS also allows for the production of medicines by companies other than the patent holder (*compulsory licensing*). TRIPS Agreement allows for the importation of medicines from countries where the product was legitimately put on the market (*parallel imports*).

Policy makers, healthcare managers and other relevant stakeholders in the delivery of healthcare services and goods need knowledge about WTO and the TRIPS Agreement and its possible implications on health and access to medicines. Necessary measures need to be undertaken at the country level to minimize the negative impacts and to best utilize this Agreement. One of the important measures is to monitor the impact of this Agreement on health and access to essential medicines.

The aim of this booklet is to inform people in the health sector about WTO, the TRIPS Agreement and the Agreement's possible impacts on access to medicines. Most of the information in this booklet is abstracted from the WHO/EDM publication (WHO/DAP/98.9). For more detailed information, readers are recommended to refer to the document:

> **Velasquez, G. Boulet, P.** ***Globalization and access to drugs, perspectives on the WTO/ TRIPS Agreement,*** **WHO/DAP/98.9 Revised, 1999**.

1. What is WTO and what is the TRIPS Agreement?

The World Trade Organization (WTO) is the institutional successor of the multilateral trade system under the General Agreement on Tariffs and Trade (GATT), which was initiated after the second World War. The objective of GATT was to promote and regulate the liberalization of international trade. The result of the last round of talks under GATT (Uruguay Round, 1986 - 1993) is the WTO Convention, under which comes a variety of multilateral and plurilateral sectoral conventions. Member States of the WTO must observe all the multilateral conventions *(Multilateral Agreements on Trade in Goods, General Agreements on Trade and Services,* and *Agreements on Trade Related Aspects of Intellectual Property Rights)*, whereas adhesion to the plurilateral conventions is optional (aeronautics, government procurement, dairy products and beef).

Trade in services is also the focus of the multilateral trade negotiations, and the General Agreement on Trade and Services (GATS) is the result of these negotiations. GATS covers different service sectors such as transportation, telecommunications, insurance, travel and tourism, and legal, education and health care services.

The WTO started functioning on 1 January 1995 and has 136 Member States. The establishment of the WTO not only institutionalized the GATT but also embraced many other wider trade-related issues. The WTO has international legal status and a large number of matters relating to international trade will fall within its jurisdiction.

Among these multilateral agreements, the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) is the most relevant to pharmaceuticals. The

objectives of the TRIPS Agreement are essentially aimed at strengthening certain aspects of the protection of intellectual property at the global level.

The TRIPS Agreement establishes minimum standards in the field of intellectual property. All Member States have to conform to these standards by modifying their national regulations to accord with the rules of the Agreement. Intellectual property rights are considered extremely important by the pharmaceutical industry. The main issue with respect to pharmaceuticals is *the obligation to grant patent protection to pharmaceutical products and process inventions.*

2. What are the implications of the TRIPS Agreement on patents for pharmaceutical products?

As soon as the Agreement comes into force in a Member State, *unauthorized copies of patented drugs can only be produced and commercialized with the authorization of the patent holders*. However, among other measures, a system of compulsory licensing and parallel imports may be applied in order to protect public health through access to affordable essential drugs.

The TRIPS Agreement requires WTO Member States to grant patent protection to all inventions in any branch of technology (**article 27.1**). This provision was expressly aimed at pharmaceutical products, for which certain developing countries, as well as developed countries, had refused to grant patents. Because of the high prices of patented drugs and the large amount of expenditure required for research and development (R&D) in the pharmaceutical field, some countries had chosen to imitate products patented in industrialized countries in order to

meet their national requirements for drugs at a lower cost and to develop their local industry. Other countries with no pharmaceutical industry could also buy these copies of patented drugs at competitive prices.

If national regulations on patents do not provide for the protection of pharmaceuticals , or if they are not respected, the Member State in question may, pursuant to the disputes settlement process, incur commercial sanctions imposed by the WTO Dispute Settlement Body.

3. How long are patented drugs protected by the TRIPS Agreement?

The duration of patent protection will not cease until a period of at least 20 years from the date on which the patent application was filed has passed. This means that, under the TRIPS Agreement, Member States have to grant patents, for a minimum of 20 years, to any inventions of a pharmaceutical product or process that fulfils the established criteria of novelty, inventiveness and usefulness.

