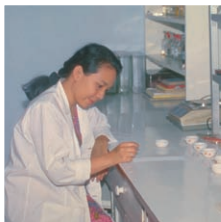


# International Trade and Health



## A Reference Guide

# International Trade and Health

*A Reference Guide*



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# Introduction

SPS, TRIPS, trade-distorting subsidies, Doha Paragraph Six ... The language of trade and health is specialized and may seem obscure. But though the language may be daunting, international trade agreements now being negotiated affect all of us, and health professionals in particular need to master the terminology if they are to participate in the national debate on trade and health. This reference guide consists of a basic dictionary of selected terms and several briefing notes that elaborate some of the issues.

As well as the dictionary and briefing notes developed by WHO headquarters or regional offices, this reference guide also includes selected resolutions bearing on public health, intellectual property and/or international trade. These materials, many already published in other forms, are brought together for the first time in one place.

The guide is intended as a starting point for those interested in but not familiar with the trade and health area. Further reading sections are included at the end of most briefing notes.



# Dictionary





# Dictionary

Term	Definition
<b>access (for example to medicines)</b>	In health services, the opportunity to obtain health care or medicines. Barriers to access include cost, non-availability at point of service, and cultural factors ( <i>see also Briefing Notes 1 and 2</i> ).
<b>accession</b>	Accession is the process by which a country becomes a member of an international organization, such as the World Trade Organization (WTO) or the European Community. Accession usually involves negotiations to determine the specific obligations a non-Member country must undertake before it will be entitled to full membership benefits.
<b>advance purchase commitment</b>	An agreement or contract, in advance of the development of a product, to purchase guaranteed amounts of the product, meeting pre-established criteria, at a specified price. ( <i>see also Briefing Note 4.</i> )
<b>August 30 Decision</b>	Decision by the World Trade Organization (WTO), on 30 August 2003, that essentially waived the restriction (imposed by TRIPS) on export of products produced under a compulsory license. This waiver applies to pharmaceuticals, active ingredients and diagnostic kits. The significance of the Decision is that it allows foreign companies to manufacture such products for countries that lack domestic manufacturing capacity and to export the total amount of the product thus produced. The Decision is the result of nearly two years of negotiations ( <i>see also "Paragraph Six Problem"; Briefing Note 2 and 5</i> ).

<b>bilateral trade agreement (BTA)</b>	An agreement between two countries that regulates the terms of trade between them. A bilateral trade agreement decreases barriers such as quotas or import duties ( <i>see also Briefing Note 6</i> ).
<b>bioequivalence</b>	The basis for comparing a generic drug with the original product. To be considered bioequivalent, the bioavailability (blood concentrations) of two different products must not differ significantly when the two products are given at the same dosage under similar conditions.
<b>biologics</b>	A class of systemic therapies that contain proteins derived from living cells, as opposed to traditional pharmaceutical drugs that are made up of non-living chemicals. Examples include vaccines, blood and other blood products, as well as genetic therapies.
<b>Bolar provision</b>	A clause that can be incorporated into patent law which allows testing and regulatory approval of generic versions of a drug before its patent expires, so that generic producers can start production and sale of a drug immediately after patent expiry. This has been upheld as conforming with the TRIPS Agreement. A Bolar provision is also called early working exception or regulatory review exception; ( <i>see Briefing Note 2</i> ).
<b>BTA</b>	See bilateral trade agreement.
<b>CBD</b>	See Convention on Biological Diversity.
<b>compound library</b>	A structurally diverse collection of chemical molecules, typically containing several hundred thousand entities, that is used to identify lead candidates for the development of new medicines.

<b>compulsory licensing</b>	A compulsory license (CL) is a license granted by a government to allow the use of a patented invention without the permission of the patent holder. This is permitted by the TRIPS Agreement for certain purposes such as protecting public health. A compulsory license can be issued in the case of a public emergency; however, it is a common misunderstanding that this is the only time a government can exercise this option (see also <i>Briefing Notes 1, 2, 5 and 6</i> ).
<b>Convention on Biological Diversity (CBD)</b>	The Convention on Biological Diversity is an international treaty which originated at the Earth Summit in Brazil in 1992. The Convention has three main goals: <ul style="list-style-type: none"> <li>(1) the conservation of biological diversity;</li> <li>(2) the sustainable use of its components; and</li> <li>(3) the fair and equitable sharing of the benefits from the use of genetic resources. The CBD is relevant to discussions on intellectual property rights for traditional knowledge and biological resources.</li> </ul>
<b>counterfeit drugs</b>	Drugs that are deliberately and fraudulently mislabeled with respect to identity or source. Counterfeiting can apply to both branded and generic products. Counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging.

<b>data exclusivity</b>	A legal provision that data collected for the purpose of obtaining marketing approval (e.g. the results of clinical trials) may not be used for a specified period by the regulatory authorities to grant approval to a generic equivalent (Note: not to be confused with data protection). ( <i>See also briefing notes 2,3 and 6.</i> )
<b>data protection</b>	An obligation imposed on third parties to protect test data (e.g. the results of clinical trials)—usually collected in order to comply with government regulations on the safety, efficacy and quality of a broad range of products (e.g. drugs, pesticides, medical devices). For example, TRIPS provides for the protection of such data against unfair commercial use ( <i>see also Briefing Note 3</i> ).
<b>differential pricing</b>	The practice of setting different prices for different markets (typically higher prices in richer markets and lower prices in poorer markets).
<b>Doha Declaration</b>	<p>The Doha Declaration on the TRIPS Agreement and Public Health was adopted by the WTO Ministerial Conference in Doha on 14 November 2001. It reaffirmed TRIPS Member States' rights to use safeguards for better access to essential medicines. The declaration furthermore points out the need to:</p> <ol style="list-style-type: none"> <li>(1) find a solution to the problems countries may face in making use of compulsory licensing if they have too little or no pharmaceutical manufacturing capacity (this was achieved in August, 2003) and</li> <li>(2) extends the deadline for least-developed countries to apply provisions on pharmaceutical patents and data protection until 1 January 2016 (<i>see also "Paragraph 6 Problem"; Briefing Note 6</i>).</li> </ol>

<b>Doha Round</b>	The WTO Ministerial Meeting in 2001 in Doha, Qatar kicked off the Development Round of multilateral trade negotiations, which is marked by a core concern: that the multilateral trading system should benefit the developing countries that constitute over three-quarters of WTO members. The Doha Round aims to lower trade barriers and has continued with successive meetings in many other sites.
<b>early working exception</b>	See Bolar provision.
<b>essential drugs/ medicines</b>	Essential medicines are those that satisfy the priority health care needs of the population. Essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. WHO maintains a Model Essential Medicines List and countries are encouraged to develop national essential medicines lists adapted from the WHO model according to the national situation (see also <i>Briefing Note 1</i> ).
<b>evergreening</b>	Evergreening is a term popularly used to describe patenting strategies that are intended to extend the patent term on the same compound; for example, by claiming a new patent on an “inventive” method for administering a pharmaceutical compound covered by an earlier patent, which would give the patent holder an extended monopoly that excludes generic drugs from the market.
<b>exhaustion of rights</b>	The principle whereby the right holders’ intellectual property rights in respect of a product are considered exhausted (i.e. he or she can no longer exercise any rights) when that product has been put on the market by the right holder, or by an authorized party (See also <i>parallel importation</i> ).
<b>FDI</b>	See foreign direct investment.

<b>Flexibility in TRIPS</b>	See TRIPS flexibilities.
<b>foreign direct investment (FDI)</b>	FDI is the purchase or construction of tangible assets (land, factories, machines, buildings and enterprises) in one country by firms from another country. This does not include investment in stock markets. Increased access to FDI is seen as one of the key benefits of globalization because it is thought to lead to capital formation, technology and knowledge transfer, higher wages and greater job opportunities. Critics are concerned that its benefits are very unequally distributed, both globally and within societies.
<b>free trade agreement (FTA)</b>	A free trade agreement (FTA) is an agreement between two or more countries which is intended to promote market access and flow of goods and services between participating countries, by lowering tariff and customs barriers and other restrictions to trade. Critics worry, however, that the pursuit of free trade agreements could detract from multilateral negotiations. There is also concern that some free trade agreements impose additional conditions on developing countries with regard to intellectual property rights. This could limit their rights to produce generic drugs and other patent-protected products (see also <i>Briefing Note 6</i> ).
<b>FTA</b>	See free trade agreement.
<b>G-7 (Group of 7)</b>	The Group of Seven (G-7) major industrial countries are Canada, France, Germany, Italy, Japan, the United Kingdom, and the United States. They began to hold annual economic summits (meetings at the level of head of state or government) from 1975. Although Russia subsequently joined the group, thereby forming the Group of Eight, the G-7 continues to function as a forum for discussion of economic and financial issues among the major industrial countries.

<b>G-8 (Group of 8)</b>	The G-8 consists of the world's eight largest industrial market economies: Britain, Canada, France, Germany, Italy, Japan, Russia and the United States. Together, these countries represent about 65% of the world economy. The leaders of these countries meet annually to discuss political and economic issues of mutual concern.
<b>G-20 (Group of 20)</b>	The G-20 brings together finance ministers and central bank governors from the G-7 countries, as well as Australia, and 11 major emerging markets (Argentina, Brazil, China, India, Indonesia, Korea, Mexico, Russia, Saudi Arabia, South Africa and Turkey), along with the European Union, International Monetary Fund and the World Bank. Supported by meetings of their G-20 deputies, G-20 ministers and governors meet annually to address key issues in international economics and finance.
<b>G-33 (Group of 33)</b>	A group of developing countries established on the eve of the WTO ministerial in Cancun in 2003. The G-33 is concerned with trade in products crucial to rural development, food security and livelihood security—generally known as “Special Products”. The group was formed to ensure that mechanisms to deal with Special Products and Special Safeguard Mechanisms (SSMs) for developing countries are included in all agricultural negotiations.
<b>G-77 (Group of 77)</b>	The Group of 77 is a loose coalition of developing nations founded in 1964. It was formed to promote the collective economic interests of its members and to strengthen their joint negotiating capacity on all major international economic issues in the United Nations system. There were 77 founding members but the group has since expanded to approximately 130 members.
<b>GATS</b>	See General Agreement on Trade in Services.



<b>GATT</b>	See General Agreement on Tariffs and Trade.
<b>General Agreement on Trade in Services (GATS)</b>	The General Agreement on Trade in Services (GATS) came into force in 1995 and constitutes the legal framework through which World Trade Organization (WTO) Members progressively liberalize trade in services. These liberalization efforts may include health-related services, such as migration of health personnel, health insurance, hospital services, telemedicine, and acquisition of medical treatment abroad (see also <i>Briefing Note 7</i> ).
<b>General Agreement on Tariffs and Trade (GATT)</b>	An agreement negotiated in 1947 among 23 countries, and now including about 150 countries, to increase international trade by reducing tariffs and other trade barriers. GATT provides a code of conduct for international commerce. It also provides a framework for periodic multilateral negotiations on trade liberalization and expansion. The World Trade Organization was established in 1996 through GATT negotiations, and is responsible for implementing GATT (see also <i>Briefing Note 1</i> ).
<b>generic drug</b>	A drug that is chemically identical to a brand name drug and which is allowed to be produced after the innovator drug's patent has expired, or, exceptionally, under TRIPS provisions before patent expiry. It is also called a "generic equivalent" (see also <i>Briefing Note 1</i> ).
<b>Global System of Trade Preferences (GSTP)</b>	The Agreement on the Global System of Trade Preferences Among Developing Countries (GSTP) was established in 1988 as a framework for the exchange of trade preferences, such as reduced tariffs, among developing countries in order to promote intra-developing-country trade.
<b>GSTP</b>	See Global System of Trade Preferences.

<b>incremental innovation</b>	Innovation that builds incrementally on previous innovation, as compared with “breakthrough” innovation (a completely novel means to prevent, treat or cure a particular disease).
<b>interchangeability</b>	A pharmaceutical product that is therapeutically equivalent to a comparator (reference) product.
<b>IHR</b>	See International Health Regulations.
<b>ILP</b>	See import licensing procedure.
<b>import licensing procedure (ILP)</b>	Administrative procedures that must be followed to obtain permission to ship goods into a country. Import licensing can be defined as administrative procedures requiring the submission of an application or other documentation (other than those required for customs purposes) to the relevant administrative body as a prior condition for importation of goods. ILPs are regulated among WTO countries by the agreement on Import Licensing Procedures developed in 1971.
<b>intellectual property (IP)</b>	Intellectual property refers to creations of the mind: inventions, literary and artistic works, and symbols, names, images, and designs used in commerce. Intellectual property is divided into two categories: <ul style="list-style-type: none"> <li>(i) industrial property, which includes inventions (patents), trademarks, industrial designs, and geographic indications of source; and</li> <li>(ii) copyright, which includes literary and artistic works such as novels, poems and plays, films, musical works, artistic works such as drawings, paintings, photographs and sculptures, and architectural designs.</li> </ul>

<b>intellectual property rights (IPR)</b>	Rights awarded by governments to individuals or organizations over inventions, literary and artistic works, symbols, names, images, and designs used in commerce. They give the titleholder the right to prevent others from making unauthorized use of their property for a limited period. Ideas, including literary and artistic works, are protected by copyright; inventions are protected by patents; and signs for distinguishing goods of an enterprise are protected by trademarks. IPR aims to strike a balance between the long-term benefits and short-term costs to society. Society benefits in the long term when the IPR system encourages creation and innovation, but the short-term effect is increased costs.
<b>International Health Regulations (IHR)</b>	A set of regulations whose purpose is to prevent, protect against, control and provide a public health response to the international spread of disease, while avoiding unnecessary interference with international traffic and trade. The first International Health Regulations were introduced in 1969 and periodically modified. The IHR (2005) broadened the scope of the 1969 regulations to cover existing, new and re-emerging diseases, including emergencies caused by non-infectious disease agents. These new regulations entered into force in June 2007 (see also <a href="http://www.who.int/csr/ihr/howtheywork/faq/en/">http://www.who.int/csr/ihr/howtheywork/faq/en/</a> ).
<b>IP</b>	See intellectual property.
<b>IPR</b>	See intellectual property rights.
<b>LDC</b>	See least developed countries.

<b>least developed countries (LDC)</b>	The world's poorest countries. LDCs are designated annually by the Economic and Social Council of the United Nations using three criteria of low income, human resources and vulnerability. In some cases, LDCs are given differential and more favourable treatment in the multilateral trading system. As of January 2009, 50 countries are listed as LDCs. In the South-East Asia Region, Bangladesh, Bhutan, Maldives, Myanmar, Nepal and Timor-Leste are LDCs.
<b>Material Transfer Agreement (MTA)</b>	A Material Transfer Agreement (MTA) is a contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own purposes. Biological materials, such as reagents, cell lines, plasmids, and vectors, are often transferred using MTAs, but these agreements may also be used for other types of materials, such as chemical compounds and even some types of software. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives.
<b>MFN</b>	See most favoured nation.

<b>modes of service supply under GATS</b>	<p>GATS distinguishes between four modes of supplying services:</p> <ul style="list-style-type: none"> <li>• Cross-border supply of services: service flows from the territory of one Member into the territory of another Member (e.g. telemedicine, e-health);</li> <li>• Consumption abroad: consumers move into another Member's territory to obtain a service (e.g. patients travelling abroad for hospital treatment);</li> <li>• Commercial presence: a service supplier of one Member establishes a territorial presence, either through ownership or lease of premises, in another Member's territory (e.g. establishment of health facilities in other countries); and</li> <li>• Presence of natural persons: persons of one Member enter the territory of another Member to supply a service (e.g. doctors or nurses practicing in other countries). (see also <i>Briefing Note 7.</i>)</li> </ul>
<b>most favoured nation</b>	<p>Most favoured nation treatment refers to the principle of not discriminating between one's trading partners. Somewhat counterintuitively, a most favoured nation does not receive particular advantages, but will be granted the same trade advantages, such as low tariffs, that any other nation also receives. In effect, having MFN status means that one's nation will not be treated worse than anyone else's nation. The members of the World Trade Organization accord MFN status to each other. Some exceptions are allowed, for example, preferential treatment of developing countries, regional free trade areas and customs unions. In general, MFN means that every time a country lowers a trade barrier or opens up a market, it has to do so for the same goods or services from all its WTO trading partners.</p>
<b>MTA</b>	See Material Transfer Agreement.

<b>Multilateral Rules-based Trading System</b>	Agreed norms and procedures for trade (exchange of goods and services) negotiated on a global basis. Examples are the TRIPS and GATS agreements administered by the World Trade Organization, which are applicable to all WTO member countries. One argument in favour of multilateral rules over bilateral agreements is that they ensure consistency and equity in trade arrangements between all trading partners.
<b>neglected diseases</b>	Diseases for which prevention and cures have received inadequate attention from global public health and research institutions and from private industry. These diseases almost exclusively affect impoverished people living in rural areas or poor urban slums of low-income countries ( <i>see also Type II and Type III disease</i> ).
<b>new molecular entity</b>	A term used by the United States Food and Drug Administration for medication containing an active substance that has never before been approved for marketing in any form.
<b>“Paragraph Six Problem”</b>	Refers to Paragraph 6 of the Doha Declaration, which recognized the problem that “WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector, could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement”. Although existing provisions of the TRIPS Agreement permit the grant of compulsory licenses to enable generic production of medicines, countries without domestic manufacturing capacity may not be able to avail of this flexibility. This is a concern because exporting countries may have difficulties exporting sufficient quantities to meet the needs of those countries due to conditions on compulsory licensing imposed by the TRIPS agreement [notably Article 31(f)]. ( <i>see also Briefing Notes 2 and 5.</i> )

<b>parallel importation</b>	The purchase of a patented product from a lawful source in an exporting country and its importation without seeking the consent of the patent holder in the importing country. Parallel importers ordinarily purchase products in one country at a price that is cheaper than the price at which they are sold in the importing country. Parallel importation is allowed under the WTO TRIPS Agreement, and is recognized as a TRIPS public health safeguard because it can enhance the affordability and availability of medicines (see <i>Briefing Notes 1 and 2.</i> )
<b>patent</b>	An exclusive right granted by government to an inventor to prevent others from making, selling, distributing, importing or using the invention, without license or authorization, for a fixed period of time, conferring a temporary monopoly. In return, the patentee discloses the invention to the public.
<b>patentability</b>	The ability of an invention to satisfy the legal requirements for obtaining a patent. There are usually three requirements for patentability: novelty (i.e. the invention should not be part of the “prior art”); inventive step or non-obviousness (i.e. the invention should not be obvious to one skilled in the field); and industrial applicability or utility. There is debate over whether scientific theories, discoveries of natural substances and new methods for medical treatment are patentable (see <i>Briefing Note 1</i> ).
<b>patent pool</b>	An agreement between two or more patent owners to license one or more of their patents to one another or third parties (See <i>Briefing Note 4</i> ).

