

# 1. TRIPS, intellectual property rights and access to medicines<sup>a,b</sup>

## What is 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 created binding international obligations among WTO Member States in 1995. In the South-East Asia Region, all countries are Members of WTO except Bhutan, Democratic People's Republic of Korea and Timor-Leste. The TRIPS Agreement deals with Member States' obligations on a number of Intellectual Property Rights: Copyright and Related Rights, Trademarks, Geographical Indications, Industrial Designs, Patents, Layout-Designs (Topographies) of Integrated Circuits and Protection of Undisclosed Information.

The TRIPS Agreement is subject to WTO's dispute settlement mechanism, which may – as a last resort – allow Member States to apply trade sanctions against a non-compliant country, thereby ensuring enforcement of WTO's rules and agreements.

## What made TRIPS happen?

TRIPS is one of the outcomes of the process of globalization. Globalization is not new; this process began when trade, sourcing of raw

materials and markets became increasingly international. The process, however, has accelerated in present times due to greater movement of goods (including medical products) and services across international borders than before, and also due to the impact of information and communication technologies (ICT). Internet, with the worldwide web and mobile phones, are contributing to globalization of products and services.

WTO is an international organization of Member States entrusted with global rules of trade between nations. Its main function is to ensure that trade flows as smoothly, predictably and freely as possible.<sup>c</sup> The main mandate of WTO is

- to reduce obstacles to international trade;
- to administer and monitor the rules for trade in goods, trade in services, and Trade-Related Intellectual Property Rights (TRIPS);
- to settle disputes among Member States regarding the interpretation and application of the agreements.

Thus, TRIPS is one of the agreements of WTO negotiated by all Member States. Countries that are members of WTO have to implement the TRIPS Agreement. This Agreement has, to a large extent, harmonized the standards for the protection of intellectual property

<sup>a</sup> This technical brief is the first of a set of five documents on international trade laws related to access for medical products for public health.

<sup>b</sup> This is an updated version of the Briefing note on Access to Medicines jointly prepared by the WHO Regional Offices for South-East Asia and the Western Pacific in January 2006.

<sup>c</sup> World Trade Organization (website) ([http://www.wto.org/english/thewto\\_e/whatis\\_e/inbrief\\_e/inbr00\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr00_e.htm), accessed 11 July 2017).

These UHC technical briefs summarize current knowledge on strengthening health systems to achieve Universal Health Coverage. They outline key technical issues and international experience relevant to health policy and practice in low- and middle-income countries in the South-East Asia Region.

rights, including patents. For developing countries, generally, TRIPS has increased the level of intellectual property protection. The introduction of these higher TRIPS standards has delayed the marketing of generic versions of new medicines, and thus the competition they entail; in several developing countries, prices of new medicines remain high for a longer time. This could result in reduced access.

## TRIPS and patents

Patents are one of the intellectual property rights in the TRIPS Agreement. Patent is a public policy tool; it was designed to promote and reward innovation, while at the same time ensure disclosure of the invention and make it widely known and available. Before TRIPS, countries could, and did, devise patent regimes in line with their level of development and their overall national priorities.

The TRIPS Agreement makes it mandatory for countries to ensure that patent protection is available in all fields of technology, for both process and product inventions. While the provisions of the TRIPS Agreement have an effect in many fields of technology, the impact on pharmaceuticals is particularly tangible. Thus, it is no longer possible for countries to exempt pharmaceuticals from patent protection (as a number of countries did, before TRIPS came into force) or limit pharmaceutical patents to process patents only (as certain countries such as India did).

The distinction between product and process patents is important. If a product is patented, only the patent holder may make, use, offer for sale, sell or import that product; nobody else may do so (during the time duration of the patent right), unless the patent holder has given permission (a license). In the case of a process patent, nobody may make, use, offer for sale, sell or import the product made by using the process that is protected. The monopoly costs associated with patents can limit the affordability of patented health-care products required by poor people in the absence of other measures to reduce prices

or increase funding. Thus, the overall effect of intellectual property regimes is context-specific – the impact in a country such as India may differ from that in Thailand or Ghana (1).

