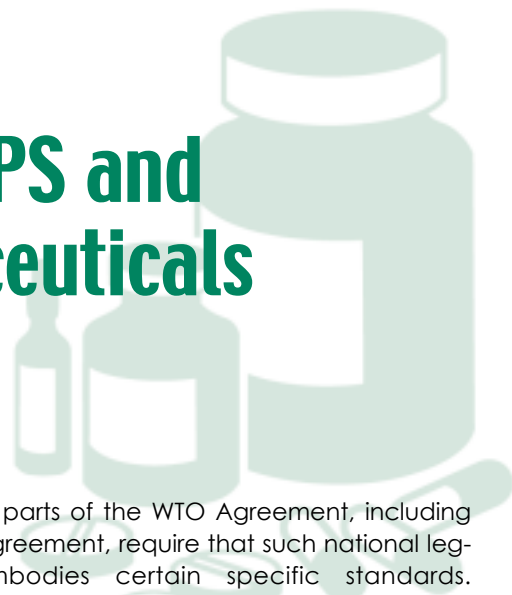




Globalization, TRIPS and access to pharmaceuticals



A new era in global trade

Creation of the World Trade Organization

The World Trade Organization (WTO) is the international organization dealing with rules of trade between nations. Although the WTO became officially operational only in January 1995, it is the successor to the GATT multilateral trading system founded in 1947. In becoming Members of the WTO, countries undertake to abide by its rules. As of 30 November 2000, the WTO counted 140 Members.

The WTO is charged with setting the legal ground rules for international trade. Its objectives are to promote: (1) non-discrimination (2) progressive liberalization of barriers to trade (3) predictable policies and transparency (4) competition and (5) special provisions for developing countries.

WTO Agreements

In joining the WTO, Members adhere to 18 specific agreements annexed to the Agreement establishing the WTO. They cannot choose to be party to some agreements but not others (with the exception of a few "plurilateral" agreements that are not obligatory). Of greatest relevance to the health sector are: the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS); the Agreement on Technical Barriers to Trade (TBT); the General Agreement on Tariffs and Trade (GATT); and the General Agreement on Trade in Services (GATS).

Of these agreements, TRIPS is expected to have the greatest impact on the pharmaceutical sector. The TBT Agreement should be of particular concern to producing countries, since its implementation may affect export markets.

Implementation and dispute settlement

The WTO Agreement is a treaty that creates international obligations among its Members. These obligations include refraining from taking actions that are inconsistent with the agreement, and implementing certain provisions via national legislation.

The various parts of the WTO Agreement, including the TRIPS Agreement, require that such national legislation embodies certain specific standards. However, in many areas, the WTO Agreement affords considerable discretion in how its obligations are implemented. This discretion, combined with the potential impact of national legislation on health, make it imperative that health officials work closely with other parts of government, such as the trade department, and use top-level legal, trade and pharmaceutical expertise when legislation is being drafted. (See Box 1.)

Disputes can arise when countries differ in their interpretation of the WTO Agreement. The WTO provides a dispute settlement process that may proceed from a consultation phase, to the establishment of and decision by a dispute settlement panel, and appeal to the Appellate Body. Trade sanctions may only be

Box 1 Points for policy-makers

- ❑ TRIPS establishes intellectual property standards for WTO Members, historically based on the standards of developed countries.
- ❑ TRIPS requires patent protection for all products and processes, with a minimum duration of 20 years from the original date of filing, without any special consideration for pharmaceuticals.
- ❑ The TRIPS Agreement permits Members some discretion in enacting and amending their laws and regulations, which can help promote public health goals.
- ❑ When establishing standards of patentability for pharmaceuticals countries should consider the implications for health of those standards. Standards which are too broad may lead to inappropriate extension of patent life beyond the period required by TRIPS.
- ❑ WTO free trade provisions can stimulate generic competition and reduce the prices for off-patent drugs, but TRIPS may also significantly delay the introduction of new generic drugs, depending on the way in which national legislation is designed and implemented.
- ❑ Developing countries should be cautious about enacting legislation more stringent than the TRIPS requirements ("TRIPS-plus").



imposed if the dispute settlement process has run its course and the losing country has failed to comply with the decision made. Thus, WTO Members may not **unilaterally** impose trade sanctions based on **alleged** failures to comply with TRIPS.

Key requirements of the TRIPS Agreement

The TRIPS Agreement introduced global minimum standards for protecting and enforcing nearly all forms of intellectual property rights, including those for pharmaceuticals. The Agreement's 73 Articles cover basic principles, standards and use of patents, enforcement, dispute settlement and a range of other subjects. The key requirements for pharmaceuticals are described below and summarized in Box 2.