<b>pre-grant flexibilities</b>	Countries have the flexibility to define the standards of patentability in order to ensure that patents are not granted unnecessarily (for example when an invention is obvious). They also can allow third parties to register their opposition to a patent before it is granted. (see <i>Briefing Note 5</i> .)
<b>(WHO) prequalification project</b>	A project originally intended to give United Nations procurement agencies, such as UNICEF, a choice of products meeting various standards as certified by WHO. With time, other agencies and governments have found this a useful service.
<b>prior art</b>	Publications or other public disclosures made before the filing (or priority) date of a patent application against which the novelty and inventiveness of the invention in the patent application is judged.
<b>regulatory approval for marketing drugs</b>	Typically, the process by which a governmental authority reviews medical interventions for marketing authorization. Although methods vary, this normally involves determination of product safety, quality and efficacy. Regulation also involves ongoing monitoring and evaluation of safety, efficacy and quality of products that have already obtained marketing authorization.
<b>regulatory review exception</b>	See Bolar provision.
<b>sanctions</b>	See trade sanctions.
<b>sanitary and phytosanitary measures (SPS)</b>	SPS measures relate to standards for protecting food safety and animal and plant health. SPS measures are subject to rules set under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement). (see also “ <i>Sanitary and Phytosanitary Measures (SPS) Agreement</i> ”.)



<b>Sanitary and Phytosanitary Measures (SPS) Agreement</b>	The WTO Agreement on Sanitary and Phytosanitary Measures provides procedures and regulations to protect human, animal or plant life or health from the risks arising from the spread of pests, diseases, and disease-causing organisms, or from additives, toxins, or contaminants found in food, beverages, or feedstuffs. It allows countries to take scientifically based measures to protect public health. Generally speaking, the SPS Agreement is a compromise that permits countries to take measures to protect public health within their borders so long as they do so in a manner that restricts trade as little as possible ( <i>see also</i> <a href="http://www.cid.harvard.edu/cidtrade/issues/spstbt.html">http://www.cid.harvard.edu/cidtrade/issues/spstbt.html</a> ).
<b>SPS</b>	See sanitary and phytosanitary measures (SPS).
<b>SPS Agreement</b>	See Sanitary and Phytosanitary Measures (SPS) Agreement.
<b>sui generis</b>	A legal expression (Latin) meaning “of its own kind”. For example, it has been proposed to develop sui generis legislation for the protection of traditional medicine, since it is difficult to protect traditional medicine under intellectual property rights.
<b>TBT</b>	See technical barriers to trade
<b>TBT Agreement</b>	See Technical Barriers to Trade Agreement.
<b>technical barriers to trade (TBT)</b>	Technical regulation or other requirement (for testing, labelling, packaging, marketing, certification, etc.) applied to imports in a way that restricts trade.
<b>Technical Barriers to Trade (TBT) Agreement</b>	The TBT Agreement is a WTO agreement that tries to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles to trade ( <i>see also</i> <a href="http://www.cid.harvard.edu/cidtrade/issues/spstbt.html">http://www.cid.harvard.edu/cidtrade/issues/spstbt.html</a> ).

<b>trade-distorting subsidies</b>	Subsidies are financial contributions given by government to producers that give those producers an advantage in the marketplace. Their support may, in turn, negatively affect other countries' industries and trade. Generally, the most "trade-distorting" subsidies are those aimed at promoting exports or displacing imports, or those given to specific industries.
<b>Trade Negotiations Committee (WTO)</b>	The body consisting of all countries participating in a GATT or WTO Round of negotiations, with responsibility for exercising overall supervision over the negotiations and for establishing appropriate plans and negotiating procedures.
<b>Trade Related Investment Measures (TRIMs)</b>	The WTO Agreement on Trade Related Investment Measures (TRIMs) contains rules that apply to the domestic regulations that a country applies to foreign investors, often as part of an industrial policy. The agreement on TRIMs recognizes that certain investment measures, such as local content or trade balancing requirements, can restrict and distort trade, and requires countries to phase them out.
<b>trade sanctions</b>	In international trade, sanctions are punitive actions taken by one or more governments against another, usually in the form of trade restrictions. Examples are import tariffs, licensing costs and administrative hurdles. These make it more difficult, if not impossible, for the nation(s) bearing the sanction to trade with the nation imposing it.
<b>trade secret</b>	Commercially valuable information about production methods, business plans, clientele, etc. They are protected as long as they remain secret through laws that prevent acquisition by commercially unfair means and unauthorized disclosure.

<b>traditional knowledge</b>	While there is no generally acceptable definition, traditional knowledge includes, but is not limited to, medical knowledge tradition-based creations, innovations, literary, artistic or scientific works, performances and designs. Such knowledge is often transmitted from generation to generation and is often associated with a particular people or territory.
<b>Transitional arrangements under TRIPS</b>	Provisions in TRIPS that allow time for countries to come into compliance with other TRIPS provisions – for example, extra time for developing countries to fully implement agreed patent protection (see also <i>Briefing Note 1</i> ).
<b>TRIMs</b>	See Trade Related Investment Measures.
<b>TRIPS Agreement</b>	The WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), negotiated in the 1986-94 Uruguay Round, introduced intellectual property rules into the multilateral trading system for the first time. The TRIPS Agreement establishes minimum levels of protection for intellectual property rights (see also <i>Briefing Notes 1 and 2</i> ).
<b>TRIPS flexibilities</b>	TRIPS flexibilities allow WTO Members to take measures that limit the rights of patent holders. Flexibilities (or safeguards) relevant to access to medicines include compulsory licensing, parallel importation, limits on data protection, use of broad research and other exceptions to patentability. Many developing countries have not incorporated TRIPS flexibilities into their legislation to the extent authorized under the Doha Declaration. (see also <i>Briefing Notes 2 and 5</i> .)

<b>TRIPS-plus</b>	An informal term for conditions or requirements placed on intellectual property protection that exceed the provisions agreed in the TRIPS agreement. Examples of “TRIPS-plus” provisions include: data exclusivity, patent term extension, limitations on the grounds for compulsory licenses, linkage between patent status and generic registration, or other administrative procedures related to patent applications or the granting and revocation of patents. The common feature of all TRIPS-plus provisions is that they have the effect of complicating or delaying the marketing of generic versions of patented products. TRIPS-plus provisions are often inserted into bilateral trade deals, including Free-Trade Agreements (FTAs). (see <i>also Briefing Notes 1, 3 and 6.</i> )
<b>Type I disease</b>	Diseases that are incident in both rich and poor countries, with large numbers of vulnerable population in each. Examples of communicable diseases in this category include measles, hepatitis B, and haemophilus influenza type b (Hib), and examples of noncommunicable diseases are diabetes, cardiovascular diseases and tobacco-related illnesses.
<b>Type II disease</b>	Diseases that occur in both rich and poor countries, but with a majority of cases in poor countries. Type II diseases are often termed neglected diseases. HIV/AIDS is an example.
<b>Type III disease</b>	Diseases that overwhelmingly or exclusively occur in the developing countries, such as African sleeping sickness (trypanosomiasis) and African river blindness (onchocerciasis). Type III diseases are often termed very neglected diseases’.
<b>UNCTAD</b>	See United Nations Conference on Trade and Development.

<b>United Nations Conference on Trade and Development (UNCTAD)</b>	The United Nations Conference on Trade and Development (UNCTAD) was established in 1964 as a permanent intergovernmental body to promote development-friendly integration of developing countries into the world economy. UNCTAD is the principal organ of the United Nations General Assembly dealing with trade, investment and development issues. It focuses attention on international economic relations and on measures that might be taken by developed countries to accelerate economic development in developing countries.
<b>Uruguay Round</b>	The Uruguay Round was a round of GATT negotiations started in Uruguay in 1986 and designed to promote free trade. It was the origin of the WTO and a range of multilateral agreements administered by the WTO.
<b>World Trade Organization (WTO)</b>	<p>The WTO is the principal international institution for the management of international trade. As of 1 January 2009, the WTO had 153 Members. The WTO is responsible for:</p> <ul style="list-style-type: none"> <li>• providing a forum for trade negotiations;</li> <li>• handling trade disputes; and</li> <li>• monitoring national trade policies.</li> </ul> <p>The WTO also administers WTO agreements (see <i>also Briefing Note 1</i>).</p>
<b>WTO</b>	See World Trade Organization.

# Briefing Notes





No. 3 March 2001  
World Health Organization  
Geneva

# Globalization, TRIPS and access to pharmaceuticals

No. 3 March 2001 World Health Organization Geneva

## 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 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.

### 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”)

## 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.

**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)	<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>
Protection of public health (Article 8)	<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>
Process and product patents (Article 27)	<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>	<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> <ol style="list-style-type: none"> <li><i>diagnostic, therapeutic and surgical methods for the treatment of humans or animals;</i></li> <li><i>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.</i></li> </ol> <p><i>However, Members shall provide for the protection of plant varieties either by patents or by an effective <i>su i 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>
<p>Exceptions which facilitate prompt marketing of generic drugs ("Bolar" provisions) (Article 30)</p>	<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)	<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>
20-year minimum term of protection (Article 33)	<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>
Reversal of burden of proof for process patents (Article 34)	<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>
Data protection and exclusivity (Article 39)	<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>
Transitional arrangements for developing country WTO Members (Articles 65 and 66)	Specific transitional arrangements are provided for developing and least-developed countries (see TRIPS text).

<p><b>Transfer of technology and technical cooperation</b> (Articles 66 and 67)</p>	<p>“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.”</p>
<p><b>Mailbox filings</b> (Article 70:8)</p>	<p>“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:</p> <p>(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...”</p>
<p><b>Review</b> (Article 71:1)</p>	<p>“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.”</p>

## ***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.

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 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.

### **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).

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 noncommercial 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 nonexclusive 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 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.

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

- Are newer essential drugs more expensive than they would have been if not under patent?
- Is the introduction of generic drugs being slowed?
- Are more new drugs for neglected diseases being developed?
- Are transfer of technology and direct foreign investment in developing countries increasing or decreasing?

## **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.)

### **Box 5: WHO perspectives on access to drugs**

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

### ***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.

### ***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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# TRIPS, intellectual property rights and access to medicines<sup>1</sup>

## The TRIPS agreement

The Agreement on Trade-related Aspects of Intellectual Property Rights (or the TRIPS Agreement) is an integral part of the World Trade Organization (WTO) Agreements, which create binding international obligations among WTO Member States. The TRIPS Agreement is subject to the WTO's dispute settlement mechanism, which may -as a last resort- allow Member Countries to apply trade sanctions against a non-compliant Country, thereby ensuring enforcement of the WTO's rules and agreements.

## TRIPS and patents

Patents are a public policy tool; they were designed to promote and reward innovation, while at the same time ensuring disclosure of the invention, in order to make it widely known and available. Before TRIPS, countries could -and did- devise a patent regime that was in line with their level of development and their overall, national priorities.

The TRIPS Agreement has to a large extent harmonised the standards for patents; notably, it makes it mandatory for countries to ensure that patent protection is available in all fields of technology, for both process and product inventions. Thus, it is no longer possible

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1 This is an updated version of antiretroviral newsletter No.8, originally published by WHO/WPRO in December 2002.

for countries to exempt pharmaceuticals from patent protection (as a number of countries did, before TRIPS came into force). Nor can countries like India continue to limit pharmaceutical patents to process patents only.

The distinction between product and process patents is important, since if a product is patented, only the patent holder may make or sell that product; nobody else may do so, unless the patent holder has given permission (a license). In the case of a process patent, nobody may make that product *by using the process that is protected*.

However, if someone can produce the same product in a different way, he/she may do so. Since for most pharmaceuticals multiple routes of synthesis can be devised, process patents offer considerably less protection than product patents<sup>2</sup>. Until 2004, India recognized only process patents for drugs. Thus, India implicitly provided incentives for local manufacturers to “invent around” the patent (i.e. to develop a different production method); generics thus produced were legal in India, and, as a result, generic versions of newly developed drugs used to be available relatively quickly in India. This will change, because from 2005 onwards India will implement TRIPS (see also below).

TRIPS furthermore requires that the minimum duration of patent protection is 20 years (prior to TRIPS, the patent term was 20 years in certain industrialized countries, but shorter in many developing countries), and mandates effective enforcement.

The introduction of these TRIPS standards will delay the marketing of generic versions of new drugs, and, thus, the competition they entail; hence it is anticipated that prices of new drugs will remain high for a longer time<sup>3</sup> which will result in reduced access for many people, notably in developing countries.

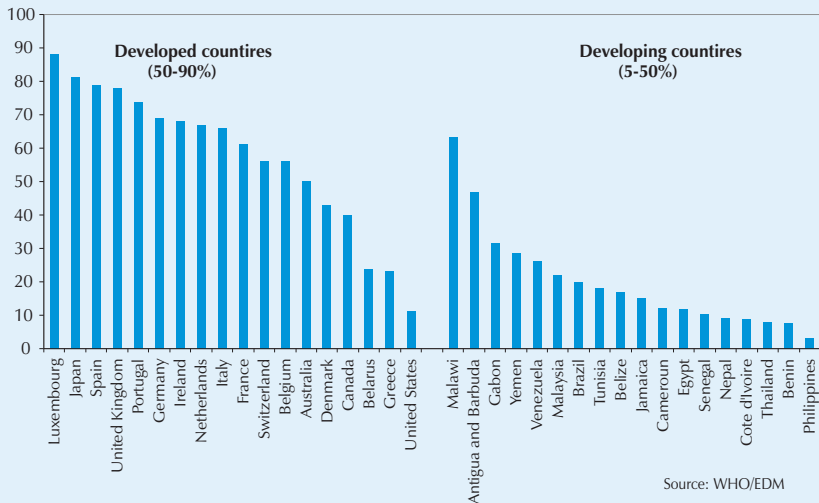
<sup>2</sup> TRIPS has however reinforced process patents.

<sup>3</sup> TRIPS does not apply retroactively, therefore there are no implications for drugs that were already off-patent when TRIPS came into force.

## Access to drugs

Access to medicines depends on many factors, notably rational selection and use of drugs, adequate and sustainable financing, affordable prices, and reliable supply systems. Prices are only one factor<sup>4</sup>. Yet prices are an important factor, especially in developing countries, since, while in developed countries pharmaceuticals are largely publicly funded, through reimbursement and insurance schemes, in developing countries, typically, 50-95% of drugs are paid by the patients themselves (see Figure 1). Thus, in developing countries, prices have direct implications for access to medicines.

**Figure 1:** Public spending as % of total spending on pharmaceuticals in selected countries



4 It should also be noted that patents are not the only reason for high drug prices; distribution costs, high mark-ups and taxes can also play an important role.

## TRIPS safeguards

It is however important to realize that TRIPS is a framework agreement; it is to be operationalized via countries' national laws. Moreover, TRIPS does contain -limited- flexibility, as well as some safeguards, which can be used to mitigate the anticipated negative impact on drug prices and on access to drugs.

The most important safeguards are (i) compulsory licensing, (ii) parallel importation and (iii) provisions for early working (often referred to as "Bolar provision").

*The "Bolar provision"* allows testing and regulatory approval of generic versions of a drug, *before* its patent expires; thus, it allows generic producers to get ready, so that they can start the production and sale of a generic drug as soon as its patent expires<sup>5</sup>. In this way, a Bolar provision facilitates generic competition.

*Parallel importation* refers to importation, without the consent of the patent holder, of a patented product that is marketed in another country. Parallel importation allows one to 'shop around' for a good price; for example, if a company sells drug X in country A at a price of \$10, while the same company sells the same drug X in country B for \$1, then someone may import drug X from country B and sell it in country A, charging for example \$3. As a result, in this example, country A would save \$7 on product X. In other words, parallel importation also enables competition, but in a different way.

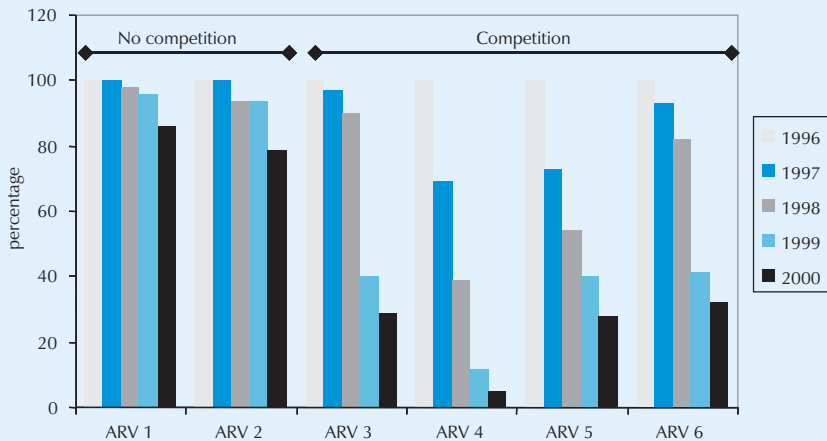
The TRIPS Agreement states that parallel importation cannot be challenged under the WTO dispute settlement mechanism, thus de facto leaving countries the freedom to choose whether or not to allow parallel importation. Moreover, during the WTO's Ministerial Meeting in November 2001, the Ministers clarified, in the Doha Declaration

<sup>5</sup> In the absence of such a provision, generic manufacturers can only start the time consuming process of testing and registration after the expiry of the patent; this can easily delay the marketing of generic drugs to 2-3 years after patent expiry.

on the TRIPS Agreement and Public Health, that countries are free to use parallel importation.

A *compulsory license* is a license to use an invention, which has been granted without the permission of the patent holder. A compulsory license can be used to allow the production and sale of generics before expiry of the patent - thus, again, increasing opportunities for competition (and competition drives prices down, as can be seen in Figure 2).

**Figure 2:** Influence of competition on drug prices 1996 prices taken as reference (100%)



Source: UNAIDS, 2000

The basic rationale for a compulsory license is that, since a patent is a privilege granted by the government, the government retains the right to limit that privilege if necessary. Many countries, including many developed countries, have provisions for compulsory licenses in their national laws, and compulsory licenses are allowed under TRIPS.



TRIPS mentions that a compulsory license can be issued for reasons of national emergency or extreme urgency, public non-commercial use and other reasons. However, it is important to note that TRIPS does *not* limit the grounds, or reasons, for issuing a compulsory license.

But the TRIPS Agreement does specify *conditions*, which are to be imposed by governments when issuing a compulsory license. These conditions include<sup>6</sup>:

- case-by-case decision
- first try to obtain a voluntary license
- adequate remuneration to the patent holder
- predominantly for the supply of the domestic market
- a compulsory license should be non-exclusive and non-assignable.

So while these conditions have made the process somewhat cumbersome, it is possible to issue a compulsory license in a TRIPS-compliant way.

A special case of compulsory licensing is ‘*Government use*’ (or a compulsory license for public non-commercial use). TRIPS imposes less stringent conditions in case of ‘*Government use*’; hence countries may find that using this mechanism is easier/faster than compulsory licensing.