However, the same product may be produced in a different way. As multiple routes of synthesis can be devised for most pharmaceuticals, process patents offer considerably less protection than product patents.<sup>d</sup> Until 2004, India recognized only process patents for drugs.<sup>e</sup> 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. In 2005, this changed as India met its deadline to implement TRIPS (see *also* below). Hence for all new medicines, India has to comply with the TRIPS Agreement and not be able to produce generic versions in the absence of authorization of the patent holder.

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

The introduction of TRIPS standards for patents in developing countries can delay the marketing of generic versions of new drugs and thus reduce competition. Hence, it is anticipated that the prices of new drugs will remain high for a longer time,<sup>f</sup> which will result in reduced access for many people, notably in developing countries. Least-developed countries (LDCs) may choose to have or not have intellectual property rights regimes.<sup>g</sup>

d TRIPS has, however, reinforced process patents.

e The terms “drug” and “medicine” are used interchangeably in this document.

f TRIPS does not apply retroactively; therefore, there are no implications for drugs that were already off-patent when TRIPS came into force.

g The WTO recognizes as least developed countries (LDCs) those countries that have been designated as such by the United Nations (UN). There are currently 48 LDCs on the UN list, 36 of which to date have become WTO Members.

They may do so in accordance with their socioeconomic development level. In the South-East Asia Region, Bangladesh, Bhutan, Myanmar, Nepal and Timor-Leste are LDCs (Maldives graduated from LDC status in 2011). The pre-TRIPS regimes in both developed and developing countries may offer some valuable insights into what approach they could adopt.

The Doha Declaration of Member States on the TRIPS Agreement in 2001 (discussed later in the document) provides additional options for LDCs who do not need to comply with the provisions of the Agreement.

## Access to medicines

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>h</sup> Yet prices are an important factor, especially in developing countries. In developed countries, expenditure on pharmaceuticals for the population is largely publicly funded through reimbursement and insurance schemes, while in developing countries, typically, the cost of 50–95% of drugs are out-of-pocket expenditure by the patients themselves. In this regard, the 2001 Doha Declaration on TRIPS and Public Health signed by all WTO Member States noted that, while intellectual property protection was important for the development of new medicines, “we also recognize the concerns about its effects on prices”. In developing countries, prices have direct implications for access to medicines.

## TRIPS safeguards

It is important to note that TRIPS is operationalized via countries’ national laws. Moreover, TRIPS has certain flexibilities as well as some safeguards, which can be used

<sup>h</sup> It should also be noted that patents are not the only reason for high drug prices; distribution costs, high mark-ups and taxes are additional factors.

to mitigate the potential negative impact on drug prices and access to drugs.

Accordingly, 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”.

Among the key safeguards are (i) provisions for early working (often referred to as *Bolar provision*), (ii) parallel importation, and (iii) compulsory licensing.

The *Bolar provision* allows testing and regulatory approval of generic versions of a drug before its patent expires. Thus, generic producers can prepare for production of the drug and its sale as soon as the patent expires. In this way, a Bolar provision facilitates the quick entry of generic drugs into the market.

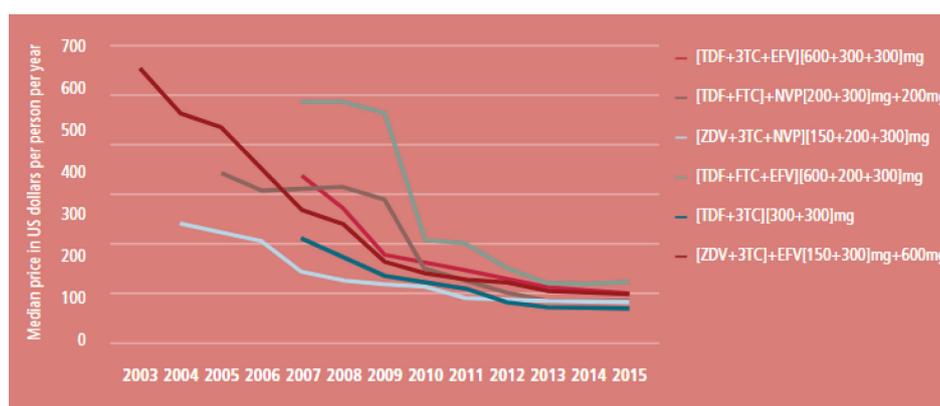
*Parallel importation* refers to importation, without the consent of the patent holder, of a patented product that is marketed in another country. Parallel importation allows one to “shop around” for a good price; for example, if a company sells drug X in country A at a price of \$10, while the same 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 \$3. As a result, in this example, country A would save \$7 on drug 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 WTO’s Ministerial Meeting in November 2001, the ministers clarified, in the Doha Declaration 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 without the permission of the patent holder of the invention. A compulsory license can be used to allow the production and sale of generic versions of the drug before expiry of