Patent protection

Members must provide patent protection for a minimum of 20 years from the filing date of a patent application, for any invention, including of a pharmaceutical product or process. The invention must fulfil the criteria of novelty, inventive step and usefulness (subject to certain exceptions – see Box 2).

Rights conferred

TRIPS specifies the rights conferred on a patent owner, but allows for limited exceptions and compulsory licensing, subject to specified conditions. The Agreement also contains provisions on: protection of undisclosed information (including test data); actions to address anti-competitive practices; protection of trademarks (relevant to generic substitution and combating counterfeit drugs); and enforcement.

Transitional arrangements

TRIPS provides transitional periods during which countries are required to bring their national legislation and practices into conformity with its provisions. The latest dates for WTO Members were/are: 1996 for developed countries; 2000 for developing countries (as a general rule); 2005 for developing countries who had not introduced patents before joining the WTO; and 2006 for least-developed countries.

TRIPS specifically recognizes the economic, financial, administrative and technological constraints of the least-developed countries. It therefore provides the possibility for further extension of the transitional period.

Public health and TRIPS

International conventions before TRIPS did not specify minimum standards for patents. Over 40 countries

provided no patent protection for pharmaceuticals, many provided only process and not product patents, and the duration of patents was much less than 20 years in many countries.

From the health sector's perspective, intellectual property standards, including those specified in TRIPS, should take protection of public health into account. However, current standards – historically derived from those of developed countries – are not necessarily appropriate for countries struggling to meet health and development needs. Developing countries can therefore use the flexibility of TRIPS provisions and its safeguards to protect public health.

Patentability

What can be patented? TRIPS specifies patents must be available for all discoveries which "...are new, involve an inventive step and are capable of industrial application (Article 27)."

The difference between the number of new drugs ("new chemical entities") that are developed globally each year, and the number of patents awarded for new uses of a drug, processes, dosage forms, formulations and different forms of the same molecule, including patents on genes and genomic sequences is enormous. The latter is influenced by national legislation and practices.

Yet because "new" and "inventive" are not defined, countries must establish their own criteria for these terms. They should recognize that patentability standards which are too broad can contribute to "ever-greening". This means that the effective patent life for a new medicine is extended beyond the 20-year TRIPS minimum. Therefore, Ministries of Health must work closely with other ministries to formulate and/or revise national patent legislation to ensure that it takes public health needs into account.

Generic drugs

Promotion of generic drugs requires appropriate legislation and regulations, reliable quality assurance capacity, professional and public acceptance of generic drugs, and economic incentives and information for both prescribers and consumers. The TRIPS Agreement does not prevent Members from requiring generic labelling and allowing generic substitution.

Trade liberalization can increase competition and reduce prices for generic drugs that are already on the market. But if the wording and implementation of TRIPS-compliant national legislation and regulations are inappropriate, the introduction of new generic drugs can be delayed. The economic cost to governments, households and public health can be enormous.

Box 2 Articles of the TRIPS Agreement of greatest relevance to pharmaceuticals

Topic (TRIPS Article)	Key phrasing from TRIPS agreement <i>(Note that a number of articles contain further specific conditions, exceptions and exemptions which are spelled out in TRIPS or other referenced agreements.)</i>
Nondiscrimination (Articles 3 and 4)	<p><i>"National Treatment...Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property..."</i></p> <p><i>"Most-Favoured-Nation Treatment...With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members..."</i></p>
Parallel importation ("exhaustion of patent rights") (Article 6)	<p><i>"Exhaustion...For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 [National Treatment] and 4 [Most-Favoured-Nation Treatment], nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."</i></p>
Objectives of TRIPS (Article 7)	<p><i>"Objectives...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 a manner conducive to social and economic welfare, and to a balance of rights and obligations."</i></p>
Protection of public health (Article 8)	<p><i>"Principles...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."</i></p>
Process and product patents (Article 27)	<p><i>"Patentable Subject Matter...patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application...[P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."</i></p>
Subject matter which may be excluded from patentability (Article 27)	<p><i>"Patentable Subject Matter...Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect <i>ordre public</i> or morality, including to protect human, animal or plant life or health..."</i></p> <p><i>"Members may also exclude from patentability:</i></p> <ul style="list-style-type: none"> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. <p><i>However, Members shall provide for the protection of plant varieties either by patents or by an effective <i>sui generis</i> system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."</i></p>
Exceptions which facilitate prompt marketing of generic drugs ("Bolar provisions") (Article 30)	<p><i>"Exceptions to Rights Conferred...Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."</i></p>
Compulsory licensing (Article 31)	<p><i>"Other Use Without Authorization of the Right Holder...Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the [twelve] provisions shall be respected."</i></p>
20-year minimum term of protection (Article 33)	<p><i>"Term of Protection...The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date."</i></p>
Reversal of burden of proof for process patents (Article 34)	<p><i>"Process Patents...Burden of Proof...For the purposes of civil proceedings in respect of the infringement of the rights of the owner...if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process."</i></p>
Data protection and exclusivity (Article 39)	<p><i>"Protection of undisclosed information...In the course of ensuring effective protection against unfair competition...Members shall protect undisclosed information...and data submitted to governments or governmental agencies..."</i></p>
Transitional arrangements for developing country WTO Members (Articles 65 and 66)	<p>Specific transitional arrangements are provided for developing and least-developed countries (see TRIPS text).</p>
Transfer of technology and technical cooperation (Articles 66 and 67)	<p><i>"Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base...[and] shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members."</i></p>
Mailbox filings (Article 70:8)	<p><i>"Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:</i></p> <ul style="list-style-type: none"> (a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed..."
Review (Article 71:1)	<p><i>"The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement."</i></p>