However, the safeguards provided for in TRIPS can only be used when incorporated in the national law. Thus, it is important that

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6 The list is not exhaustive; moreover, certain conditions may be waived in specific circumstances. For instance, the condition to first try to obtain a voluntary license does not apply if a compulsory license is issued to remedy anti-competitive behavior of the patent holder, in case of an emergency or in case of public non-commercial use.

countries design and enact legislation which allows them to protect the public interest, including the public health interest.

## Flexibility in TRIPS

In addition, as mentioned above, there is some flexibility in TRIPS. For example, one of the conditions for issuing a compulsory license is that the patent holder should receive adequate remuneration. But TRIPS does not define “adequate”; thus, countries have some leeway in this respect.

Similarly, TRIPS leaves countries free to use either very strict or more flexible criteria for patentability. Applying flexible criteria of novelty and inventiveness enables for instance the issuing of patents for formulations or for isomers of known drugs, thus allowing pharmaceutical companies to apply for additional patents, and providing them with opportunities to expand the duration of protection beyond that of the original patent. In this way, originator companies can seek to postpone generic competition.

Yet whether this flexibility is actually used in order to facilitate access to medicines ultimately depends on national standards and (administrative) procedures.

## Other TRIPS provisions

Patents are not the only type of intellectual property rights addressed in TRIPS, and some of the other forms of intellectual property can also have implications for access to drugs. For example, TRIPS mandates protection of undisclosed data submitted to national Drug Regulatory Authorities in order to obtain marketing authorization for new drugs. These registration data have to be protected against disclosure, and against unfair commercial use. Thus, the national authorities may not publish such data or share them with competing (e.g. generic) companies.

Some parties however try to argue for *data exclusivity*, which means that the regulatory authorities would not be allowed to rely on these data for the purpose of registration of generic versions of the drug. By implication, as long as the exclusivity lasts, generic producers would either have to submit their own data -which would oblige them to repeat the clinical trials and other tests- or they would have to delay the launch of their product until the end of the exclusivity period. Thus, data exclusivity diminishes the likelihood of speedy marketing of generics, and delays competition and price reductions.

TRIPS, however, mandates data protection, but not data exclusivity and national laws need not have requirements that are more stringent than TRIPS<sup>7</sup>.

Similarly, it is important that national trademark laws do *not* hinder pro-public health measures such as generic prescription, generic substitution and/or requirements that a drug's label includes the generic name.

## Country experiences

Two countries that are at the forefront of the fight against HIV/AIDS, especially with regard to making HIV/AIDS drugs, including antiretrovirals (ARVs), available and affordable, are Thailand and Brazil. Thailand focuses on producing and selling generic ARVs at the lowest possible price<sup>8</sup>, while Brazil is providing free ARV treatment in its public health facilities. Their strategies, with regard to intellectual property rights, are summarized below:

### Thailand

The Government Pharmaceutical Organization (GPO) in Thailand is producing a number of generic ARVs. The GPO is only producing

7 Unfortunately, data exclusivity and other requirements that go beyond TRIPS are increasingly being incorporated in bilateral/regional free trade agreements.

8 The Thai Ministry of Public Health also provides highly subsidized ARV treatment via its universal coverage scheme (the '30 Baht scheme').

products that are not patented in Thailand, or for which the Thai patent has expired. One important drug, didanosine or ddl, used to be under patent in Thailand; however, the patent only applied to ddl tablets. Hence the GPO has been producing ddl powder; the powder form, while not as convenient or as accurate a dosage form as tablets, did not infringe the patent.

Some years later, following a challenge by NGOs representing people living with HIV/AIDS, Thailand's Central Intellectual Property and International Trade Court has ruled that the ddl patent was only valid for tablets containing 5-100 mg ddl. Since then, it has been possible for generic producers, such as the GPO, to produce ddl tablets outside that dosage range (e.g. tablets containing 125 mg ddl).

### ***Brazil***

Brazil, like Thailand, has a government-owned company that produces generic versions of certain ARVs, which are not under patent in Brazil. In addition, Brazil has used the fact that it is capable of producing generic versions of crucial HIV drugs, and that it would be willing to issue a compulsory license if necessary, to negotiate substantial price discounts for those drugs that are patented. So far, this strategy has been quite successful, and Brazil has not yet had to actually issue a compulsory license.

### ***Malaysia and Indonesia***

Increasingly, other countries are also taking action in order to make ARVs more available and affordable. In Oct. 2003, Malaysia decided to apply 'Government use' provisions in its national law in order to import generic ARVs. A year later, Indonesia used the 'Government use' mechanism for domestic production of several generic ARVs.

## **Options for others**

So what can other countries do? What options are available to increase access to HIV/AIDS drugs? Clearly, the answer will vary considerably

from country to country, depending on relevant national laws, production capacity and other factors. But in principle, the following options exist:

***Countries with pharmaceutical production capability*** could initiate local production of generic versions of those drugs that are not patented or whose patents have expired<sup>9</sup>. They could also consider, *if their national law and regulations allow*, to apply compulsory licensing or 'Government use' to enable local production of generic versions of those drugs that are patent protected.

***Countries where local production is not feasible or not viable*** can import generics, for example from India, provided the drug concerned is not under patent in their territory. In case the drug of interest is patent protected in the importing country, parallel importation could be considered, as long as national legislation allows it - and if a cheaper source of the drug can be found.

The option to (parallel) import obviously is also open to countries that do have manufacturing facilities. Yet a problem looms: major international producers of generics are primarily located in countries such as India, which now have to comply with TRIPS (see Figure 3; India falls in category c). Fortunately, transitional provisions in India's new patent law allow the continued production of generic medicines marketed before 2005. However, Indian pharmaceutical enterprises will have to wait until patent expiry before they can commence the production of new generics. Thus, even when patents in their own territory do not stand in the way, importing countries may face problems in finding a source of supply of generic versions of second line ARVs and other new drugs.

Meanwhile, countries that lack national production capacity would face difficulties in making effective use of compulsory licensing

<sup>9</sup> The first generation of ARVs that were patented in the 1980s will continue to come off patent.

provisions. The basic problem is that while the importing country could use compulsory licensing or ‘Government use’ for importation of the drug from abroad<sup>10</sup>, foreign companies would -because of TRIPS’ condition that a compulsory license should be issued “predominantly for the supply of the domestic market”- face potentially severe restrictions on their capacity to export.

During the WTO meeting in Doha, Ministers recognized this problem, and instructed the WTO’s TRIPS Council to find an expeditious solution. But because of diverging views there has been considerable debate on how to best tackle this inconsistency.

A solution was finally agreed to on 30 August 2003. This solution, which may require two compulsory licenses to be issued (one in the importing and one in the exporting country)<sup>11</sup> and has been criticized as being cumbersome, has not yet been used in practice. This may, among other reasons, be due to the fact that most exporting countries would have to amend their national laws before they can actually export generic medicines produced under a compulsory license – something that Canada, Norway, India, South Korea and China have recently done.

**Figure 3:** Deadlines for implementation of the TRIPS Agreement

a) Developed countries	1996
b) Developing countries (except those under c)	2000
c) Developing countries that did not grant pharmaceutical product patents prior to TRIPS	2005
d) Least developed countries	2016*

\* The original TRIPS implementation deadline for least-developed countries was 2006; however during the WTO Ministerial Meeting in Doha, it has been agreed to extend this deadline.

<sup>10</sup> Using a compulsory license for importation appears to be permissible under TRIPS.

<sup>11</sup> In addition, there are requirements to report to the WTO and on labelling/packaging of the concerned medicines.

## Further reading

1. Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement – WHO, Geneva, 1998.
2. The TRIPS Agreement and Pharmaceuticals – (ASEAN workshop report) MOH/WHO, Indonesia, 2000.
3. Integrating Public Health Concerns into Patent Legislation in Developing Countries – South Centre, Geneva, 2000.
4. Manual on Good Practices in Public-Health-Sensitive Policy Measures and Patent Law – Third World Network, 2003.
5. Implications of the Doha Declaration on the TRIPS Agreement and Public Health – WHO, Geneva, 2002.
6. Protection of Data Submitted for the Registration of Pharmaceuticals – South Centre/WHO, Geneva, 2002.
7. Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health – WHO, Geneva, 2004.
8. Remuneration guidelines for non-voluntary use of a patent on medical technologies – UNDP/WHO, 2005.

Documents 1, 2, 5, 7 and 8 (as well as other relevant materials) can be downloaded from: <http://www.who.int/medicines/>

Documents 3 and 6 can be found at: <http://www.southcentre.org/>

# Data exclusivity and other “TRIPS-plus” measures

## Regulating medicines

The pharmaceutical market is highly regulated. Two sets of laws and regulations play a crucial role in this market. These are i) the intellectual property laws and ii) the laws and regulations about drug registration. These two sets of laws have different objectives, and are administered by different government agencies.

Intellectual property rights, notably patents (on which this briefing note will focus, since they have the most profound implications on access to medicines) are meant to reward innovation by providing inventors with temporary monopoly rights. Patents, however, confer negative rights: a patent on a certain pharmaceutical product means that the patent holder can prevent others from producing or selling that product. But it does not give the patent holder the right to actually sell that medicine. In order to be allowed to sell a medicine, it has to be registered by the national Drug Regulatory Authority.

The drug regulatory system, or registration system, seeks to ensure that only medicines of assured safety, quality and efficacy are available on the national market. This is important, since consumers do not normally have sufficient information and knowledge about a pharmaceutical product to make their own assessment about its quality, safety and efficacy. In addition, medicines that are ineffective or of poor quality can be dangerous, both for the patient and for public health.

In order to assess the quality, safety and efficacy of a product, the Drug Regulatory Authority will normally require the manufacturer to provide relevant information. For instance, in order to assess the quality of the product, samples will have to be tested, the production



procedures will have to be documented and validated, and the production facility may have to be inspected.

Meanwhile, the safety and efficacy of pharmaceuticals is demonstrated mainly via pre-clinical and clinical trials. Safety and efficacy can also be demonstrated by showing that a product is chemically and biologically equivalent to an existing medicine (the safety and efficacy of which are already known). However, by definition, 'bio-equivalence' can *not* be demonstrated for entirely new pharmaceuticals, since there will be no similar existing medicines with which to compare them. Thus, in practice, only generic manufacturers can demonstrate the safety and efficacy of their products via bio-equivalence tests.

This latter point is important, since bio-equivalence tests are much smaller in scale than full-fledged clinical and pre-clinical trials. Thus, they can be conducted faster, and are considerably less expensive.

## Data exclusivity

The clinical and pre-clinical trial data that originator companies submit to the Regulatory Authority are at the centre of the debate on "data exclusivity".

Because bio-equivalence data only prove that a generic medicine behaves in the body in the same way as the original product (the safety and efficacy of which have already been established), one could say that the generic company and the Regulatory Authority indirectly rely on the clinical trial data provided by the originator company.

Originator companies argue that, since they made substantial investment in these trials, they deserve a period of "data exclusivity"; a certain length of time during which the Regulatory Authority cannot rely on the originator's data in order to register a generic version of the same product.

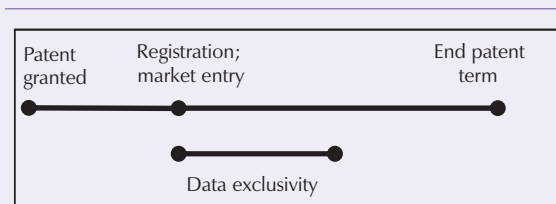
By implication, as long as the exclusivity lasts, generic producers would have to submit their own data to prove safety and efficacy, which would oblige them to repeat the clinical trials and other tests. This is something that would cause significant delay, and that many generic manufacturers cannot afford. Moreover, it would raise serious ethical questions, since it would mean that clinical trials will have to be repeated, purely for commercial reasons.

Alternatively and in practice much more likely generic producers would have to delay the launch of their product until the end of the exclusivity period<sup>1</sup>. Thus, data exclusivity diminishes the likelihood of speedy marketing of generics, and delays competition and price reductions.

## Implications of Data Exclusivity

Proponents of data exclusivity at times point out that data exclusivity does not have major implications, since the period of data exclusivity would normally be shorter than the patent duration (see Figure 1a).

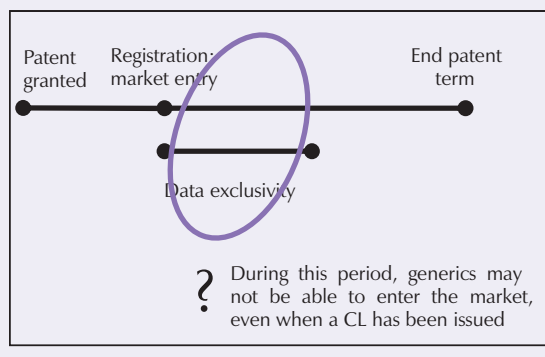
Figure 1a: “standard” situation



Yet, there are some questions as to whether data exclusivity could prevent the registration of medicines produced under a compulsory license (see Figure 1b). If so, data exclusivity would effectively render the compulsory license useless.

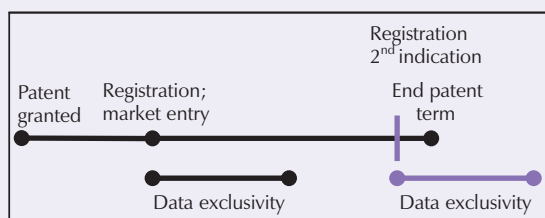
<sup>1</sup> In the United States, data exclusivity lasts five years for new chemical entities and three years for new indications. In the European Union, it is 10 years with a possible one year extension in case the drug is registered for a significant new indication.

Figure 1b: “standard” situation



Secondly, if a period of data exclusivity is also granted when an existing medicine obtains marketing authorization (or registration) for a second or new indication, data exclusivity could (be used to) extend the period of exclusivity of the originator product (see Figure 2).

Figure 2: Second indication



Finally, data exclusivity could prevent the registration of generic versions of medicines even when there is no patent on a medicine, for example when a pharmaceutical does not meet the standards for patentability (e.g. because it is not new), when a country has no patent law, or when no patents are granted for pharmaceuticals. The latter situation can arise in least-developed World Trade Organization

(WTO) Member Countries, which do not have to grant patents for pharmaceuticals until 2016.<sup>2</sup>

## TRIPS does not require data exclusivity

It has at times been argued that Article 39.3 of the TRIPS Agreement makes it mandatory for countries to grant data exclusivity. However, careful reading of Article 39.3 (see Box 3) does not warrant this conclusion; the text of the Article does not make any reference whatsoever to exclusivity or exclusive rights.

Article 39.3 requires countries to protect undisclosed registration data about new chemical entities i) against disclosure and ii) against unfair commercial use. Thus, regulatory authorities may not publish registration data<sup>3</sup>, or share them with third parties (e.g. generic competitors). This is a clear requirement. But there is some debate as to what exactly is meant by ‘unfair commercial use’. Does the use of bio-equivalence studies instead of full clinical trials represent ‘unfair commercial use’?

Clearly, there is no ‘unfair commercial use’ by the generic company. The generic manufacturer never uses the originator’s data, and does not even have access to them. Meanwhile, the regulatory authorities also do not normally use the originator’s data – though, as mentioned above, they may (indirectly) rely on them. But even if the regulators would use those data, this is not commercial use, since the regulatory agency is not a commercial organization. Legal experts have also pointed out that, in the context of Article 39 of TRIPS, the term ‘unfair commercial use’ refers to, and prohibits, practices such as industrial espionage, but was not meant to provide exclusive rights (Correa, 2002). Nor was it meant to interfere with the work of a government body tasked with protecting the public.

2 According to the Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference, Doha, Nov. 2001 (or the “Doha Declaration”).

3 Though it is important to note that they may do so when this is necessary to protect the public.

Thus, legal and public health experts believe that TRIPS requires data protection, but not data exclusivity – and national laws do not need to be more stringent or more restrictive than TRIPS.

### **Box 3: Article 39.3 of TRIPS**

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

It is also worthwhile to note that in developing countries, regulatory authorities often rely on data that are already published or otherwise in the public domain – and that therefore do not fall within the scope of Article 39.3 (which only imposes protection for *undisclosed* data).

## **Mitigating the impact**

As mentioned above, from the perspective of public health and access to medicines, it is preferable not to grant data exclusivity. Moreover, there is no requirement under international law that countries grant data exclusivity; countries only have to provide for data protection.

But if a country, for some reason (see below), *does* grant data exclusivity or otherwise provides data protection beyond that mandated by TRIPS, it is important to limit its potential negative implications on access to medicines. This can for example be done by limiting its duration and/or scope (e.g. only for new chemical entities) and by providing that reliance on the originator's safety and efficacy data is allowed in case of compulsory licensing.

## Other “TRIPS-plus” provisions

Requirements to offer exclusive rights to originator products that go beyond what is mandated by the TRIPS Agreement are sometimes referred to as “TRIPS-plus” requirements. Data exclusivity is an important example. But it is not the only example. Other “TRIPS-plus” requirements are for instance:

- *Patent term extensions*, i.e. provisions to extend the duration of a patent beyond the 20 years required by TRIPS, in order to compensate for delays in granting the patent or in registering the medicine. It is important to note that there is no obligation, from an international/legal perspective, to grant such extensions<sup>4</sup>.
- *Limitations of the grounds for compulsory licenses*, which may preclude issuing a compulsory license for reasons of public health. Requirements to limit the grounds (or reasons) for issuing a compulsory license go directly against the Doha Declaration<sup>5</sup>, which has unambiguously confirmed that countries are free to determine the reasons for granting compulsory licenses.
- *Linkage between patent status and generic registration*, meaning that the Regulatory Authority may not register generic versions of a pharmaceutical that is under patent. This would be problematic, since the Regulatory Authority would probably lack the resources and manpower to check the patent status of each product. Moreover, in case there is a patent, regulators may not have the expertise to assess whether the patent is valid and would be infringed<sup>6</sup>. As a result, it is likely that they will enforce *all* patents, even invalid ones – and thus create additional and unnecessary hurdles for generic competition<sup>7</sup>. “Linkage” is also problematic in

4 Moreover, it should also be noted that at times the patent holder is responsible for those delays.

5 Declaration on the TRIPS Agreement and Public Health, see footnote 2.

6 For these reasons, Regulatory Agencies in the EU have so far refused to implement such “linkage” between patent status and registration of medicines.

7 In 2002, the US Federal Trade Commission found that when generic companies initiate patent litigation, they prevail in a significant number of cases.

view of the fact that patents are private rights; as such, they should be enforced by the right holders, not by the government.

Other “TRIPS-plus” requirements deal with the administrative procedures related to patent applications and/or the granting and revocation of patents. The common feature of all “TRIPS-plus” provisions is that they have the effect to complicate and/or delay the marketing of generics, and thereby reduce access to medicines.

Yet, while these requirements are going beyond the TRIPS Agreement or, in other words, are not required by TRIPS— in recent years, “TRIPS-plus” requirements have at times been incorporated in bilateral or regional free trade negotiations, in bilateral investment agreements and in other international agreements and treaties. From the perspective of access to medicines, this is a worrying trend; countries should therefore be vigilant and should not ‘trade away’ their people’s right to have access to medicines.