This will result in an increase in the duration of the patent owner's monopoly in many Member States. In the pharmaceutical field, the logical consequence of this provision is that *drugs will be subject to monopoly rights for a longer period and manufacturers of generic products will have to wait longer before they can produce the drug in question and sell it at a more affordable price.*

4. Does the TRIPS Agreement strengthen the monopoly patenting of *processes*?

The TRIPS Agreement protects not only the process through which the product is produced but also the product itself. Therefore it is not possible to manufacture and sell a patented drug made through a new process. Some countries (India, China, Brazil, Malaysia, Thailand, Mexico, Argentina, Egypt and Canada), prior to the TRIPS Agreement, had either excluded pharmaceuticals from their patent system or provided only process patent. In the absence of product patents, the local companies could develop the drugs through different processes than those patented and could make locally developed cheaper versions of the product.

5. What are the impacts of the TRIPS Agreement on prices and availability of pharmaceutical products?

- Twenty years of monopoly on a pharmaceutical product will enable the patent holder to keep the price of the patented drugs high.

- Copies of the drugs under patent either produced locally or imported should be banned from the market.

- The generic equivalents would come onto the market only after the expiry of the patent of a patented drug. During this period of patent protection, there will be no cheaper alternatives.

6. What can Member States do to counteract the impact of TRIPS on drug prices?

Several measures may be used to secure public interest in relation to WTO/TRIPS Agreement. These include:

A. parallel imports,

B. compulsory licensing, and

C. early submission of application for registration of patented drugs by generic manufacturers.

A. Parallel imports

If a manufacturer has patented a product in several countries, he may - for a number of reasons - decide to sell it at a different price in different countries. If the price in country A is substantially lower than that in country B, an importer in country B may buy the product at the cheaper price in country A, and sell it in country B at a price which is lower than the price set by the patent holder. This is called "parallel importation". The TRIPS Agreement allows for such importation of products patented in countries other than the country of origin or the country to which the drug is imported. This mechanism may be used if the price of the product is cheaper in other countries than on the local market.

The TRIPS Agreement leaves Member States free to decide whether or not to apply parallel imports. If applied, the relevant legislation will have to provide for this possibility.

B. Compulsory licensing

Compulsory licensing means that the law allows the granting of a license without permission from the patent holder. In practical terms, this means that a Member State may allow the national authority to grant a third party the permission to manufacture or commercialize a drug which is still under patent. However, the TRIPS Agreement imposes specific conditions on Member States to admit compulsory licenses:

- authorization of such use will be considered on its individual merits;
- authorization will be granted in some cases only if the proposed user has made efforts to obtain the license on reasonable commercial terms;
- the scope and duration of the authorization must be limited;
- authorization is non-exclusive;
- the predominant objective of the authorization must be to supply the domestic market;
- the authorization may be suspended if the circumstances that led to it cease to exist, while protecting the interests of the authorized party; and

- the patent holder will be given adequate remuneration, taking into account the economic value of the authorization.

These are the minimum conditions stipulated by the Agreement, and Member States must fulfil them when they grant compulsory licenses. The conditions must, therefore, be included in the new national patent legislation.

C. Early submission of application for registration of patented drugs by generic manufacturers (Bolar provision)

A Bolar provision allows interested (generic) manufacturers to start producing test-batches of a product before patent expires, in order to collect necessary data for submission to regulatory authorities.

Manufacturers of generic drugs can submit an application for the registration of a drug which is still under patent. When the patent expires, the manufacturer may immediately start marketing the product if already approved for registration. This will reduce the delay for generic products to enter the market after the patent has expired, and thereby enhance competition.

7. The balance between the protection of intellectual property rights and public policy objectives

It is generally accepted that pharmaceutical products cannot be regarded as ordinary commodities. In the first

place, this is because consumers are not in a position to judge the usefulness, prices and quality of drugs. Secondly, this is because drugs play a significant social role in that they are an integral part of the realization of a fundamental human right – the right to health. That is why they are classified as essential goods, to emphasize that they have to be accessible.

The concept of accessibility is very important. It means that the policies pursued must aim to make drugs available for all who need them, and at affordable prices.

The general part in the TRIPS Agreement (preamble and general provisions) stresses the need to promote adequate and effective protection of intellectual property rights, but to do so as part of a series of broader economic objectives. The protection of intellectual property rights is not an absolute and exclusive obligation. Several general provisions were included in the Agreement to provide a balance between the rights of patent holders and their obligations vis-à-vis society.