Prompt introduction of generic drugs can be facilitated by: drafting appropriate legislation and regulations on patentability; use of exceptions to exclusive rights which permit early testing and approval of generics ("Bolar" provision) (including allowing access to pre-registration test data); and compulsory licensing. (See further reading list.)

Compulsory licensing

Compulsory licensing enables a competent government authority to license the use of an invention to a third party or government agency without the consent of the patent-holder. The patent-holder, however, retains intellectual property rights and "shall be paid adequate remuneration" according

Box 3 Checklist for policy-makers

Government process and resources:

- Identify trade-and-pharmaceuticals focal point within Ministry of Health.
- Establish contacts, perhaps a working group, with trade and other key ministries.
- Obtain reliable specialized legal advice.
- Develop a mechanism to monitor the health impact of new trade agreements.

National patent and related legislation should:

- Promote standards of patentability that take health into account.
- Establish process and product patents for 20 years.
- Incorporate exceptions, trademark provisions, data exclusivity and other measures to support generic competition.
- Permit compulsory licensing, parallel importation and other measures to promote availability and ensure fair competition.
- Permit requests for extension of transitional period for TRIPS implementation, if needed and if eligible.
- Carefully consider national public health interests before instituting TRIPS-plus provisions (see text).

to the circumstances of the case (Article 31). In the pharmaceutical sector compulsory licenses have been used to stimulate price-lowering competition and to ensure availability of needed medicines. Most developed countries and many developing countries now provide for compulsory licensing through national legislation.

A comprehensive patent regime should include adequate provision for the granting of compulsory licenses. Grounds for compulsory licensing may include public interest, problems linked with national emergencies such as epidemics, public non-commercial use, or anti-competitive practices (Article 31). Whether or not compulsory licenses are

issued, national legislation which provides for compulsory licensing allows governments to provide the medicine in the case of abuse of rights by the patent-holder, or commercial non-availability. Any such use should be authorized predominantly for the supply of the domestic market of the Member authorizing such use (Article 31f).

Compulsory licenses must be granted on a non-exclusive basis. Since the TRIPS Agreement provides for non-discrimination between locally produced and imported products (Article 27:1), a compulsory license may be granted for importation to satisfy local needs (Article 31).

Parallel importation

Parallel importation is importation, without the consent of the patent-holder, of a patented product marketed in another country either by the patent-holder or with the patent-holder's consent. Parallel importation enables promotion of competition for the patented product by allowing importation of equivalent patented products marketed at lower prices in other countries. If the importing country's patent regime provides that the patent-holder's right has been "exhausted" (in TRIPS terminology) when the patented product has been placed on the market in another country by or with the consent of the patent-holder, the patent-holder cannot use his/her patent right in the importing country to prevent parallel importation.

Article 6 of the TRIPS Agreement explicitly states that practices relating to parallel importation cannot be challenged under the WTO dispute settlement system, provided that there is no discrimination on the basis of the nationality of the persons involved. It is widely understood to mean that parallel importation is effectively a matter of national discretion.

TRIPS-plus provisions

"TRIPS-plus" is a non-technical term which refers to efforts to: extend patent life beyond the 20-year TRIPS minimum; limit compulsory licensing in ways not required by TRIPS; and limit exceptions which facilitate prompt introduction of generics.

Since the public health impact of TRIPS requirements have yet to be fully assessed, WHO recommends that developing countries be cautious about enacting legislation that is more stringent than the TRIPS requirements.