#### **Box 4: Expanding data exclusivity requirements**

Initially, requirements for data exclusivity focused on undisclosed data that have been submitted to regulatory authorities. However, more recently, there have been cases where such demands just referred to ‘information’ which could potentially expand the scope of data exclusivity significantly by preventing regulators from relying on data that are in the public domain in order to register a generic medicine.

## **Conclusion**

Medicines fall under two separate legal and regulatory systems: the intellectual property system and the drug regulatory system. These systems have different objectives, are administered separately and function independently. Recent efforts to integrate these two systems via data exclusivity, “linkage” or other means are likely to have negative

implications for access to medicines. Thus, (developing) countries would be well advised to keep these systems separate, and to reject any and all efforts to make connections between them.

## References and further reading

1. Carlos M. Correa. Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement. Geneva: South Centre/WHO, 2002. Available at <http://www.southcentre.org/>
2. Frederick M. Abbott. The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements. Geneva: Quaker United Nations Office, occasional paper no. 14, April 2004. Available at <http://www.quno.org/>
3. MSF. Access to medicines at risk across the globe: what to watch out for in free trade agreements. Medecins Sans Frontieres, May 2004. Available at <http://www.accessmed-msf.org/>
4. Robert Weissman. Public health-friendly options for protecting pharmaceutical registration data. International Journal of Intellectual Property Management (forthcoming).





## Innovation for diseases that mainly affect developing countries: issues and ideas<sup>\*</sup>

This note provides a brief summary of recent thoughts and discussions on stimulating the development of new medicines, vaccines and diagnostics for diseases that are particularly prevalent in developing countries.

### Innovation examined

Medical innovation—the development of new diagnostics, vaccines and treatments—is an important factor in addressing the burden of disease, and there is widespread agreement that it should continue. Moreover, scientific progress, exemplified by the decoding of the human genome, appears to hold enormous promise for the development of new and better medicines. Yet this promise has thus far failed to materialize; the number of new drugs entering the market appears to be decreasing rather than increasing. There also are concerns that the number of products in research and development (R&D) pipelines is insufficient.<sup>1</sup>

Detailed reviews have furthermore drawn attention to the fact that of 1 556 new drugs approved between 1975 and 2004, only 21 (1.3 %) were specifically developed for tropical diseases and TB—diseases that account for over 10% of the global disease burden.<sup>2</sup>

Dissatisfaction with this state of affairs led the World Health Assembly in 2003 to set up an independent Commission on

<sup>\*</sup> Updated version; originally published in November 2006.

- 1 United States Food and Drug Administration. Challenge and opportunity on the critical path to new medical products. Rockville, 2004.
- 2 Pierre Chirac, Els Torreele. Global framework on essential health R&D. *Lancet* 2006; 367: 1560-61.

Intellectual Property Rights, Innovation and Public Health (CIPIH). Its main mandate was to “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”.<sup>3</sup> Members of the CIPIH were drawn from academia, the public health community and the pharmaceutical industry. The CIPIH published its report in April 2006.

### **Box 1: Terms of Reference of the CIPIH**

- Summarize the existing evidence on the prevalence of diseases of public health importance with an emphasis on those that particularly affect poor people and their social and economic impact;
- Review the volume and distribution of existing research, development and innovation efforts directed at these diseases;
- Consider the importance and effectiveness of intellectual property regimes and other incentive and funding mechanisms in stimulating research and the creation of new medicines and other products against these diseases;
- Analyse proposals for improvements to the current incentive and funding regimes, including intellectual property rights, designed to stimulate the creation of new medicines and other products, and facilitate access to them;
- Produce concrete proposals for action by national and international stakeholders.

3 World Health Assembly Resolution WHA 56.27, May 2003.

## IPR, innovation and incentives

The main mechanism to stimulate the development of new medicines is via intellectual property rights (IPR), especially patents—and this has been so for several decades. A patent provides a time-limited monopoly. During the monopoly period, the company that developed the drug (and holds the patent) can sell it at a relatively high price, since there is no competition. Thus, it is during this time that the innovator company that developed the drug earns the most profit from it. These profits, in turn, motivate the innovator to continue investing in research and development (R&D).

The amount of profit depends on the profit margin and the sales volume. However, if only a few people need a particular drug, or if the people who need the drug cannot afford to buy it, sales will be low. As a result, the company will not earn much—may be not even enough to recover the costs of developing the drug.

Intellectual property rights therefore do not—and cannot be expected to—provide effective incentives for the development of new medicines for diseases that mainly or exclusively affect the poor. Nor do they provide sufficient incentives for the development of medicines for ‘orphan’ diseases, that is, rare diseases that affect only a small number of people.

But whereas basic medical research (the “R” in R&D) is conducted in public institutions as well as the private sector (pharmaceutical industry), the development of new products (the “D” in R&D) is almost exclusively undertaken by the pharmaceutical industry. Thus the industry determines to a large extent which new medicines will be developed and marketed, and which ones will not. For companies this is a commercial decision.<sup>4</sup> And because the IPR system’s incentives are linked to sales, companies prioritize

<sup>4</sup> It should however be noted that companies do at times develop or take part in the development of medicines for ‘diseases of poverty’, among others for philanthropic reasons.

the development of medicines for which there is a viable market. The development of medicines for “diseases that disproportionately affect developing countries” gets accorded a low priority—and, as mentioned above, very few such medicines have been developed in the last three decades.

This should not come as a surprise. Nor should the pharmaceutical industry be blamed for what is an inherent limitation of the intellectual property system.

## Means and objectives

It is important to bear in mind that intellectual property rights are a policy tool. The objective is to stimulate innovation.

Yet intellectual property rights have failed to achieve their objective with regard to the development of medicines for diseases that mainly affect developing countries, such as HIV/AIDS, malaria, TB, leishmaniasis and trypanosomiasis. Policy-makers therefore ought to consider making adjustments, or complementing intellectual property rights with other measures.

A prerequisite for inducing positive change is to identify alternative mechanisms. This is one of the issues—and probably the one closest to its mandate—that the CIPIH looked at. The main alternatives considered by the CIPIH are listed below.

## Possible alternative mechanisms to fund R&D

Growing awareness of the limitations of IPR to provide incentives to stimulate R&D for diseases that mainly affect the poor, has led to several proposals to address this problem. Some of those ideas have been developed further than others, and some are more radical than others. The main ideas are summarized below.<sup>5</sup>

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5 For more details, see pages 66-68, 88-94 and 104-107 of the CIPIH report.

- *Public-private partnerships*: These partnerships bring together donors, researchers and private sector actors. The private sector usually contributes ‘in kind’ expertise and is involved in screening for drug candidates. Most partnerships focus on a specific issue or disease; examples include the Medicines for Malaria Venture and the Global Alliance for TB Drug Development. Others, such as the Drugs for Neglected Diseases Initiative, target several diseases.

Public-private partnerships have successfully revitalized R&D in some disease areas that were previously neglected. It is however too early to assess whether these partnerships will succeed in effectively developing new products and making them affordable enough to improve the options for prevention and treatment in developing countries. Moreover, the long-term sustainability of such partnerships is often not ensured.

- *“Sensible” patenting and licensing strategies*: Public research and funding institutions should bear in mind the importance of access to products created based on their inventions, and should adjust their strategies for patenting and licensing accordingly. For example, they could decide not to apply for patents in developing countries. Or they could insist on non-exclusive licensing of their inventions/ the inventions they fund, thereby enabling competition and facilitating access. Since public institutions often focus on ‘upstream’ inventions, this would furthermore facilitate the downstream development of health care products.

Spurred by students, initiatives along these lines—albeit with a focus on access rather than innovation— have garnered support from prominent academics and are being considered by some university technology managers. At least one major pharmaceutical company has announced that, as a matter of policy, it will not file new patent applications in least-developed countries, nor will it enforce its existing patents in those countries.

A leading university in the United States of America has proposed that a broad research exemption be included in licences granted over its patented inventions; this would allow all universities and public research institutions to use those inventions for research purposes. Several other universities have licensed technologies relevant for the development of treatments for Chagas disease, malaria and TB on favorable terms to non-profit enterprises or public-private partnerships.

Moreover, in France, Germany and the United States, rules have been introduced to prevent the granting of overly broad patents on genetic inventions,<sup>6</sup> which could hinder further research and innovation. In the United States of America, the National Institutes of Health have developed draft guidelines that, as a general rule, support non-exclusive licensing of genetic inventions.<sup>7</sup>

- *Patent pools:* A patent pool is an arrangement between several patent holders for the collective management of their patents. Patent pools can be voluntary or imposed by governments. By pooling patents for (certain areas of) medical research, licensing procedures can be centralized and streamlined<sup>8</sup>. The CIPIH recommends this strategy especially for research tools. It is anticipated that, when implemented, patent pools would make access to research tools easier, which in turn would facilitate research in both the public and private sector.

6 Note however that views differ as to whether genetic ‘inventions’ are inventions or discoveries; in the latter case they are not patentable.

7 United States National Institutes of Health. Best practices for the licensing of genomic inventions. Washington, 2004.

8 A patent pool would act as a ‘one-stop-shop’ to obtain a license for all patents relevant to the research that will be undertaken.

The idea of a patent pool is in fact not new; in 1917, the Government of the United States created a mandatory pool of patents that were crucial for the continued development of the aircraft industry. More recently, patent pools have been used in the area of DVD-video and DVD-ROM technology. A patent pool has also been proposed to facilitate access to biotechnology patents.<sup>9</sup>

### **Box 2: Practicalities pertaining to patent pools**

A patent pool can be defined as “the aggregation of intellectual property rights which are the subject of cross-licensing, whether they are transferred directly by the patentee (patent holder) to licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool.”<sup>10</sup>

Patent pools can eliminate problems caused by ‘blocking’ patents, make it easier and faster to obtain licences and reduce transaction costs (e.g. by reducing or eliminating the need for litigation). This, in turn, can accelerate the development of new technologies and products.

Patent pools have been criticized for their potential anti-competitive effect—but it has equally been recognized that they can facilitate competition. In the United States, guidelines exist that specify when a patent pool would be anti-competitive, and when it is pro-competitive.<sup>9</sup>

- *Advance purchase commitments*: The idea is to create a market where there is none, by guaranteeing in advance the purchase of a drug or vaccine that does not yet exist (e.g. a malaria vaccine). It is believed that if the amount and price are high enough, and the commitment

9 Jeanne Clark et al., “Patent pools: a solution to the problem of access in biotechnology patents?”, United States Patent and Trademark Office, White Paper, December 2000.

10 Joel I Klein, United States Department of Justice, quoted in Clark et al (footnote 9).



originates from credible organizations with sufficient financial backing, this would provide an incentive for the development of the desired medicine. Procedural issues are yet to be clarified.

The International AIDS Vaccine Alliance (IAVI) and the Global Alliance for Vaccines and Immunization (GAVI) are considering whether an advance market commitment could play a role in the development of respectively an AIDS vaccine and a vaccine for pneumonia strains commonly encountered in developing countries. Meanwhile, several of the G8 countries have recently pledged funds for a pilot project with advance market commitments.<sup>11</sup>

- *Prize fund:* A “prize fund” is in fact a variation on the idea of an advance purchasing commitment. Instead of rewarding innovators indirectly, via profits on the sale of the final product, a prize fund would directly pay a significant sum as a reward or “prize” to whoever invented a new drug or vaccine for specified diseases. Thus, the innovator would directly be rewarded for his or her invention. The prize would have to be substantial in order to be effective. Here, too, procedures need to be clarified.

But procedural issues can be addressed; in the United States, a Bill to this end has been drafted.<sup>12</sup> Meanwhile, experiments have started as well: one large pharmaceutical company has set up an independent virtual research and development laboratory. This reportedly successful laboratory operates online and offers prizes for solutions to specific problems in biology and chemistry.<sup>13</sup>

11 G8. Fight against infectious diseases. G8 Summit, St Petersburg, 16 July 2006.

12 H.R. 417, The Medical Innovation Prize Fund Act, was introduced to the United States House of Representatives by Representative Sanders on 26 January 2005.

13 William C Taylor, “Here’s an idea: let everyone have ideas”, *New York Times*, 26 March 2006.

### Box 3: A “prize fund” experiment?

On Innocentive’s website (<http://www.innocentive.com>), “seeker” companies and scientists interact in a marketplace. Companies post specific problems (see examples below), and offer rewards for a solution. Reportedly, over US\$ 1.5 million has been paid out over a four year period, and more than 90 000 scientists have registered with the site.<sup>14</sup>

INNOCENTIVE 3084371

Detection of specific DNA sequences

POSTED: Nov 04, 2005

DEADLINE: Under Evaluation

US\$ 5 000

Ideas for rapid and simple detection of specific DNA sequences are needed.

INNOCENTIVE 3159934

Identification of an enzyme

POSTED: Dec 06, 2005

DEADLINE: Mar 07, 2006

US\$ 50 000

Identification of an enzyme with specific properties is required

INNOCENTIVE 3060616

DNA separation

POSTED: Oct 19, 2005

DEADLINE: Feb 20, 2006

US\$ 40 000

A method to separate DNA molecules is needed.

<sup>14</sup> New Scientist, 8 April 2006, p. 59.

- *Medical R&D treaty*: The basic idea of an R&D treaty is that governments commit to spending a certain percentage of the national income on medical R&D, but would be free to decide the mechanism for doing so. Governments would be able to choose the current IPR system, or to fund medical research directly, or to select any of the mechanisms listed above. If a government for example would opt to directly fund research (e.g. by giving grants to research institutions or via a prize fund), it would not have to respect patents on pharmaceuticals, since the country would already have paid its fair share of medical R&D.

Most of these proposals and ideas need to be developed and examined further, with a critical but open mind—and efforts to do this are already taking place. Moreover, it should be borne in mind that this is not an exhaustive list; it merely is a brief overview of some of the main ideas that have been assessed by the CIPIH.

## Thoughts on the way forward

The fact that all but one of the above-mentioned suggestions are already being considered or tried out seems to indicate that they may have potential. The exception is the “R&D treaty”, which is not being tried or tested, since the majority of countries are—via international (trade) treaties and/or other obligations—locked into the current IPR system.

At the same time, some of the proposals have been criticized for lack of evidence that they will work. This is true, but new and innovative approaches suffer by definition from such a lack of evidence. There is however evidence that the current IPR system is not particularly successful in delivering new treatments for diseases that disproportionately affect developing countries.

#### Box 4: Dubious proposals

Several ideas have been examined and discarded by the CIPIH. These include:

- *orphan drug schemes*: developed originally in the United States, these schemes have successfully provided incentives for the development of medicines for rare diseases. One of their main features is the provision of exclusive marketing rights, which provide an incentive since the target population, while small, has the ability to pay. But it is unlikely that such schemes would effectively stimulate the development of medicines for which there is no market;
- *tax credits/tax reduction*: such schemes cannot be expected to work where there is no market and hence no profit to be made (and no tax to be paid);
- *transferable IPR*: if a company develops a drug for a ‘disease of poverty’ (on which it will not make a profit), it would be rewarded by an extension of the patent term of another, existing drug of its choice on which it is making a profit. However, this essentially means solving one problem by creating another.

It must be underlined that these proposals are not mutually exclusive; rather, they should be seen as a menu of options. The challenge is to find the right mix, at the national and global level.

Moreover, none of the ideas listed above seek to replace or abandon the IPR system. Rather, they are attempts to fine-tune its implementation or to create alternatives that can be implemented side-by-side. Contrary to the belief of some, even the R&D treaty does not seek to abandon the IPR system *per se*; any country would be free to choose IPR as its preferred mechanism to fund R&D. The treaty would simply provide countries with other ways and means—that may be better suited to their domestic capacity and priorities—to achieve the objective of encouraging medical R&D.

### Box 5: Expanding the clinical trial infrastructure

Other CIPIH recommendations focus on expanding the infrastructure and capacity to conduct clinical trials in developing countries. If implemented, this could accelerate late stage development and marketing of products already in the pipeline. It could also facilitate product development by national companies in developing countries—though as long as they are subject to the prevailing commercial incentives there is little a priori reason to believe that these companies will specially target ‘diseases of poverty’. Meanwhile, expanding the infrastructure and capacity for clinical trials will, by itself, probably do little to increase (basic) innovation in developing countries.

### Further reading

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# Addendum

## CIPIH recommendations pertaining to alternative mechanisms to fund R&D

The report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) contains a number of specific recommendations pertaining to alternative mechanisms for encouraging medical R&D for diseases that disproportionately affect developing countries. These recommendations are listed below.

### ***“Sensible” patenting and licensing strategies (Recommendation 2.7)***

Countries should seek through patenting and licensing policies to maximize the availability of innovations, including research tools and platform technologies, for the development of products of relevance to public health, particularly to conditions prevalent in developing countries. Public funding bodies should introduce policies for sensible patenting and licensing practices for technologies arising from their funding to promote downstream innovation in health-care products.

### ***Patent pools (Recommendation 2.8)***

Patent pools of upstream technologies may be useful in some circumstances to promote innovation relevant to developing countries. WHO and WIPO should consider playing a bigger role in promoting such arrangements, particularly to address diseases that disproportionately affect developing countries.

## ***Public-private partnerships (Recommendations 3.2 and 3.3)***

To enhance the sustainability of public–private partnerships:

- Current donors should sustain and increase their funding for R&D to tackle the health problems of developing countries.
- More donors, particularly governments, should contribute to increase funding and to help protect public–private partnerships and other R&D sponsors from changes in policy by any major donor.
- Funders should commit funds over longer time frames.
- Public–private partnerships need to continue to demonstrate that they are using their money wisely, that they have transparent and efficient mechanisms for accountability, that they coordinate and collaborate, and that they continue regularly to monitor and evaluate their activities.
- The pharmaceutical industry should continue to cooperate with public–private partnerships and increase contributions to their activities.
- Research institutions in developing countries should be increasingly involved in executing research and trials.

WHO should initiate a process to devise mechanisms that ensure the sustainability and effectiveness of public–private partnerships by attracting new donors, both from governments and the private sector, and also to promote wider participation of research institutions from developing countries. However, governments cannot passively rely on what these partnerships could eventually deliver; there is a need for a stronger commitment on their part for an articulated and sustainable effort to address the research gaps identified in this report.

### ***Advance purchase commitments (Recommendation 3.5)***

Governments should continue to develop forms of advance purchase schemes which may contribute to moving later stage vaccines, medicines and diagnostics as quickly as possible through development to delivery.

### ***Medical R&D treaty (Recommendation 3.6)***

Recognizing the need for an international mechanism to increase global coordination and funding of medical R&D, the sponsors of the medical R&D treaty proposal should undertake further work to develop these ideas so that governments and policy-makers may make an informed decision





## Country experiences in using TRIPS safeguards

This note provides a brief overview of countries' experiences in using the safeguard mechanisms available in the TRIPS Agreement to protect public health and access to medicines. It is written in response to requests to share such experiences.