Member States may, therefore, base the provisions of their national regulations on these principles. They can also bring their regulations into line with the obligations of the Agreement in such a way that their national objectives for the protection of intellectual property also accord with those established for other sectors.

In particular, the provisions in Article 7 and Article 8 of the Agreement may be considered by Member States as a framework to define limitations to exclusive rights, as well as the enactment of legislative provisions concerning compulsory licensing, for instance, in order to keep prices at a reasonable level or to ensure access to particular medicines by the population.

Article 7 :

> *"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in manner conducive to social and economic welfare, and to a balance of rights and obligation*".

Article 8:

1. *"Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement"*

2. *"Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by rights holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology".*

"Appropriate measures" could be, for instance, compulsory licensing and parallel imports.

8. When will the TRIPS Agreement be applied?

With regard to the dates of application of the TRIPS Agreement, a distinction is made between the least developed countries and developing countries, and also between countries with or without a system of patent protection for pharmaceuticals at the time of the expiration of the general transitional period (31 December 1999).

8.1 Industrialized countries

The TRIPS Agreement has been applicable since 1996.

8.2 Transitional period for developing countries.

By the year 2000, they should have introduced into their national regulations on intellectual property the various rules of the Agreement they accepted by joining to the WTO.

However, the Agreement grants an extra five year transitional period for those countries that did not issue patents before 31 December 1999. In this case, the Agreement grants them a total transitional period of ten years (i.e. until 2005)

8.3 Transitional period for least-developed countries

Least-developed countries are given 11 years, (i.e. until 2006), with a possible extension, to harmonize their regulations with the new international obligations.

Countries should have adapted/modified their national legislation on Intellectual Property Rights (such as patents) before the end of the applicable transition period.

9. What is WHO's view and position on WTO/ TRIPS Agreement?

On international trade agreements and pharmaceuticals, WHO has five key public health messages.

First, patent protection is a necessary and effective incentive for research and development for needed new drugs. Essential drugs are not just another ordinary commodity. Patents must therefore be managed in an impartial way to benefit both the patent holders and the public. Protectionism has never benefited public health. *WHO supports governments to enact national legislation which can draw advantage from more open trade and a better regulated international system. WHO also supports governments in incorporating the safeguards that have been built into the WTO/TRIPS Agreement to protect the rights of the public.*

Second, priority-setting for research and development in the pharmaceutical market is imperfect. There are also striking market failures when there is a desperate demand for products that are available – but not within the reach of those in need. *WHO has initiated with other partners innovative mechanisms to stimulate research and development in areas of high public health need such as malaria and tuberculosis. WHO is actively encouraging public sector financing for critical public health problems and neglected tropical diseases.*

Third, *WHO strongly supports the development of mechanisms for preferential low prices for essential drugs in lower-income countries*. Lower-income countries simply cannot be expected to pay the same price for essential drugs as the wealthier countries. For governments, industry, and other stakeholders, there is a range of measures which might be used to achieve preferential pricing. But where there is an abuse of patent rights, where patented essential drugs are not on the market, or where a national emergency exists, recourse to compulsory licensing is a legitimate measure consistent with the TRIPS Agreement.

Fourth, *WHO supports the implementation of the TRIPS Agreement to ensure prompt availability of generic drugs upon patent expiration*. WHO has long promoted the use of generic drugs of assured quality. Experience from countries with "generic-friendly" policies clearly demonstrates that the market competition created by these policies increases affordability of medicines, stimulates true innovation within the research-based industry, and encourages increased production efficiency by the generic industry.

Fifth, trade agreements should not create barriers to trade. An important WTO principle is that technical regulations, standards and assessment procedures should be based on international standards, guides and recommendations. In the area of pharmaceuticals, WHO norms, standards and guidelines represent such international consensus. WHO will actively promote these guidelines.

10. What are the recommendations for Member States?

- Public health concerns should be considered when implementing the TRIPS Agreement. Member States should provide limited exceptions to the patent holder's exclusive rights in their domestic laws. The issue of compulsory licenses and parallel imports should be allowed.

- Member countries should make the fullest use of the periods of transition for incorporating the necessary provisions into their domestic laws.

- Member countries should undertake necessary measures to monitor the impact of the Agreement on access to essential drugs.

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