Non-WTO Members

As of December 2000, over 50 WHO Member States were either not WTO Members or had observer status only at the WTO. From a public health perspective, countries which are not bound by TRIPS should

evaluate TRIPS requirements, and incorporate into national legislation and trade-related practices those elements which clearly benefit national public health interests.

Evaluating impacts of trade agreements

Protection of intellectual property rights aims to promote innovation by providing an incentive to invest in research and development. Yet the TRIPS Agreement, which seeks to fulfil this aim, has proven to be one of the most controversial WTO agreements. At least four questions are commonly raised from a public health perspective (Box 4). In view of the impact that the TRIPS Agreement could have on pharmaceuticals, WHO (in accord with World Health Assembly Resolution WHA52.19) is using these four

Box 4 Key questions for monitoring the public health impact of TRIPS

- 1 Are newer essential drugs more expensive than they would have been if not under patent?
- 2 Is the introduction of generic drugs being slowed?
- 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?

questions to monitor and analyse the effects of globalization and trade agreements on the pharmaceutical sector.

Concurrently, having been awarded observer status on an ad hoc basis by the WTO Council for TRIPS, WHO is able to monitor all relevant issues under discussion at WTO that may have implications for the health sector.

WHO perspectives on access to drugs

Access to essential drugs is a human right

Access to essential drugs is part of the human right to health. 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. Since most poor people in developing countries currently pay for health care, including drugs, out of their own pockets, access to medicines is particularly sensitive to cost. Governments, the UN family, the private sector and civil society each have vital roles and responsibilities in achieving universal access to essential drugs. (See Box 5.)

Patent protection has been an effective incentive for research and development for new drugs

Patent protection has been an incentive for research and development for new drugs. But questions remain as to whether the patent system will ensure investment in medicines needed by the poor. Of the 1223 new chemical entities developed between 1975 and 1996, only 11 were for the treatment of tropical diseases. The market fails when it comes to ensuring adequate pharmaceutical research and development (R&D) for neglected diseases such as malaria, a range of other tropical diseases and tuberculosis. Strong public sector involvement, including through public-private partnerships, is necessary to ensure development of new drugs for developing country priority health problems.

Affordability of essential drugs is a public health priority

Current financial resources are woefully inadequate for meeting the health care and medicine needs of the world's poorest populations. Governments, donor agencies and development banks all have a vital role to play in increasing those resources. But affordable prices are also very important.

Among the four elements needed to ensure access, the affordability of essential drugs – specifically those still on patent – is most likely to be affected by trade agreements. Patent protection awards exclusive rights to an invention and prevents generic competition. But poorer populations in developing countries should not be expected to pay the same price as do the wealthy for newer essential drugs. TRIPS-compliant mechanisms can be used to lower drug prices.

Other options to improve affordability include exchange of price information; price competition and price negotiation within public procurement and insurance schemes; price controls; reduced duties and taxes; improved distribution efficiency; reduced distribution and dispensing costs and reduced marketing expenses.

Essential drugs are not simply another commodity – TRIPS safeguards are crucial

WHO supports its Member States in the use of WTO/TRIPS-related safeguards, as appropriate, to enhance affordability and availability of existing medicines, while not discouraging the development of needed new medicines. These safeguards include setting standards for patentability which reflect public health concerns, legislative provision for compulsory licensing, exceptions to exclusive rights and other measures which promote generic



competition, and extension of the transitional period. Parallel importation of a patented drug from countries where it is sold more cheaply can also be authorized by governments.

Based on available experience, WHO does not recommend applying TRIPS-plus requirements or extending TRIPS requirements to non-WTO Members before the public health impacts of so doing have been fully assessed.

Box 5 WHO perspectives on access to drugs

- 1 Access to essential drugs is a human right.
- 2 Essential drugs are not simply another commodity – TRIPS safeguards are crucial.
- 3 Patent protection has been an effective incentive for research and development for new drugs.
- 4 Patents should be managed in an impartial way, protecting the interests of the patent-holder, as well as safeguarding public health principles.
- 5 WHO supports measures which improve access to essential drugs, including application of TRIPS safeguards.

Countries must develop informed approaches to health and trade

Countries with least capacity for interpreting and acting on international trade agreements have 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 trade and health at national, sub-regional and regional levels. Countries are advised to carefully monitor the implementation of the TRIPS Agreement in order to formulate comprehensive proposals for the future review of the TRIPS Agreement as provided for in Article 71:1. A network of legal experts who have specialized knowledge and understanding of international trade agreements, pharmaceuticals and public health is also being developed as a resource for developing countries.

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