### Compulsory licensing in developing countries

While the TRIPS Agreement contains several safeguard mechanisms, probably the most important one is compulsory licensing. A compulsory license (CL) is a license granted by the government to allow the use of a patented invention, without the permission of the patent holder. Virtually all patent laws contain provisions for compulsory licensing, and compulsory licensing is allowed under TRIPS. A CL allows the production, import, sale and use of generic products before expiry of the patent. A special case of compulsory licensing is "government use" (or a CL for public non-commercial use), i.e. when a government itself uses, or authorizes a third party to use, a patented invention for government purposes, without the permission of the patent holder.

In the past five years, several developing countries have issued compulsory licences in order to increase access to medicines<sup>1</sup>.

#### Malaysia

In November 2002, after efforts to negotiate price reductions had failed, the Ministry of Health (MoH) of Malaysia proposed the use of "government rights" to the Cabinet. In January 2003, upon receiving approval, the MoH applied to the Ministry of Domestic Trade and Consumer Affairs

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1 The examples listed in this briefing note do not represent a complete or comprehensive list.

(custodian of the Patents Act) for an authorization to import generic versions of patented antiretrovirals (ARVs). In spite of the Cabinet approval, the authorization was opposed by some other government agencies, citing concerns that it would deter foreign investors.

On 29 October 2003, however, the authorization for the exploitation of a patented invention on behalf of the government (government use authorization) was issued. It allowed a local company to import didanosine tablets, zidovudine tablets and a fixed-dose combination (FDC) of didanosine+zidovudine from a generic manufacturer in India.

The authorization was valid for two years. It required that the medicines be labelled with the words “Ministry of Health Malaysia” and imposed several other conditions, including a maximum price and a requirement that royalties be paid to the patent holder(s) within two months of importation of each successive batch. While the authorization did not specify the royalty rate, the MoH offered the patent holders 4% royalties. The patent holders however showed little interest in accepting or negotiating the proposed remuneration.

Following the government use authorization, the patent holders reportedly reduced their prices by 50-80%. However, treatment costs were still lower when using generics, and the number of patients treated with (generic) ARVs in the public sector more than doubled.

In reaction to the government use authorization, one of the patent holders filed a lawsuit –which, however, was never activated– while complaints were received at some Malaysian embassies.

On 1 November 2005, the authorization expired. It was not renewed, since price reductions offered by the patent holders were considered satisfactory.

## ***Zimbabwe***

On 8 April 2003, Zimbabwe issued a CL for all HIV and AIDS-related medicines. The licence was issued after a period of emergency on

HIV/AIDS was declared. The declaration of emergency was issued in accordance with Zimbabwe's own national law; it is not a TRIPS requirement (see box 1). The CL allows a local company, Varichem Pharmaceuticals Ltd, to produce ARVs or HIV/AIDS-related medicines during the emergency period. The licence requires the company to supply three quarters of its production to state-owned health institutions and specifies that the medicines produced under the licence will be subject to price controls.

Varichem reportedly launched its first ARV in Zimbabwe in October 2003, and has since launched several other ARVs. It supplies to both the government and private sector.

### **Box 1: The “emergency myth”**

There is a widespread misunderstanding that TRIPS allows for compulsory licensing only when there is an emergency. This is not correct; TRIPS leaves countries free to decide the grounds, or reasons, for issuing a compulsory license. TRIPS does however impose a number of conditions.

One of those conditions is that there should first be an effort to obtain a voluntary license from the patent holder. This particular condition is waived in three cases: i) when there is an emergency, or in case of “other circumstances of extreme urgency”; ii) in case of public non-commercial use (or government use); or iii) when the compulsory license is granted to remedy anti-competitive behaviour.

## ***Zambia***

On 29 September 2004, Zambia issued a CL to allow a domestic company to manufacture a FDC of lamivudine+stavudine+nevirapine. The CL prohibits export, and specifies that the total amount of royalties payable to the patent holder(s) shall not exceed 2.5% of the turnover of the product.

## ***Indonesia***

On 5 October 2004, a presidential decree was issued in Indonesia authorizing the Minister of Health to appoint a manufacturer to exploit patents on lamivudine and nevirapine on behalf of the government. The decree specifies a royalty rate of 0.5% of the net (generic) sales price. The authorization lasts for seven years (nevirapine) and eight years (lamivudine), i.e. for the remaining patent term. In March 2007, the decree was amended to include efavirenz. The decree was issued –and amended– in a low key manner, and does not appear to have attracted any criticism.

## ***Thailand***

In the late 1990s, the Government Pharmaceutical Organization (GPO) started producing generic versions of ARVs that were not patented in Thailand, or for which the Thai patent had expired. One important drug, didanosine (ddI), was under patent in Thailand; however, the patent only applied to ddI tablets. Hence in January 2000, the GPO started producing ddI powder; the powder form, while not as convenient or as accurate a dosage form as tablets, did not infringe the patent.

Subsequently, in October 2002, following a challenge by people living with HIV/AIDS, Thailand's Central Intellectual Property and International Trade Court ruled that the ddI patent was only valid for tablets containing 5-100 mg ddI. This ruling allowed generic manufacturers, such as the GPO, to produce ddI tablets outside that dosage range (e.g. tablets containing 125 mg ddI).

Thailand issued its first CL in November 2006, for efavirenz. About two months later, the first consignment of generic efavirenz was imported from India<sup>2</sup>, at half the original price. In January 2007, two

<sup>2</sup> Generic efavirenz is being imported, at least initially. Meanwhile national companies have started preparations for local production.

more CLs were issued, for lopinavir/ritonavir and for a cardiovascular drug, clopidogrel. This was the first time a developing country used compulsory licensing in relation to a non-communicable disease.

Thailand's actions were widely reported in national and international media, and drew mixed reactions. Notably the inclusion of a cardiovascular drug generated controversy<sup>3</sup>. One of the affected companies withdrew seven pending applications for registration of new drugs in Thailand, thus effectively withholding them from the Thai market<sup>4</sup>. Meanwhile the United States Trade Representative referred to these CLs when adding Thailand to its "priority watch list" of countries whose level of intellectual property protection and/or enforcement it considers to be inadequate<sup>5</sup>, while at the same time acknowledging that Thailand had the right to issue compulsory licenses.

### **Box 2: Authorizing "government use"**

Procedures for issuing a compulsory license vary among countries. In Indonesia, government use has to be authorized by presidential decree. In Malaysia, the Minister of Domestic Trade and Consumer Affairs has the authority to do so, while in Thailand "any ministry, bureau or department of the government" has this authority.

These differences are caused by differences in the national laws; TRIPS does not specify at what level a compulsory license/government use can or should be authorized.

- 3 The TRIPS Agreement does not limit compulsory licensing to particular products or to products for certain diseases.
- 4 On 25 May 2007, Abbott announced it had resumed efforts to register one of the products (the heat-stable version of lopinavir/ritonavir).
- 5 Countries on this list are the focus of increased US attention. If they do not attempt to address the policies/actions at issue, they may be marked as "Priority Country", which may, eventually, lead to trade sanctions.

In January 2008, the Ministry of Public Health of Thailand endorsed government use of patents on several cancer medicines.

## **Brazil**

Brazil, like Thailand, has a government-owned company that produces generic versions of certain ARVs, which are not under patent in Brazil. In addition, Brazil has used the fact that it is capable of producing generic versions of crucial HIV drugs, and that it would be willing to issue a CL if necessary, to negotiate substantial price discounts for those drugs that are patented. For several years, this strategy was quite successful, and Brazil did not actually have to issue a CL.

However, on 24 April 2007, the Minister of Health passed Decree n° 866, declaring that efavirenz would be eligible for compulsory licensing for public non-commercial purposes. This was followed, on 4 May 2007, by the issuing of a CL for public non-commercial use of efavirenz. The CL is valid for a period of five years, and specifies a royalty rate of 1.5%.

This action was taken after price negotiations with the patent owner, begun in 2006, failed. The time lag between the passing of Decree n° 866 and the issuing of the CL was intended to allow the patent owner to submit a better price offer. Reportedly, a 30% price reduction was proposed, which however was considered insufficient, since the patent holder had offered a significantly lower price to Thailand.

Following the issuing of the CL, the first consignment of generic efavirenz was imported<sup>2</sup> on 2 July 2007, at a price reduction of 65-70% (depending on dosage).

The decision to issue a CL has been criticised, among others, by the patent holder, citing it would have a negative impact on Brazil's ability to attract inward investment.

## Compulsory licensing in developed countries

Compulsory licences have also been used in developed countries. Some examples are listed below<sup>1</sup>.

### Canada

Before it acceded to the North-American Free Trade Agreement (NAFTA) in 1992<sup>6</sup>, Canada made extensive use of compulsory licensing to promote the public interest; thus, between 1969 and 1992, there were 1030 applications to import or manufacture medicines under such licences, of which 613 were granted<sup>7</sup>. From 1970 to 1978, 142 CLs were issued on 47 prescription drugs. Prices of generic versions were 20-60% below the original price, depending on the number of competitors.<sup>8</sup>

### United States of America

Unlike most other countries, the United States of America has never enacted a law that generally authorizes compulsory licensing of patents in the public interest. However, “the United States Government has broad powers to seize and use any invention protected by privately owned patents, subject to the payment of reasonable and entire compensation, and it makes extensive use of this power.”<sup>7</sup> Compulsory licences are also granted in cases of antitrust violations. In the United States, any department of the federal government can use or authorize “government use” of a patent. The United States government does not have to negotiate first, and neither the government nor its contractors can be sued for infringement; the patent holder’s only remedy is to seek compensation.

6 NAFTA is a pre-TRIPS trade agreement, but contains provisions on intellectual property rights that are very similar to those in TRIPS.

7 ICTSD/UNCTAD, 2003. *Non-voluntary licensing of patented inventions: historical perspective, legal framework under TRIPS, and an overview of the practice in Canada and the USA*.

8 Lexchin, J. Pharmaceuticals, patents, and politics: Canada and Bill C-22. *Int J Health Serv*, 1993; 23(1): 147-160.



While the majority of compulsory licences in the United States are not for pharmaceuticals, the possibility of using this mechanism has been contemplated seriously for ciprofloxacin, in the wake of the 2001 anthrax scare.

Examples related to medical devices include a compulsory license on intellectual property related to drug-eluting stents with a rapid exchange delivery system (granted in 2005), and on patents directed to guiding-catheters for performing angioplasty (granted in 2006).

## Compulsory licensing under the WTO “30 August decision”

The WTO’s decision of 30 August 2003<sup>9</sup> sets up a system that allows production of a pharmaceutical product under a compulsory license for export to a country that lacks domestic manufacturing capacity, provided certain procedures are followed<sup>10</sup>.

### *Canada and Rwanda*

In July 2007, Rwanda notified the WTO secretariat of its intention to import 260 000 packs of a FDC of zidovudine + lamivudine + nevirapine from Apotex, a generic manufacturer in Canada. This is the first attempt to make use of this system. The notification states that Rwanda reserves the right to modify the quantity as necessary. It furthermore states that Rwanda will make use of its right, as a least-developed country, not to enforce any patent rights that may have been granted with regard to this product.

Following this request, the Canadian Commissioner of Patents granted, in September 2007, a CL to Apotex, allowing Apotex to manufacture the concerned product exclusively for export to Rwanda. This CL is valid for a period of two years.

<sup>9</sup> WTO document WT/L/450.

<sup>10</sup> For more information, see documents 1 and 3 in the further reading section (at the end of this briefing note).

**Summary Table: Examples of compulsory licenses by/for developing countries<sup>1</sup>**

Date	Country	Type	Product	Duration	Royalties
April 2003	Zimbabwe	CL	all HIV/AIDS-related medicines	not indicated	not indicated
Oct. 2003	Malaysia	GU	<ul style="list-style-type: none"> <li>• didanosine</li> <li>• zidovudine</li> <li>• FDC didanosine + zidovudine</li> </ul>	2 years	not indicated
Sept. 2004	Zambia	CL	FDC of lamivudine + stavudine + nevirapine	until notification of expiry of the compulsory licence	2.5%
Oct. 2004	Indonesia	GU	<ul style="list-style-type: none"> <li>• lamivudine</li> <li>• nevirapine</li> </ul>	7-8 years (remaining patent term)	0.5%
Nov. 2006	Thailand	GU	efavirenz	until 31 December 2011	0.5%
Jan. 2007	Thailand	GU	lopinavir/ritonavir	until 31 January 2012	0.5%
Jan. 2007	Thailand	GU	clopidogrel	patent expiry or no longer needed	0.5%
March 2007	Indonesia	GU	efavirenz	until 07 August 2013	0.5%
May 2007	Brazil	GU	efavirenz	5 years	1.5%
Sept. 2007	Canada for export to Rwanda	CL	FDC of lamivudine + zidovudine + nevirapine	2 years	2%
Jan. 2008	Thailand	GU	several cancer drugs	patent expiry or no longer needed	3-5%

CL = compulsory license; GU = government use (CL for public non-commercial use).

## Other TRIPS flexibilities

Compulsory licensing, and other safeguards such as parallel importation, are important mechanisms that allow governments to protect the public health interest after a patent has been granted (i.e. these are “post-grant” safeguards). However, some countries have focused on using “pre-grant” flexibilities instead. Pre-grant flexibilities seek to ensure that patents are not granted unnecessarily (e.g. when a country has no obligation to grant patents, or when an invention does not deserve a patent). Examples of pre-grant flexibilities include pre-grant opposition (see example of India below) and the right to define the standards for patentability.

### ***Cambodia***

Cambodia enacted a TRIPS-compliant patent law in 2003, and joined the WTO in October 2004. Under the Doha Declaration on the TRIPS Agreement and Public Health, Cambodia and other least-developed WTO Member States have the right to postpone the implementation of patents for pharmaceuticals until 2016. Cambodia has made use of this right by explicitly incorporating it in its patent law (see box 3).

#### **Box 3: Article 136 of Cambodia’s Law on Patents**

“The pharmaceutical products mentioned in the Article 4 of this Law shall be excluded from patent protection until January 01, 2016, according to the Declaration on Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health of the Ministerial Conference of World Trade Organization dated November 14, 2001 in Doha of Qatar.”

### ***India***

In March 2006, a coalition of public-interest groups filed an opposition against GlaxoSmithKline (GSK)’s application for a patent on Combivir

(a FDC of zidovudine+lamivudine). Referring to section 3(d) of India's Patents Act (see box 4), they argued that "a combination of two drugs in one pill is not considered an invention under Indian patent law"<sup>11</sup>; therefore no patent should be granted. Following the filing of the pre-grant opposition and public protests, in June 2006, GSK announced the withdrawal of pending patent applications for a FDC of zidovudine+lamivudine in India (as well as Thailand).

#### **Box 4: Section 3(d) of India's Patents Act (2005)**

"The following are not inventions within the meaning of this Act, - [...]

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation – For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."

In 1998, Novartis filed a patent application for the beta crystalline form of imatinib mesylate (Gleevec), an anti-cancer drug. The application was opposed by several Indian generic manufacturers as well as a cancer patient group, who alleged, among others things, that the claimed invention was not patentable under section 3(d) of the Patent (Amendment) Act 2005. According to the opponents, Gleevec

<sup>11</sup> Pepper, D. "Patently unfair". *Fortune Magazine*, 18 Sept. 2006.

is a polymorph form of imatinib mesylate; section 3(d) considers polymorphs to be the same substance unless they differ significantly in proprieties with regard to efficacy – which they held was not the case. The patent office rejected the application, and the patent was not granted in India.

Novartis challenged the decision to reject the patent application in Court<sup>12</sup>. Moreover, in a separate court case, the company challenged the relevant section (section 3(d) ) of the Patents Act under both the Indian Constitution and the TRIPS Agreement.

The Chennai High Court found that the concerned article did not run counter to the Indian Constitution, and dismissed the second challenge, on the ground that it has no jurisdiction to decide compliance with TRIPS.

## Competition law

Another important mechanism to protect access to medicines is competition law (or anti-trust law). The examples below briefly illustrate this.

### *South Africa*

In September 2002, several people living with HIV/AIDS and a nongovernmental organization filed a complaint with the Competition Commission of South Africa against GlaxoSmithKline and Boehringer Ingelheim. According to one of the complainants, the complaint was filed after a campaign that lasted nearly four years, requesting pharmaceutical companies to issue unconditional voluntary licences, against a fair royalty rate of 4-5%. Since companies failed to respond, “now we are asking the Competition Commission to investigate the complaint and to refer it to the Competition Tribunal”<sup>13</sup>.

<sup>12</sup> In April 2007, the case was transferred to the Intellectual Property Appellate Board. As of 29 February 2008, it is still pending.

<sup>13</sup> Treatment Action Campaign. Statement on Excessive Pricing Complaint to Competition Commission. 19 Sept. 2002.

The case was settled on 9 December 2003. Boehringer Ingelheim agreed to offer licences for nevirapine to Aspen Pharmacare Holdings Ltd and to two other appropriate “entities”. According to the settlement, these licences would allow supply to both the public and private sectors, permit export to other sub-Saharan African countries and carry a maximum royalty rate of 5%. A very similar settlement was concluded with GlaxoSmithKline for zidovudine and lamivudine.

Since receiving these licences, Aspen has obtained WHO prequalification for several of its products. Its prices for the public sector are competitive; in March 2005, the company was granted a significant share of the South African government’s ARV tender.

### *Italy*

In March 2007, the Italian Competition Authority ordered Merck & Co. Inc. to provide free licences for the manufacture and sale in Italy of the active ingredient finasteride (used in the treatment of prostate hypertrophy) and related generic drugs. In an earlier investigation in 2005, the Competition Authority had already obliged Merck to grant licenses for its antibiotic combination imipenem+cilastatin, in order to rectify alleged abuse of a dominant market position, while in February 2006 its investigations led GSK to license its migraine drug sumatriptan succinate.

### **Lessons**

Some preliminary conclusions and lessons can be drawn from these experiences. These include:

- compulsory licensing can be used, and has been used, to protect public health, in developed and developing countries;
- while the number of instances of compulsory licensing by developing countries is relatively limited, those experiences

show that compulsory licensing/government use can be an effective mechanism;

- a compulsory license, or a “credible threat” to issue one, can be instrumental in obtaining price reductions from the patent holder;
- various “pre-grant” flexibilities can play a complementary role in safeguarding access to medicines. In addition, the role of competition law could be explored further.

This underscores the need for incorporating workable provisions for compulsory licensing and government use, as well as other (pre-grant) safeguards, in national laws. Yet even though compulsory licensing is allowed under TRIPS, some developing countries have experienced criticism and/or pressure when using this safeguard mechanism<sup>14</sup> – thus there appears to be a need to safeguard the safeguards.

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14 However, no country has had its decision to issue a compulsory license challenged at the WTO Dispute Settlement Body, which would be the appropriate forum for dealing with actions that contravene the TRIPS Agreement.