**Fig. 1.** Average prices for first-line ART regimens for adults, 2003–2015



Source: Global Price reporting Mechanism [online database] (160).

TDF: tenofovir; 3TC: lamivudine; EFV: efavirenz; FTC: emtricitabine; NVP: nevirapine; ZDV: zidovudine

the patent on the drug; thus, again, increasing opportunities for competition (and competition drives prices down, as can be seen in Fig. 1) (2).

The basic rationale for a compulsory license is that, as 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 provides for a compulsory license to 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.

The TRIPS Agreement specifies certain conditions for issuing a compulsory license. These conditions include:<sup>i</sup>

- ⦿ a case-by-case decision, which means a decision on each drug separately;
- ⦿ first trying to obtain a voluntary license from the patent holder;

- ⦿ adequate remuneration to be paid to the patent holder;
- ⦿ being predominantly for the supply of the domestic market (amended in January 2017);
- ⦿ being non-exclusive and non-assignable.

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. The condition of first trying to obtain a voluntary license is waived in the case of compulsory licenses that are issued for a national public health emergency, extreme urgency or in dealing with the anti-competitive behaviour of the industry.

In January 2017, the TRIPS Agreement was amended to include Article 31bis. The amendment provides the legal basis for WTO Members to grant special compulsory licenses exclusively for the production and export of affordable generic medicines to other Member States that cannot domestically produce the needed medicines in sufficient quantities for their patients (3).

<sup>i</sup> 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 behaviour of the patent holder, in case of an emergency or in case of public non-commercial use.

However, the safeguards provided for in TRIPS can be used only when incorporated in the national law. Thus, it is important that countries design and enact legislation that allows them to protect public interest, including public health interest.

## Further flexibility in TRIPS

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 a leeway in this respect.

A key flexibility that has been increasingly used over the past decade relates to the freedom under TRIPS for countries to define what is patentable. Thus, countries use either very strict or more flexible criteria for patentability. Applying flexible criteria for novelty and inventiveness enables, for instance, the issuing of patents for formulations or for isomers of known drugs, allows pharmaceutical companies to apply for additional patents, and provides them with opportunities to expand the duration of protection beyond that of the original patent. In this way, originator companies that own the patent can postpone generic entry of drugs and restrict competition. Applying strict criteria, as several developing countries have done, on the other hand, has encouraged generic production.

Yet whether this flexibility is actually used in order to facilitate access to medicines depends ultimately 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 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 entry of generic medicines, 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>j</sup>

Trademarks are another form of intellectual property and recognized as such in the TRIPS Agreement. National trademark laws should 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 experience with ARVs

Many countries have been at the forefront of the fight against HIV/AIDS, especially with regard to making HIV/AIDS drugs, including antiretrovirals (ARVs), available and affordable. Their strategies, with regard to intellectual property rights for access to medicines, are relevant and these have been used for noncommunicable disease medications as well.

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



## Thailand

The Government Pharmaceutical Organization (GPO) in Thailand is producing a number of generic ARVs. The GPO has primarily produced products that are not patented in Thailand, or for which the Thai patent has expired. One important drug, didanosine (ddl), used to be under patent in Thailand; however, the patent only applied to ddl tablets. Hence, the GPO began 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 ruled that the ddl patent was valid only for tablets containing 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). Between 2006 and 2008, Thailand issued a series of compulsory licenses for drugs for HIV, heart disease and cancer. The GPO was tasked under these licenses to produce or import the generic versions of these drugs.

## 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. This strategy was successful in the case of some medicines where the government was able to arrive at price agreements with the patent holders. In the case of efavirenz, however, in 2007, Brazil issued a compulsory license (CL). In 2012, the CL was renewed for an additional 5 years. Between 2007 and 2010, Brazil imported generic formulations of efavirenz from India. After this, the drug was locally produced and supplied to the government programme. Brazil is estimated to have saved more than 50% of the costs due to the lower generic prices.