# Implications of bilateral free trade agreements on access to medicines<sup>1</sup>

## Abstract

The TRIPS Agreement of the World Trade Organization (WTO) mandated the introduction of protection of intellectual property rights, notably patents, for pharmaceutical products. While the implications for the access to medicines contained in the terms of this Agreement raised significant concerns, a recent new wave of free trade agreements, negotiated outside the WTO, requires even higher levels of intellectual property protection for medicines than those mandated by that Agreement. The measures involved include the extension of the patent term beyond 20 years; prohibition of use of test data on drug efficacy and safety for certain periods for the approval of generic products; the linkage between drug registration and patent protection; in some cases, limitations to the grounds for granting compulsory licences. This article reviews some of these measures that further limit the competition of generic products and discusses their possible implication for access to medicines.

<sup>1</sup> Carlos Maria Correa. Originally appeared in Bulletin of the World Health Organization 2006; 84:399-404.



## Introduction

Medicines, like any other products, can be protected by intellectual property rights, such as patents. Such protection means that their production, importation and commercialization are subject, for a given period, to exclusive rights that allow title-holders to charge prices above marginal costs. These prices may mean, especially for poor people living in developing countries, that a large part of the population is deprived access to the medicines they need.

With the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),<sup>1</sup> most countries have accepted to provide a minimum level of protection of intellectual property rights, including patent protection for 20 years (calculated from the date of filing of the patent application). The TRIPS Agreement has generated a massive change in the legislation of developing countries, which now provide patent and data protection for pharmaceutical products (i.e. protection on clinical data against unfair commercial use). Only the least developed countries were permitted to delay introduction of such protection until 2016.<sup>2</sup>

While developing countries were adapting to the new intellectual property rules mandated by the TRIPS Agreement (which generally entered into force in these countries in 2000) and implementing measures to manage the foreseeable increase in the cost of medicines, a further wave of international agreements, in this case of a bilateral nature, has emerged. These new free trade agreements (FTAs), negotiated outside the World Trade Organization (WTO), require even higher levels of intellectual property protection for medicines than those mandated by the TRIPS Agreement, and in some cases go beyond what is required in the developed countries that are promoting them.

This article reviews certain clauses contained in some of the FTAs that may have an important impact on access to medicines, since they delay or restrict competition from generics. The focus will be on the FTAs negotiated by the USA, which are more comprehensive and elaborate than those negotiated by the European Union (EU) and European Free Trade Association (EFTA) countries.

## Background and method

The requirements imposed by the TRIPS Agreement on medicines, and the flexibilities left for their implementation, have been extensively studied by scholars, nongovernmental organizations, and international organizations such as WHO.<sup>3</sup> Since 2001 the USA has initiated 11 bilateral and regional free trade agreements with 23 countries. In this respect, agreements with Chile, Jordan, Morocco, Singapore, the countries of Central America (plus the Dominican Republic) have been ratified by the US Congress (see Footnote a), while six free trade agreements with 13 additional countries have been initiated and are under negotiation (see Footnote b). Other FTAs have been signed by or are under negotiation between developing countries and the EU or EFTA (see Footnote c).

A common feature of these agreements is that they include TRIPS-plus standards, i.e. they require the protection of intellectual property rights beyond what was internationally agreed upon in the TRIPS Agreement. It is to be expected that the longer and stronger intellectual property rights required by such TRIPS-plus standards will reduce access to medicines in low- and middle-income countries considerably more than in high-income countries. Although these FTAs have only started to be implemented (or are yet to enter into force), there is a growing body of literature critically examining their likely impact, particularly on public health.<sup>4-12</sup> In contrast, there is still a dearth of studies on the reasons why developing countries opt to enter into FTAs, as well as on the extent to which the associated expected commercial benefits (which may be ephemeral as competitive

situations change) might outweigh the higher public health costs they are likely to bear. Substantial health-related costs were estimated in the context of the FTA negotiations between Andean countries and the USA,<sup>13,14</sup> but the governments of Peru and Colombia accepted a broad set of TRIPS-plus standards, despite the adverse opinion of their public health authorities.

This paper is based on an extensive review of the literature, including some studies that estimate the possible public health costs of introducing TRIPS-plus protection for pharmaceuticals.<sup>13,14</sup>

## Findings

### *The TRIPS Agreement*

The TRIPS Agreement obliged all WTO Members to provide patent protection for pharmaceuticals, defined the exclusive rights conferred to patent owners, limited the possible exceptions to such rights, and determined the conditions for the granting of compulsory licences. It also introduced, for the first time in an international agreement: the obligation to protect data against unfair competition.<sup>15</sup>

Soon after the adoption of the Agreement, serious concerns were raised about its possible impact on public health.<sup>3</sup> As a result of strong tensions arising from its implementation (as illustrated by the case initiated by a number of pharmaceutical companies against the Government of South Africa,<sup>16</sup> the Fourth WTO Ministerial Conference (held on 9–14 November 2001) adopted the Doha Declaration on the TRIPS Agreement and Public Health.<sup>17</sup> The Declaration recognized the “gravity” of the public health problems afflicting many developing and least developed countries, especially — but not limited to — those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. While acknowledging the role of intellectual property protection “for the development of new medicines”, it 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". The Declaration confirmed a number of flexibilities that Members can use to implement the Agreement, including the adoption of an international principle of exhaustion of rights (under which parallel imports may be accepted) and the granting of compulsory licences (under which the government or a third party can, subject to certain conditions, use a patented invention without the consent of the patent owner).

The adoption of this Declaration and, subsequently, of a Decision aimed at facilitating the importation of medicines by developing countries without manufacturing capacity in pharmaceuticals,<sup>18</sup> was an attempt to ensure, through the effective use of the permitted flexibilities, some balance in the implementation of the TRIPS Agreement and, in particular, that public health be given priority in case of conflict with intellectual property rules. The wave of FTAs referred to above represents a drastic setback in this respect, since they not only erode such flexibilities but impose a number of additional obligations on states that can further restrict their access to medicines.

## **TRIPS-plus under free trade agreements**

Analysis of the FTAs already signed and those under negotiation indicates that the inclusion of a number of TRIPS-plus provisions is a common feature. Although there are differences, all these FTAs increase the term and scope of protection for pharmaceuticals, on the general argument that the current levels of protection (even if TRIPS compliant), do not permit adequate recovery of R&D costs. Some of the additional standards that are likely to have significant implications for access to medicines are examined below.

## Patent term extension

Under the TRIPS Agreement, patents must last for 20 years from the date of application. Economists have for a long time debated about the optimal patent life, only to come to the conclusion that depends on each particular invention or class of inventions, and that determining it a priori would be costly and in some cases simply impossible.<sup>19,20</sup> The pharmaceutical industry, using the argument that, in the case of pharmaceuticals, the need to obtain marketing approval of new chemical entities reduces the *effective* term of patent protection and the possibility of recovering research and development R&D costs, has obtained the right to extend the patent term to compensate for delays in the examination of the patent application and in the process of marketing approval in some settings (e.g. the USA and in the EU).

The FTAs promoted by the USA oblige the partner signatory countries to extend the patent term to compensate for “unreasonable” delays beyond a certain period, a) in the procedures for the marketing approval of a medicine and b) in the examination of patent applications.

As far as the delays in procedures for the marketing approval of a medicine are concerned, most agreements do not mention whether the extension shall apply only to delays in the country where it is sought (although it would be legitimate to interpret that it this way) or whether the delay in the country where the first approval was obtained should also be taken into account. This has been clarified, however, in the case of Bahrain, which has been obliged to take into account the delays also in a foreign country (FTA Article 15.6. (b)(ii)).

No maximum period is provided for the extension. Paradoxically, this constitutes a remarkable difference between these FTAs and the current law in the USA, where provision is made for some time-limits. The extension in the USA to compensate for delays in the marketing approval process does not exceed five years and, in no case, should exclusivity exceed fourteen years from the date of approval by the Food and Drug Administration (35 U.S.C. § 156 Extension of patent

term, see: [http://www.uspto.gov/web/offices/pac/mpep/documents/appxl\\_35\\_U\\_S\\_C\\_156.htm](http://www.uspto.gov/web/offices/pac/mpep/documents/appxl_35_U_S_C_156.htm)). In addition, the extension applies to only one patent per product. Due to the shortening of the marketing approval time in the last years,<sup>21</sup> the extension provisions in the USA are not applied in practice.

## ***Data exclusivity***

The TRIPS Agreement requires WHO Members to protect *undisclosed* test data on pharmaceutical (and agrochemical) products against unfair competition (TRIPS Article 39.3). Under this rule, correctly interpreted, Members are not obliged to grant exclusive rights over data, as is done under the *sui generis* regimes established in the USA, the EU, and in other countries.<sup>22</sup>

The FTAs negotiated by the US drastically depart from the TRIPS standard. They oblige the Parties to grant exclusive rights for at least five years counted from the date of approval of the product, irrespective of whether it is patented or not and, in most cases, of whether the data are undisclosed or not. Such exclusivity will apply irrespective of whether the national health authority requires the submission of the data or not (i.e. even in cases where it relies on the approval made in a foreign country) and covers chemical entities that are not “new”, as they may have been previously approved in other territories. In addition, in the case of the CAFTA–Dominican Republic FTA, a waiting period of five years is provided for. According to Article 15.10.1 (b) of this agreement, a Party may require that the person providing the information in another territory seek approval in the Party within 5 years of obtaining marketing approval in the other territory. Thus, the originator of the test data enjoys a full ten years of exclusivity during which no other individual would be able to use, without his consent, directly or indirectly, the relevant test data.

## ***Linkage***

The US FTAs require a *linkage* between drug registration and patent protection, which is absent in the TRIPS Agreement. As a result, the national health authority must refuse marketing approval to a generic version of a product if a patent thereon is in force, unless by consent or acquiescence of the patent owner. In addition, such authority must inform the patent owner about applications for the approval of generic products.

## ***Other standards***

In addition to the TRIPS-plus standards mentioned above, some FTAs restrain WTO Members' freedom, confirmed by the Doha Declaration, to determine the grounds for compulsory licences. Thus, in the case of the FTAs agreed between the US and Australia, Jordan, and Singapore, such grounds are limited to cases of anticompetitive practices, public non-commercial use, national emergency or other circumstances of extreme urgency. This limitation, which openly contradicts the Doha Declaration, does not appear in other FTAs that the US has entered into with developing countries after the adoption of the Declaration.

The possibility of parallel importing of medicines and other products (i.e. importing a patented product that has been legitimately put on the market abroad, without the consent of the patent owner) has also been limited in some FTAs (those between the US and Australia, Morocco and Singapore) that permit the patent owner to prevent parallel imports through the use of contract or other means.

Finally, some FTAs (e.g. that with Morocco) require the recognition of patents over the "second indication" of a pharmaceutical product. This obligation unnecessarily expands the scope of patentability and ignores the right, recognized by the TRIPS Agreement, to exclude the patentability of therapeutic methods.

## Discussion

### Extension of patent term

There is no sound justification for the extension of the patent term as required by these FTAs. First, in the case of commercially successful medicines, the R&D costs may be recovered by several months of sales at the prices that can be charged in isolation from competition, under the exclusive rights enjoyed by the patent owner. Second, the time necessary to comply with marketing approval procedures has shortened. Third, only a few patents protect new active ingredients; the great majority cover logical extensions of existing knowledge or developments that are patented with the deliberate aim of delaying competition.<sup>23</sup>

The extension of the patent term to compensate delays in the process of examination of patent applications overlooks the fact that in many developing countries patent offices are under-staffed and delays are common. In addition, an extension is unnecessary where patent laws, as is often the case, confer rights to applicants before the patent has been granted, as soon as the application has been published. This would effectively exclude competitors for at least 18.5 years, since such publication normally takes place 18 months after filing. The possibility of such extension creates uncertainty for generic producers and, when effected, will have obvious consequences on public health: it will delay the introduction of competing products with the ensuing loss of consumer welfare and increased barriers to access to medicines, especially by the poor.

Since the grounds for the extension of the patent terms under the FTAs are *independent*, *cumulative* and with *no maximum period*, nothing seems to prevent a patent from being extended for x years due to a delay in its granting process, and for y more years due to a delay in the marketing approval process. Thus, patents on pharmaceutical products may last for several months or years after the 20-year term required by the TRIPS Agreement. These mechanisms will have the effect of making the public pay for any administrative delays,



and generate an increased flow of payments to pharmaceutical companies that can hardly be justified by any additional benefits to patients in developing countries. Since the revenues obtained from such countries contribute only a small extent to the profits of drug companies, the amounts involved have only a small effect on the R&D decisions made by them.<sup>24</sup> Similarly, longer patent rights (depending upon various factors such as administrative delays) are unlikely to increase foreign direct investment or transfer of technology, which in any case are only weakly related to the level of intellectual property protection.<sup>25</sup>

### ***Data exclusivity***

Particularly in countries that have only recently introduced patent protection for pharmaceutical products, the implications of data exclusivity will also be significant since medicines that are off-patent may then become subject to exclusive rights. These provisions create an effective barrier to competition from generics, since even where a product is off-patent, no marketing approval can be granted to generic manufacturers unless they replicate the full set of test data necessary to obtain approval, which is costly, time-consuming, and questionable under the Declaration of Helsinki.<sup>26</sup> A study in Peru of 43 products that could have been subject to data exclusivity, estimated that their average price would have been 94.3–114.4% higher than that in the absence of these provisions.<sup>27</sup>

### ***Linkage***

The patent-registration linkage ignores that patents are *private rights* — as stated in the Preamble to the TRIPS Agreement. It shifts to the Members the responsibility of preventing possible infringement. Members also assume any liability for unduly preventing the approval of a generic product if it is finally determined that the patent is invalid or that there is no infringement. Health authorities do not have the knowledge or experience to assess the claims of a patent and/or its possible infringement. Pharmaceutical patents do not cover only

the active ingredients but a wide range of other aspects (such as salts, esters, ethers, polymorphs, formulations, active metabolites, isomers).<sup>23</sup> Under a linkage system, such patents — in many cases, susceptible to validity challenges — may erect a formidable barrier to legitimate generic competition.

The patent-registration linkage goes beyond the standards applied in the USA and the EU. For example, US Food and Drug Administration does not substitute patent owners in enforcing their rights. It must only inform them about the existence of a third party's application on the same drug, provided that the relevant patents have been registered in the so-called "Orange Book". It is the patent owner's responsibility to act before the courts if an alleged infringement exists. A report of the US Federal Trade Commission reveals, however, that in most cases patent owners failed to prove such infringement.<sup>28</sup> Moreover, in the EU there is complete independence between patent protection and registration. Health authorities limit their function to ensuring the compliance with the relevant standards of safety, quality and efficacy of medicines and do not assume any role in enforcing patent rights.

### ***Other standards***

Compulsory licences and parallel imports have been widely recognized as important instruments for promoting access to medicines at affordable prices.<sup>29,30</sup> The data exclusivity and the patent-registration linkage can make illusory the granting of compulsory licences and non-commercial government use, since prospective compulsory licensees are unlikely to replicate test data, and governments cannot normally wait until a new set of test data has been developed. In some cases, "side letters" or "understandings" have been signed suggesting that the FTAs' provisions are compatible with the Doha Declaration and, in particular, that the use of compulsory licences to protect public health would not be impeded. However, these letters or understandings — which contain language that is inconsistent with the right to adopt measures to protect public health recognized under

the Doha Declaration — only have interpretive value. In the event that a pharmaceutical company that has a brand-name drug decides to challenge a decision to approve a generic drug produced under a compulsory licence, the conflict will only be “informed” by the letter and will have to be resolved on the merits of a particular case.<sup>12</sup>

## Conclusions

A number of developing countries have agreed, or are in the course of negotiating, FTAs in order to attain perceived commercial advantages. As a result, they have been bound to accept standards of protection of intellectual property rights for medicines that go well beyond what they had already consented to at the multilateral level. Although the FTAs that have been discussed here are too recent to be able to assess fully their effects on public health, their higher standards of protection will, by their very nature, delay or restrict generic competition and thereby reduce access to medicines. Accepting those standards negates the letter and spirit of the Doha Declaration, and will limit the capacity of States to progressively realize the human right to health.

**Competing interests:** none declared.

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**Footnote b:** Andean agreement with Colombia, Ecuador and Peru (signed in December 2005); a Southern Africa agreement with Botswana, Lesotho, Namibia, South Africa, and Swaziland; and bilateral agreements with Oman, Panama, Thailand, and the United Arab Emirates.

**Footnote c:** The EU has signed agreements with South Africa (1999), Tunisia (1998) and the Palestinian Authority (1997), among others, which require the signatories to ensure adequate and effective protection of intellectual property rights “in conformity with the highest international standards”. EFTA is composed of Iceland, Liechtenstein, Norway, and Switzerland. FTAs have been negotiated with Chile, Egypt, Jordan, Lebanon, Mexico, Morocco, the Palestinian Authority, South Africa and Tunisia. A requirement in these agreements is generally the obligation to provide an “effective patent protection for inventions in all fields of technology on a level similar to that prevailing in the European Patent Convention”.



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## GATS and health related services

### Managing liberalization of trade in services from a health policy perspective

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#### ***Liberalization of trade in health-related services: the importance of GATS to health policy***

Since the establishment of the World Trade Organization (WTO) in 1995, the importance of international trade law to public health and health care has become obvious. Traditionally, the multilateral trading system regulated the trade in goods between nations. The WTO's creation expanded trade rules into new areas, such as aspects of intellectual property protection and trade in services.

The provision and consumption of services have become an increasingly important part of modern economies. The incorporation of services into the multilateral trading system through the General Agreement on Trade in Services (GATS) represents one of the most important developments to emerge from the creation of the WTO.

Services of many kinds play important roles in the protection of public health (e.g., sanitation services) and the delivery of

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health care to individuals (e.g., hospital services). GATS affects health-related services in many ways that are essential for health policymakers to comprehend. In addition, GATS establishes a process designed to progressively liberalize trade in services and health policy-makers must be prepared to participate in this process to ensure that such liberalization unfolds in a way sensitive to the needs of national governments in ensuring the provision and regulation of health-related services.

## Health policy principles to inform the GATS process

Any liberalization under GATS should aim to produce better quality, affordable, and effective health-related services, leading to greater equity in health outcomes.

Liberalization should also ensure the necessary policy and regulatory space governments require to promote and protect the health of their populations, particularly those in greatest need.

### **Box 1: Health policy principles to guide liberalization of health-related services.**

- Liberalized trade in health-related services should lead to an optimal balance between preventive and curative services.
- Involvement of both private industry and civil society is important to ensure that liberalization of health-related services promotes participatory health policy towards achieving national goals.
- Improving access and affordability of health-related services should be a goal of liberalization of trade in health-related services.
- Developing countries, and least-developed countries in particular, deserve special consideration in the process of liberalizing trade in health-related services.
- The status of health as a human right should inform and guide proposals to liberalize trade in health-related services.

GATS creates health opportunities and challenges, especially for developing countries. GATS accords countries considerable choice, discretion, and flexibility so that proper management of the process of liberalization of trade in health-related services can adequately protect health. Countries are encouraged to embed the health policy principles summarized in Box 1 in the process of managing GATS.

## Choices under GATS

In key areas of GATS, governments face choices about the breadth and depth of liberalization of trade in health related services and the impact of such liberalization on health policy. In fact, countries are free to decide whether liberalization in the health sector should be pursued or not and to what extent. Countries are not obliged to liberalize health services if they do not wish to do so. These choices make it imperative that health officials understand the structure and substance of GATS, collaborate with other government agencies on GATS implementation and liberalization, and act to ensure that the GATS process does not adversely affect national health policy (see Box 2).

## Key provisions of GATS

GATS creates the multilateral legal framework for international trade in nearly every type of service. The Agreement's 29 articles establish the scope of its rules' coverage, impose general obligations, structure the making of specific commitments, construct a process for progressive liberalization of trade in services, and link the treaty to the WTO's dispute settlement mechanism. The key provisions for health policy are described below and summarized in Table 1.

## *Scope of GATS*

GATS applies to all measures by WTO members affecting trade in services (Article I:1). GATS defines all elements of this rule—"measures," "affecting," and "trade in services"—broadly. For example, GATS covers all possible ways in which services are provided (see Box 3). GATS' scope is expansive and overlaps significantly with the wide



range of activities governments undertake in regulating health-related services.

### **Box 2: Points for Policy-Makers**

- GATS establishes the multilateral legal framework for international trade in services among WTO members.
- The scope of GATS is very broad, which means it applies to a wide range of health-related services.
- GATS covers policies, practices and laws that affect trade in services among WTO members.
- GATS contains general obligations and disciplines, such as most-favored-nation treatment, that apply to all measures affecting services within the scope of the Agreement.
- GATS allows WTO members to make specific commitments on market access and national treatment and to tailor those commitments to national policy ends.
- GATS sets the objective of progressive liberalization of trade in services, meaning that WTO members will negotiate over new specific commitments in service sectors subject to the Agreement.
- The process of progressive liberalization under GATS requires the active involvement of health policy-makers.
- Before making any specific commitment under GATS, governments should ensure they have thoroughly assessed the implications of opening health systems to foreign services and the potential costs and benefits of making legally binding commitments. Countries may wish to experiment through autonomous liberalization of certain health related services, and only make commitments under GATS after a careful assessment of its effects.

**Table 1: Articles of GATS of greatest relevance to health policy**

Topic (GATS Article)	Substance of the GATS Provision (Note that a number of articles contain further detail that are spelled out in GATS)
<b>Scope of GATS (Part I)</b>	
Scope and Definitions (Article I)	GATS applies to measures by WTO members affecting trade in services. Trade in services is defined as the supply of a service (1) from the territory of one WTO member into the territory of any other WTO member; (2) in the territory of one WTO member to the service consumer of any other WTO member; (3) by a service supplier of one WTO member through commercial presence in the territory of any other WTO member; and (4) by a service supplier of one WTO member through presence of natural persons of a WTO member in the territory of any other WTO member.
	"Services" includes any service in any sector except services supplied in the exercise of governmental authority.
	A "service supplied in the exercise of governmental authority" means any service which is supplied neither on a commercial basis nor in competition with one or more service suppliers.
<b>General obligations and disciplines (Part II)</b>	
Most-favored-nation treatment (Article II)	With respect to any measure covered by GATS, each WTO member shall accord immediately and unconditionally to services and service suppliers of any other WTO member treatment no less favorable than that it accords to like services and service suppliers of any other country.

Domestic regulation (Article VI)	The Council for Trade in Services shall develop any necessary disciplines on measures relating to qualification requirements, technical standards, and licensing requirements to ensure that such measures do not constitute unnecessary barriers to trade in services. Such disciplines shall aim to ensure that such requirements are, inter alia, not more burdensome than necessary to ensure the quality of the service.
Monopolies and exclusive service suppliers (Article VIII)	If a WTO member grants monopoly or exclusive service rights regarding the supply of a service covered by specific commitments, then that WTO member must make compensatory arrangements with any WTO member adversely affected by such granting of monopoly or exclusive service rights.
General exceptions (Article XIV)	WTO members may restrict trade in health-related services in violation of general obligations or specific commitments when such restrictive measures are necessary to protect human, animal, or plant life or health, and the application of which does not constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on trade in services.
<b>Specific commitments (Part III)</b>	
Market access (Article XVI)	With respect to market access through the modes of supply identified in Article I, each WTO member shall accord services and service suppliers of any other WTO member treatment no less favorable than that provided for under the terms, limitations, and conditions agreed and specified in its Schedule of Specific Commitments. WTO members must list measures restricting market access they wish to maintain in sectors subject to a market access commitments.

National treatment (Article XVII)	In the sectors inscribed in its Schedule of Specific Commitments, and subject to any conditions and qualifications set out therein, each WTO member shall accord to services and service suppliers of any other WTO member, in respect of all measures affecting the supply of services, treatment no less favorable than that it accords to its own like services and service suppliers.
<b>Progressive liberalization (Part IV)</b>	
Negotiation of specific commitments (Article XIX)	WTO members shall enter into successive rounds of negotiations with a view to achieving a progressively higher level of liberalization in trade in services.
Modification of schedules (Article XXI)	To withdraw or modify a Schedule of Specific Commitments, a WTO member must make compensatory arrangements for WTO members adversely affected by such withdrawal or modification; and such compensatory arrangements are then available to all WTO members on a most-favored-nation basis.
<b>Institutional provisions (Part V)</b>	
Dispute settlement and enforcement (Article XXIII)	Disputes that arise under GATS are subject to the WTO Dispute Settlement Understanding.
Council for Trade in Services (Article XXIV)	The Council for Trade in Services shall facilitate the operation of GATS and advance its objectives.

### Box 3: Modes of Service Supply under GATS and Health Opportunities and Risks

Supply Modes	Opportunity	Risk
<b>Mode 1:</b> Cross-border supply of services (telemedicine, e-health)	Increased care to remote and under-served areas	Diversion of resources from other health services
<b>Mode 2:</b> Consumption of services abroad (patients traveling abroad for hospital treatment)	Generates foreign exchange earnings for health services of importing country	Crowding out of local population and diversion of resources to service foreign nationals
<b>Mode 3:</b> Commercial presence (establishment of health facilities in other countries)	Creates opportunities for new employment and access to new technologies	Development of two-tiered health system, with an internal brain drain
<b>Mode 4:</b> Presence of natural persons (doctors or nurses practicing in other countries)	Economic gains from remittances of health care personnel working overseas	Permanent outflow of health personnel, with loss of investment in educating and training such personnel

The Agreement excludes from its coverage services supplied in the exercise of governmental authority (Article 1:3(b)). Services supplied pursuant to governmental authority only fall within this exclusion if the services are provided neither on a commercial basis nor in competition with one or more service suppliers (Article 1:3(c)). The scope of this exclusion remains ambiguous and controversial, meaning that this provision deserves close attention from health

ministries. Various members have used different techniques to avoid the ambiguities associated with Article 1:3. Some have decided not to undertake commitments at all, others have sought to narrow the scope of commitments to the commercial segment only.

### ***General obligations and disciplines***

For all measures affecting services within GATS' scope, the Agreement imposes general obligations and disciplines. From a health policy perspective, the most important general obligations involve rules on domestic regulation of services, specifically disciplines on granting or extending monopoly or exclusive service rights and the duty to engage in negotiations to develop rules on domestic regulation, subsidies, government procurement, and emergency safeguards. While some general obligations, such as the rules on extending monopoly or exclusive service rights, present health policy with challenges, the development of rules on domestic regulation, subsidies, government procurement, and emergency safeguards remains an on-going process that health ministries should monitor.

### ***Specific commitments***

GATS creates a structure for countries to make specific market access and national treatment commitments in service sectors in which they wish to liberalize trade. Market access commitments remove barriers to foreign services, and national treatment commitments require that foreign and domestic services be treated the same. Under GATS, each WTO member decides for itself whether to make binding market access and national treatment commitments.

At the same time, GATS imposes a “list it or lose it” process on countries making specific commitments. When making market access or national treatment commitments, countries have to list all measures they wish to retain that would otherwise violate the specific commitment being made. Some measures that restrict market access

may be important for health policy reasons, such as limitations on the number of service suppliers through an economic needs test, which illustrates the importance of thoroughly analysing proposals to liberalize trade in health-related services.

### ***Progressive liberalization***

Countries will face decisions whether to liberalize trade in services through market access and national treatment commitments in periodic negotiations designed to produce the progressive liberalization of trade in services. The current round of liberalization talks, known as “GATS 2000,” is now under-way.

## **Managing the GATS 2000 process from a health policy perspective**

The structure and substance of GATS create a challenge for ministries of health to develop capabilities to manage the GATS 2000 process effectively from a health policy perspective in two key areas: (1) evaluating requests for, and offers of, specific commitments; and (2) negotiations on GATS rules.

### ***The request/offer process and specific commitments***

At the heart of this challenge will be the assessment of other countries’ requests for, and a country’s own offers of, liberalization in health-related services. Requests will seek, and offers will make, new specific commitments on market access and national treatment. Health policy analysis of GATS indicates that requests for new market access commitments will pose the most difficulties for health policy-makers because measures that restrict market access may be used by health ministries to pursue health service objectives.

The tabling of requests for, and making offers of, specific market access and national treatment commitments will raise questions health-policy makers will have to address (see Box 4).

#### **Box 4: Key Questions for Monitoring the Impact of GATS 2000 on Health Policy**

In connection with a request for, or offer of, market access and/or national treatment commitments in a health-related service sector:

- To what extent is the sector already open to foreign service providers, and what have been the regulatory concerns posed by existing foreign competition?
- Do the commitments fit the strategies and directions identified by national health policy?
- What effect would the commitments have on government-provided health-related services?
- What regulatory burdens would the commitments create for the government in health-related sectors?
- Would the commitments eliminate or weaken regulatory approaches necessary for the protection and promotion of health?
- What scientific and public health evidence and principles can be brought to bear to analyze the possible effect of the commitments?
- Can the commitments be crafted both to protect health policy and to liberalize trade progressively?and only make commitments under GATS after a careful assessment of its effects.

### ***Negotiations on GATS rules***

The GATS 2000 process also involves negotiations on GATS rules on domestic regulation, subsidies, emergency safeguards, and government procurement. These negotiations also deserve the



attention and analysis of health ministries because these negotiations have the potential to adopt rules that would affect health policy, especially with regard to rules on domestic regulation.

## **Building capacity at the national level to inform the GATS negotiations and monitor health implications of GATS**

Although experts acknowledge that GATS has not, to date, significantly affected trade in health-related services, the potential for GATS to do so through the progressive liberalization process is tremendous. In the GATS 2000 negotiations, countries may be receiving requests from and may consider submitting offers to other WTO members for market access and national treatment commitments in many different health-related service sectors.

Such requests/offers will place a premium on a government's ability to develop inter-agency cooperation and collaboration in order to ensure that decisions made on new specific commitments do not adversely affect national health policy and regulatory capabilities. Health ministries were not actively involved in the Uruguay Round negotiations on GATS but should be pro-active about their responsibilities with respect to the GATS 2000 process (see Box 5).

Building GATS capacity at the national level will require countries, among other things, to analyze their current level and types of trade in health-services, the benefits and costs existing trade has produced, the barriers to expanding such trade and the policy objectives behind those barriers, what gains and losses can be anticipated by liberalization proposals and who gains and loses, and what regulatory and policy changes would be needed to harness liberalization for the maximum benefit to health (See Box 6).

### **Box 5: Checklist for Policy-Makers on Trade in Health-Related Services**

- Identify a focal point for trade in health-related services within the Ministry of Health.
- Establish contacts and systematic interactions (e.g., a GATS working group) with trade and other key ministries and with representatives from private industry and civil society.
- Collect and evaluate relevant information on the effect of existing trade in health-related services within the country.
- Obtain reliable legal advice not only on GATS but also on other international trade and investment agreements (e.g., bilateral investment agreements) that may affect trade in health-related services.
- Develop a sustainable mechanism for monitoring the impact of trade in health-related services generally and the GATS 2000 process specifically.
- Utilize the information and technical assistance provided by WHO on matters concerning trade in health-related services.
- Subject all requests for, and offers of, liberalization of trade in health-related services to a thorough assessment of their health policy implications.

### **Box 6: Elements of a General Framework for Country Analysis of GATS**

- General macroeconomic and trade environment in the country.
- State of the domestic public health and health care systems.
- State of trade and investment in health-related service sectors.
- The quality of information on the health sector.
- Institutional capacity and capabilities for handling liberalized trade in health-related services.

## **WHO's work on GATS and policy recommendations to date**

WHO's work on GATS has, to date, focused on collecting evidence on the potential and actual impact of GATS on the functioning of health systems. These efforts involve:

- Collecting data on trade in health-related services;
- Undertaking a wide range of country-based studies;
- Conducting regional and national training programs;
- Supporting a legal review of GATS from the perspective of health policy;
- Developing a Handbook on Trade in Health-Related Services and GATS; and
- Tracking and disseminating information on the GATS 2000 negotiations.

The following general policy recommendations are based on this work to date.

- *Get Your House in Order:* National stewardship of the health system in the context of GATS requires a sophisticated understanding of how trade in health-related services already affects and may affect a country's health systems and policy.
- *Know the Whole House, Not Just Select Rooms:* The GATS process can affect many sectors related to health, and this fact places a premium on health ministries understanding the importance of a comprehensive outlook on trade in health-related services.
- *Remember Who Owns the House:* GATS provides countries with choices and does not force them to make liberalization commitments that are not in their best interests. If a country is unsure about the effects of making specific commitments, it is fully within its rights to decline to make legally binding commitments to liberalize.
- *Home Improvement Means Health Improvement:* Health principles and criteria, as outlined in Box 1, should drive policy decisions on trade in health-related services in the GATS negotiations.

## Conclusion

GATS constitutes one of the most important trade agreements from the perspective of health. Unlike the relationship between health and other WTO agreements, the GATS and health interface will be most significantly shaped by the on-going and subsequent efforts to liberalize progressively trade in services. In light of this reality, countries must develop informed and sophisticated approaches to managing the GATS 2000 process, its results, and future liberalization efforts. WHO is developing capabilities to assist countries in this endeavor

but, without commitment by national governments, the protection and promotion of health in the GATS process may be compromised.

## Further Reading

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# **Selected Resolutions**





## SEA/RC59/R7 – Public Health, Innovation, Essential Health Research and Intellectual Property Rights

The Regional Committee,

Recalling World Health Assembly resolutions WHA59.24 on Public Health, Innovation, Essential Health Research and Intellectual Property Rights: towards a global strategy and plan of action, and WHA56.27 on Intellectual Property Rights, Innovation and Public Health,

Having considered the report and recommendations of the Commission on Intellectual Property Rights, Innovation and Public Health,

Noting that an intergovernmental working group will be convened before the end of 2006 with a view to developing a global strategy and plan of action to provide the medium-term framework based on the recommendations of the WHO Commission on Intellectual Property Rights, Innovation and Public Health,

Aware of the emerging resistance to some of the currently available drugs and the need for affordable treatment for neglected diseases, and that insufficient research is being conducted in this area,

Considering the need to ensure appropriate incentives for research and development of treatments for neglected and the most neglected diseases<sup>1</sup> predominantly affecting the

<sup>1</sup> Diseases that are overwhelmingly or exclusively incident in developing countries. These diseases receive extremely little R&D and essentially there is no commercially-based R&D in the rich countries (Reference: Public health: Innovation and



Member States in the Region, and the need to address issues related to distribution, delivery and pricing of medicines at the end-user level,

Recognizing the importance of intellectual property rights in fostering research and development in innovative medicines but also acknowledging the necessity for alternative incentive systems,

Recalling that the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) should not prevent member from taking other measures to protect public health in their efforts to promote access to affordable medicines, and

Reaffirming the critical need to achieve the Millennium Development Goals to reduce poverty and promote human rights,

1. URGES Member States:
  - a. to actively participate in the work of intergovernmental working group;
  - b. to ensure an enabling environment including financial supports for health research in public and private settings to better respond to the pressing public health needs in the Region with particular emphasis on the new drugs, vaccines and diagnostics in order to address the high burden of neglected diseases in the Region, and
  - c. to make full use of the flexibilities allowed in the TRIPS agreement, and
2. REQUESTS the Regional Director:
  - a. to support the participation of Member States in the work of intergovernmental working group;

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Intellectual Property Rights, Report of the Commission on Intellectual Property Rights, Innovation and Public Health, April 2006)

- b. to convene a regional consultation of Member States to develop a regional perspective prior to the meeting of the intergovernmental working group;
- c. to continue to provide technical support and mobilize financial resources to Member States in undertaking research capacities with particular emphasis on the neglected diseases, and
- d. to report to the 62nd Regional Committee Meeting in the 2009 on progress made by this Resolution.



## SEA/RC59/R9 – International Trade and Health

The Regional Committee,

Recalling World Health Assembly resolution WHA59.26 on “International Trade and Health” as well as resolutions WHA52.19, WHA53.14, WHA56.27, WHA57.14 and WHA57.19;

Recognizing that Member States of WHO’s South-East Asia Region are increasingly involved in international trade and agreements which have implications for public health in the Region,

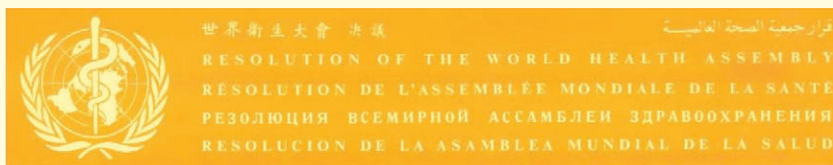
Considering the need for coherence in health and trade policy, and mechanisms to secure better coordination among relevant ministries responsible for trade and health,

Recognizing that a sound policy on trade and health would secure balanced and coordinated interests between trade and health, and

Appreciating WHO’s initiatives to promote an effective health dimension to economic policies in a changing international context,

1. URGES Member States:
  - a. to implement the World Health Assembly resolution WHA59.26;
  - b. to ensure the involvement of health ministries in the processes of negotiating trade agreements in order

- to identify opportunities and mitigate the possible risks of these agreements with regard to public health;
  - c. to develop capacity in relevant ministries in the assessment of the implications of international trade agreements on health of the population in order to effectively participate in the trade negotiations, and
  - d. to improve the capacity of the National Regulatory Authorities, and
2. REQUESTS the Regional Director:
- a. to support Member States in their efforts to implement the World Health Assembly resolution WHA59.26;
  - b. to continue to assist Member States in their efforts to build capacity, and identify and assess the public health implications of international trade agreements;
  - c. to provide technical support and expertise to Member States to draft policies, laws and regulations or establish practices and to promote the exchange of information among Member States to address public health challenges and leverage opportunities to improve health in the context of international trade agreements;
  - d. to mobilize resources to support the works related to Trade and Health;
  - e. to assist Member States in developing necessary legal and economic frameworks within the country to avail of the flexibilities allowed in TRIPS Agreements, and
  - f. to assist Member States in strengthening their National Regulatory Authorities.