## Indonesia and Malaysia

Increasingly, other countries are also taking action to make ARVs more available and affordable. In October 2003, Malaysia decided to apply "government use" provisions in its national law in order to import generic ARVs. In 2004, 2007 and 2012, Indonesia used the "government use" mechanism for domestic production of several generic ARVs.

## Ecuador

In 2009, Ecuador issued two presidential decrees; one declaring access to medicines of public interest and authorizing the use of compulsory licenses, and the second establishing Enfarma, a public pharmaceutical company. Enfarma was established to carry out research and development (R&D) for manufacturing generic medicines. Since the compulsory licensing decree, there have been 32 applications, of which nine were filed by Enfarma and two were granted.

## Options for countries

So what can countries do? What options are available to increase access to high-cost patented medicines? Clearly, the answer will vary considerably from country to country, depending on relevant national laws, production capacity and other factors.

The LDCs in our Region (Bangladesh, Bhutan, Myanmar, Nepal, Timor-Leste) do not have to comply with the TRIPS Agreement and can source/produce medical products from any jurisdiction.

Moreover, Bhutan, Democratic People's Republic of Korea and Timor-Leste are currently not WTO Members. Thus, they are not bound by any of the WTO agreements, including the TRIPS Agreement.

In principle, the following options exist.

*Countries with pharmaceutical production capability* could initiate local production of generic versions of those drugs that

**Table 1.** 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	2021*
e. Least developed countries to enforce or grant patents and data protection on pharmaceutical products	2033**

\*Under Article 66 of TRIPS, LDCs originally had a ten-year transition period to comply with the TRIPS Agreement. In 2005, the transition period was extended by 7.5 years to June 2013 when it was further extended till 2021.

\*\*In 2002, as part of the Doha Declaration on TRIPS and Public Health, LDCs received a waiver from their obligations to grant or enforce patents and test data protection on pharmaceuticals, and of their obligations to provide exclusive marketing rights during the transition period, till 2016.<sup>m</sup>

On 6 November 2015, the TRIPS Council extended the transition period relating to pharmaceutical products to 2033 (4). On 30 November 2015, a further decision was taken to waive the mailbox and exclusive marketing rights requirements (5).

are not patented or whose patents have expired.<sup>k</sup> They could also consider, if their national law and regulations allow, applying for compulsory licensing or “government use” to enable local production of generic versions of those drugs that are patent protected. The African Union’s Pharmaceutical Manufacturing Plan for Africa Business Plan (PMPABP) 2012 is a notable development in this regard. It “is based on the belief that industrial development and the development of the pharmaceutical sector is not in conflict with public health imperatives, and that the industry should in fact be developed with the long-term aim of promoting access to quality essential medicines”.<sup>l</sup> The plan identifies the use of TRIPS flexibilities and particularly the use of the LDC transition periods as central to the success of local pharmaceutical production.

*Countries where local production is not feasible or not viable* can import generics. 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, e.g. from India, provided the drug is not under patent in their territory. 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 Table 1; 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, for example, newer ARVs that may be patented.

Meanwhile, countries that lack national production capacity may face difficulties in making effective use of compulsory licensing provisions. While the importing country could use compulsory licensing or “government use” for importation of the drug from abroad,<sup>n</sup> foreign companies would face potentially severe restrictions on their capacity to export (because of TRIPS’ condition that a compulsory license should be issued “predominantly for the supply of the domestic market”).

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

<sup>l</sup> African Union, 2012

<sup>m</sup> “Least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement”, WTO 2001. See also WTO 2005.

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



During the WTO meeting in Doha, ministers recognized this problem, and instructed the WTO's TRIPS Council to find an expeditious solution. A solution was 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>o</sup>

has been criticized as being cumbersome, after the one instance in which it was used by Rwanda to import an ARV from Canada. In January 2017, this system became an amendment to the TRIPS Agreement as Article 31bis. This amendment applies to those WTO Members who have accepted it so far and, those who have not, have till 31 December 2017 to agree to it.

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

## Further reading

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