## WHA61.21 – Global strategy and plan of action on public health, innovation and intellectual property

The Sixty-first World Health Assembly,

Having considered the report of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property;<sup>1</sup>

Recalling the establishment pursuant to resolution WHA59.24 of an intergovernmental working group to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission on Intellectual Property, Innovation and Public Health, and to secure, inter alia, an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area;

Recalling resolutions WHA49.14 and WHA52.19 on revised drug strategy, WHA53.14 and WHA54.10 and WHA57.14 on HIV/AIDS, WHA56.27 on intellectual property rights, innovation and public health, WHA58.34 on the Ministerial Summit on Health Research, WHA59.26 on international trade and health; and WHA60.30 on public health, innovation and intellectual property;

<sup>1</sup> Document A61/9.

Welcoming the progress made by the Intergovernmental Working Group in elaborating the global strategy and the identification of the stakeholders in the plan of action,

1. ADOPTS the global strategy and the agreed parts of the plan of action<sup>2</sup> on public health, innovation and intellectual property, attached to this resolution;
2. URGES Member States:<sup>3</sup>
  - (1) to implement the specific actions recommended in the global strategy and plan of action on public health, innovation and intellectual property;
  - (2) to support actively the wide implementation of the global strategy and plan of action on public health, innovation and intellectual property, and to consider providing adequate resources for its implementation;
3. CALLS UPON relevant international organizations and other relevant stakeholders to give priority within their respective mandates and programmes to implementing the global strategy and plan of action on public health, innovation and intellectual property;
4. REQUESTS the Director-General in implementing the global strategy and agreed parts of the plan of action without prejudice to the existing mandates:
  - (1) to provide support for Member States, upon request, in implementing the global strategy and plan of action on public health, innovation and intellectual property and in monitoring and evaluating its implementation;

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2 On the specific actions and stakeholder components.

3 Where applicable, also regional economic integration organizations.

- (2) to support effective promotion and implementation of the global strategy and plan of action on public health, innovation and intellectual property;
- (3) to continue to implement the mandates contained in resolutions WHA49.14 and WHA52.19 on revised drug strategy, WHA53.14 and WHA54.10, WHA57.14 and WHA56.30 on HIV/AIDS, WHA56.27 on intellectual property rights, innovation and public health, WHA59.26 on international trade and health, and WHA60.30 on public health, innovation and intellectual property, as well as WHA55.11 on health and sustainable development, WHA55.14 on ensuring accessibility of essential medicines, and WHA60.18 on malaria, including proposal for establishment of World Malaria Day;
- (4) to finalize urgently the outstanding components of the plan of action, concerning timeframes, progress indicators and estimated funding needs, and to submit the final plan of action including the open paragraphs on stakeholders for consideration by the Sixty-second World Health Assembly through the Executive Board;
- (5) to coordinate with other relevant international intergovernmental organizations, including WIPO, WTO and UNCTAD, to effectively implement the global strategy and plan of action;
- (6) notwithstanding the request in subparagraph (4) above, to prepare a quick start programme with adequate budget provision and begin immediately to implement the elements of the global strategy and plan of action on public health, innovation and intellectual property that fall under the responsibility of WHO;
- (7) to establish urgently a results-oriented and time-limited expert working group to examine current financing and

coordination of research and development, as well as proposals for new and innovative sources of funding to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases, and open to consideration of proposals from Member States, and to submit a progress report to the Sixty-second World Health Assembly and the final report to the Sixty-third World Health Assembly through the Executive Board;

- (8) to reflect, as appropriate, the global strategy and plan of action on public health, innovation and intellectual property in the further development of WHO's research strategy;
- (9) to include adequate resources in the forthcoming proposed programme budgets for effective implementation of the global strategy and plan of action on public health, innovation and intellectual property;
- (10) to monitor performance and progress in implementing the global strategy and plan of action on public health, innovation and intellectual property, and to report progress to the Sixty-third World Health Assembly through the Executive Board, and subsequently every two years, until the fulfilment of the time frame, to the Health Assembly, through the Executive Board.





## WHA60.30 – Public health, innovation and intellectual property

The Sixtieth World Health Assembly,

Recalling resolution WHA59.24, creating an intergovernmental working group with the purpose of elaborating a draft global strategy and plan of action to provide a medium-term framework based on the recommendations of the Commission on Intellectual Property, Innovation and Public Health, and to secure, inter alia, an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area;

Concerned that communicable diseases account for approximately 50% of the burden of disease in developing countries, and that access to medicines, vaccines and diagnostic kits is hampered by, inter alia, inadequate health-care systems, lack of resources and prices that are beyond the reach of many in the developing world;

Conscious of the growing burden of disease and conditions that disproportionately affect developing countries, particularly those affecting women and children, including an upsurge in noncommunicable diseases;

Noting that the Doha Ministerial Declaration on the TRIPS Agreement and Public Health confirms that the Agreement does not and should not prevent Members from taking measures to protect public health;

Noting that intellectual property rights are an important incentive for the development of new health-care products;

Welcoming with enthusiasm the commitment of the Director-General to the process spearheaded by the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property,

1. EXPRESSES appreciation to the Director-General for her commitment and encourages her to guide the process to draw up a global strategy and plan of action that will provide a medium-term framework for needs-driven essential health research and development;
2. URGES Member States to support fully and actively the Intergovernmental Working Group process and provide adequate resources to WHO;
3. REQUESTS the Director-General:
  - (1) to ensure technical and financial support to the Intergovernmental Working Group in order to facilitate completion of its tasks in time for its report to the Sixty-first World Health Assembly;
  - (2) to provide as appropriate, upon request, in collaboration with other competent international organizations, technical and policy support to countries that intend to make use of the flexibilities contained in the agreement on Trade-Related Aspects of Intellectual Property Rights

and other international agreements in order to promote access to pharmaceutical products,<sup>1</sup> and to implement the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments;

- (3) to provide technical and financial support for regional consultative meetings in order to set regional priorities that will inform the work of the Intergovernmental Working Group;
- (4) to encourage the development of proposals for health-needs driven research and development for discussion at the Intergovernmental Working Group that includes a range of incentive mechanisms including also addressing the linkage between the cost of research and development and the price of medicines, vaccines, diagnostic kits and other health-care products and a method for tailoring the optimal mix of incentives to a particular condition or product, with the objective of addressing diseases that disproportionately affect developing countries;
- (5) to prepare background documents on each of the eight proposed elements of the plan of action, as identified by the Intergovernmental Working Group, including:
  - a matrix on ongoing activities and current gaps;
  - a matrix on current proposals referring to key stakeholders;
  - the financial implications of those proposals.

Eleventh plenary meeting, 23 May 2007

A60/VR/11

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1 The WTO General Council in its Decision of 30 August 2003 on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health decided that “pharmaceutical product” means any patented product, or products manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.



## WHA59.26 – International trade and health

The Fifty-ninth World Health Assembly,

Having considered the report on international trade and health;<sup>1</sup>

Recalling resolutions WHA52.19, WHA53.14, WHA56.23, WHA56.27, WHA57.14 and WHA57.19;

Recognizing the demand for information on the possible implications of international trade and trade agreements for health and health policy at national, regional and global levels;

Mindful of the need for all relevant ministries, including those of health, trade, commerce, finance and foreign affairs, to work together constructively in order to ensure that the interests of trade and health are appropriately balanced and coordinated,

1. URGES Member States:

- (1) to promote multi-stakeholder dialogue at national level to consider the interplay between international trade and health;

<sup>1</sup> Document A59/15.

- (2) to adopt, where necessary, policies, laws and regulations that deal with issues identified in that dialogue, and to take advantage of the potential opportunities, and address the potential challenges, that trade and trade agreements may have for health, considering, where appropriate, using their inherent flexibilities;
  - (3) to apply or establish, where necessary, coordination mechanisms involving ministries of finance, health, and trade, and other relevant institutions, to address public-health related aspects of international trade;
  - (4) to create constructive and interactive relationships across the public and private sectors for the purpose of generating coherence in national trade and health policies;
  - (5) to continue to develop capacity at national level to track and analyse the potential opportunities and challenges of trade and trade agreements for health-sector performance and health outcomes;
2. REQUESTS the Director-General:
- (1) to provide support to Member States, at their request and in collaboration with the competent international organizations, in their efforts to frame coherent policies to address the relationship between trade and health;
  - (2) to respond to Member States' requests for support of their efforts to build the capacity to understand the implications of international trade and trade agreements for health and to address relevant issues through policies and legislation that take advantage of the potential opportunities, and address the potential challenges, that trade and trade agreements may have for health;

- (3) to continue collaborating with the competent international organizations in order to support policy coherence between trade and health sectors at regional and global levels, including generating and sharing evidence on the relationship between trade and health;
- (4) to report to the Sixty-first World Health Assembly, through the Executive Board, on progress made in implementing this resolution.

(Ninth plenary meeting, 27 May 2006 –  
Committee A, sixth report)



## WHA59.24 – Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action

Recalling resolution WHA56.27, which requested the Director-General to establish terms of reference for an appropriate 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;

Further recalling resolutions WHA52.19, WHA53.14, WHA54.10, and WHA57.14;

Having considered the report of the Commission on Intellectual Property Rights, Innovation and Public Health;<sup>1</sup>

Conscious of the growing burden of diseases and conditions disproportionately affecting developing countries, particularly those affecting women and children, including an upsurge in noncommunicable diseases;

Considering the need to continue to develop safe and affordable new products<sup>2</sup> for such communicable diseases as AIDS, malaria and

1 Public health, innovation and intellectual property rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health. April 2006.

2 The word “products” hereafter should be understood to include vaccines, diagnostics and medicines.

tuberculosis, and for other diseases or illnesses disproportionately affecting developing countries;

Conscious of the opportunities opened up by advances in biomedical science, and the need to harness them more effectively to develop new products, particularly in order to meet public health needs in developing countries;

Aware of the considerable progress that has been made in recent years by governments, industry, charitable foundations, and nongovernmental organizations in funding initiatives to develop new products to fight diseases affecting developing countries, and to increase access to existing ones;

Recognizing, however, that much more needs to be done in relation to the scale of avoidable suffering and mortality;

Concerned about the need for appropriate, effective and safe health tools for patients living in resource-poor settings;

Considering the urgency of developing new products to address emerging health threats such as multidrug-resistant tuberculosis, and other infectious diseases of particular relevance to developing countries;

Aware of the need for additional funding for research and development for new vaccines, diagnostics and pharmaceuticals, including microbicides, for illnesses, including AIDS, that disproportionately affect developing countries;

Recognizing the importance of, and need for, public/private partnerships devoted to the development of new essential drugs and research tools, and aware of the need for governments to set a needs-based priority agenda for health, and to provide political support and sustainable sources of funding for such initiatives;



Recognizing the importance of public and private investment in the development of new medical technologies;

Considering that a number of developing countries have been strengthening their research and development capacity in new health technologies, and that their role will be increasingly critical, and recognizing the need for continued support for research in and by developing countries;

Noting that intellectual property rights are an important incentive for the development of new health-care products;

Noting, however, that this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain;

Noting that the Doha Ministerial Declaration on the TRIPS Agreement and Public Health confirms that the Agreement does not and should not prevent Members from taking measures to protect public health;

Further noting that the Declaration, while reiterating commitment to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) affirms that the Agreement can and should be interpreted and implemented in a manner supportive of the rights of WTO Members to protect public health and, in particular, to promote access to medicines for all;

Taking into account Article 7 of the TRIPS agreement that states that “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”;

Stressing that the Universal Declaration of Human Rights provides that “everyone has the right freely to participate in the cultural

life of the community, to enjoy the arts and to share in scientific advancement and its benefits” and that “everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author”;

Concerned about the impact of high prices of medicines on access to treatment;

Aware of the need to promote new thinking on the mechanisms that support innovation;

Recognizing the importance of strengthening capacity of local public institutions and businesses in developing countries to contribute to, and participate in, research and development efforts;

Noting that the report of the Commission requests that WHO should prepare a global plan of action to secure enhanced and sustainable funding for developing and making accessible products to address diseases that disproportionately affect developing countries,

1. WELCOMES the report of the Commission on Intellectual Property Rights, Innovation and Public Health and expresses its appreciation to the Chair, Vice-Chair and Members of the Commission for their work;
2. URGES Member States:<sup>3</sup>
  - (1) to make global health and medicines a priority sector, to take determined action to emphasize priorities in research and development addressed to the needs of patients, especially those in resource-poor settings, and to harness collaborative research and development initiatives involving disease-endemic countries;

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3 Where applicable, also regional economic integration organizations

- (2) to consider the recommendations of the report and to contribute actively to the development of a global strategy and plan of action, and to take an active part, working with the secretariat and international partners, in providing support for essential medical research and development;
  - (3) to work to ensure that progress in basic science and biomedicine is translated into improved, safe and affordable health products – drugs, vaccines and diagnostics – to respond to all patients’ and clients’ needs, especially those living in poverty, taking into account the critical role of gender, and to ensure that capacity is strengthened to support rapid delivery of essential medicines to people;
  - (4) to encourage trade agreements to take into account the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health;
  - (5) to ensure that the report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health is included on the agendas of WHO’s regional committees in 2006;
3. DECIDES:
- (1) to establish, in accordance with Rule 42 of the Rules of Procedure of the World Health Assembly, an intergovernmental working group open to all interested Member States to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission. Such a strategy and plan of action aims at, inter alia, securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases

- that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area;
- (2) that regional economic integration organizations constituted by sovereign States, Members of WHO, to which their Member States have transferred competence over matters governed by this resolution, including the competence to enter into international legally binding regulations, may participate, in accordance with Rule 55 of the Rules of Procedure of the World Health Assembly, in the work of the intergovernmental working group referred to under paragraph (1);
  - (3) that the above-mentioned working group shall report to the Sixtieth World Health Assembly through the Executive Board on the progress made, giving particular attention to needs-driven research and other potential areas for early implementation action.
  - (4) that the working group shall submit the final global strategy and plan of action to the Sixty-first World Health Assembly through the Executive Board;
4. REQUESTS the Director-General:
- (1) to convene immediately the intergovernmental working group and to allocate the necessary resources to it;
  - (2) to invite, as observers at the sessions of the intergovernmental working group, representatives of non-Member States, of liberation movements referred to in resolution WHA27.37, of organizations of the United Nations system, of intergovernmental organizations with which WHO has established effective relations, and of nongovernmental organizations in official relations with WHO, who shall attend the sessions of the working group in accordance

with the relevant Rules of Procedure and resolutions of the Health Assembly;

- (3) to invite experts and a limited number of concerned public and private entities to attend the sessions of the intergovernmental working group and to provide advice and expertise, as necessary, upon request of the Chair, taking into account the need to avoid conflicts of interest;
- (4) to continue to issue public health-based research and development reports, identifying from a public health perspective, gaps and needs related to pharmaceuticals, and to report on them periodically;
- (5) to continue to monitor, from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the Commission's report, on the development of, and access to, health care products, and report thereon to the Health Assembly.

Ninth plenary meeting, 27 May 2006

A59VR/9



## WHA56.27 – Intellectual property rights, innovation and public health

The Fifty-sixth World Health Assembly,

Having considered the report on intellectual property rights, innovation and public health;<sup>1</sup>

Considering that available data indicates that of some 1400 new products developed by the pharmaceutical industry between 1975 and 1999, only 13 were for tropical diseases and three were for tuberculosis;

Aware that the developed countries represent nearly 90% of global pharmaceutical sales, whereas of the 14 million global deaths due to infectious diseases, 90% occur in the developing countries;

Concerned about the insufficient research and development in so-called “neglected diseases” and “poverty-related diseases”, and noting that research and development in the pharmaceutical sector must address public health needs and not only potential market gains;

Mindful of concerns about the current patent protection system, especially as regards access to medicines in developing countries;

1 1 Document A56/17.

Recalling that, in accordance with the Declaration on the TRIPS Agreement and Public Health (Doha Declaration), the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) does not and should not prevent Members from taking measures to protect public health and, in particular, to promote access to medicines for all;

Noting that the TRIPS Agreement contains flexibilities and that in order to use them adequately, Member States need to adapt national patent legislation;

Reaffirming resolution WHA52.19 on the revised drug strategy, resolution WHA54.11 on WHO medicines strategy and resolution WHA55.14 on ensuring accessibility of essential medicines;

Considering that Member States should urge the pharmaceutical industry to reinvigorate its efforts to develop innovations that add real therapeutic advantage in treating the world's major killer diseases, especially in developing countries;

Recognizing the importance of intellectual property rights in fostering research and development in innovative medicines and the important role played by intellectual property with regard to the development of essential medicines;

Taking into account that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination;

Further considering the continuing efforts of WTO Members to reach a solution for paragraph 6 of the Doha Declaration which recognizes that "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement";

Reasserting the need to accomplish target 7 of Millennium Development Goal 6 and target 17 of Millennium Development Goal 8;

Noting resolutions 2001/33 and 2003/29 of the Commission on Human Rights on access to medicines in the context of pandemics such as HIV/AIDS,

1. URGES Member States:

- (1) to reaffirm that public health interests are paramount in both pharmaceutical and health policies;
- (2) to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS);
- (3) to maintain efforts aimed at reaching, within WTO and before the Fifth WTO Ministerial Conference, a consensus solution for paragraph 6 of the Doha Declaration, with a view to meeting the needs of the developing countries;
- (4) to seek to establish conditions conducive to research and development that spur the development of new medicines for diseases that affect developing countries;

2. REQUESTS the Director-General:

- (1) to continue to support Member States in the exchange and transfer of technology and research findings, according high priority to access to antiretroviral drugs to combat HIV/AIDS and medicines to control tuberculosis, malaria and other major health problems, in the context of paragraph 7 of the Doha Declaration which promotes and encourages technology transfer;
- (2) by the time of the 113th session of the Executive Board (January 2004), to establish the terms of reference for



an appropriate 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, and to submit a progress report to the Fifty-seventh World Health Assembly and a final report with concrete proposals to the Executive Board at its 115th session (January 2005);

- (3) to cooperate with Member States, at their request, and with international organizations in monitoring and analysing the pharmaceutical and public health implications of relevant international agreements, including trade agreements, so that Member States can effectively assess and subsequently develop pharmaceutical and health policies and regulatory measures that address their concerns and priorities, and are able to maximize the positive and mitigate the negative impact of those agreements;
- (4) to encourage developed countries to make renewed commitments to investing in biomedical and behavioural research, including, where possible, appropriate research with developing country partners.

Tenth plenary meeting, 28 May 2003

A56/VR/10

SPS, TRIPS, trade-distorting subsidies, Doha Paragraph Six ...  
The language of trade and health is specialized and may seem obscure. But though the language may be daunting, international trade agreements now being negotiated affect all of us, and health professionals in particular need to master the terminology if they are to participate in the national debate on trade and health. This reference guide consists of a basic dictionary of selected terms and several briefing notes that elaborate some of the issues.



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