

The danger of TRIPS

This document will be of interest to anyone who wants to know more about Trade-Related Intellectual Property Rights (TRIPS). It provides some basic information on the TRIPS Agreement and how it affects access to HIV medication, and gives tips on what you or your organisation can do about it.

Brand-named and generic drugs

There are two types of medicines: proprietary or brand-named drugs, and generic drugs. Brand-named drugs are developed and produced by pharmaceutical multinationals and are patented in order to prevent them being copied and produced by other companies. Generic drugs are copies or the basic form of a brand-named drug. They are usually much cheaper. A WHO pre-qualification guarantees a level of quality equal to that of the brand-named originals.

First-line and second-line medicines – and the need for generic drugs

When patients have been taking HIV medication for some time, or if they have not adhered to the therapy, the virus can develop resistance to antiretroviral. In that case, the patient has to switch from first-line to second-line drugs. Many first-line antiretroviral drugs have generic versions. As a result of pressure from NGOs, the pharmaceutical companies now sell these to developing countries at lower prices. The majority of the second-line drugs, however, do not have generic versions. A lack of competition allows the pharmaceutical companies producing them to charge much higher prices. This puts them out of reach of people in low-resource areas. In Cameroon, as the international AIDS charity AVERT says, the recommended first-line treatment costs \$ 277 per person per year; these are generic drugs. For second-line treatment, the costs are \$ 4.763; these are proprietary drugs.

TRIPS

In 1994 the World Trade Organisation (WTO) reached an agreement on the intellectual property of products, the so-called TRIPS Agreement. TRIPS stands for Trade-Related Aspects of Intellectual Property Rights. The TRIPS Agreement protects ideas developed in WTO member countries from being stolen or copied. The patents within TRIPS offer protection for a minimum of twenty years.

WTO TRIPS Agreement feared to result in exclusion of generic competitors

Many developing countries are in direct need of cheaper drugs. In their view, the TRIPS Agreement does not sufficiently take their interests into account as it chiefly serves the interests of the big pharmaceutical companies. It is feared that the WTO TRIPS Agreement and its globalised patent rights will, in the coming decade, provide a few pharmaceutical industries with a monopoly in the HIV-related medicines market, thus excluding lower-cost generic competitors.

Compulsory licensing

During the WTO Doha ministerial meeting in 2001, it was decided that the TRIPS Agreement should not prevent WTO members from taking measures to protect public health. A compulsory licensing measure was introduced, enabling governments to issue licences for the production of a generic drug without the permission of the patent holder of a comparable brand-named drug. Unfortunately, a lot of the countries in urgent need of drugs lack the capacity and know-how to produce generic drugs, and this makes it difficult for them to effectively benefit from compulsory licensing. NGOs therefore argued that all WTO members should allow the production of a patented product to address the health needs in another country where the product is either not patented or where a compulsory licence has been granted. This approach was eventually approved by the WTO. Although compulsory licences can be used to authorise imports of generic pharmaceuticals made elsewhere, in practice the Agreement makes it difficult for countries with a sufficient generic drugs stock to export them. It states that the drugs should be used 'predominantly' for supplying their own domestic market.

Free trade in exchange for TRIPS+

Pharmaceutical companies are often wealthy, well-structured organisations with a strong lobby. They know where, when and how they should lobby in order to get the best outcome, which is always profit-related. In relation to TRIPS+ they successfully influence governments in rich countries like the US. As a result, their interests are well represented in the commissions participating in the negotiation of

patents. This is also the case in multilateral negotiations (like TRIPS within the WTO) and bilateral or regional **Free Trade Agreements** (FTA). The interests and needs of people living with HIV/AIDS in developing countries are often insufficiently represented in multilateral and bilateral negotiations. This imbalance constitutes a threat for developing countries, since compromises which have been reached in multilateral negotiations can be avoided in bilateral and regional negotiations. The US government is negotiating with other countries about signing so-called **TRIPS+** agreements that go beyond the TRIPS requirements. Within these bilateral FTAs, developing countries do not apply for compulsory licensing in exchange for free access to the markets of developed countries. And this means that the high price of medications will be protected for more than 20 years!

A country such as **Ghana** is currently trying (with the help of DFID) to withstand an unfavourable free trade agreement. The **Southern African Customs Union** (SACU) does not want to give in to American pressure, and has withdrawn from the FTA negotiations.

Challenges

Gaining a compulsory licence or the rights to import generic drugs from another WTO member country is very complicated because:

- ⌘ there is often a lack of cooperation and communication between the Ministry of Trade, which deals directly with the TRIPS Agreement, and the Ministry of Health;
- ⌘ many patent offices in developing countries have a badly-functioning administration;
- ⌘ interpreting the validity of patents is quite difficult, so some countries have decided to let *regional* patent organisations handle patent applications on their behalf. These organisations' recommendations automatically turn into valid patents, unless a country's Ministry of Health raises objections. Unfortunately, the outcomes are not always to the advantage of the developing countries in need of medicines.

Achievements

There has been much progress in the production of generic drugs. In some countries, e.g. **Brazil, China, India, South Africa and Thailand**, these drugs have been manufactured for some time now.

Brazil has an extensive generic drugs industry that enables the government to supply antiretroviral AIDS drugs free of charge to whoever needs them.

In **India**, local pharmaceutical companies produce both generic drugs *and* the raw materials and chemicals used in their manufacture. The raw materials are often exported to major companies for the production of their brand-named drugs.

In 2001, the government of **South Africa** was taken to court by 39 pharmaceutical companies for passing the *Medicines and Related Substance Control Amendment Act*. The government stood firm and the multinationals had to abandon their case. This had a positive effect on the prices of HIV/AIDS medication in South Africa, making it more accessible.

With the help of expertise from Brazil, India and Thailand, a number of African countries, including **Ghana, Mozambique, Tanzania, Uganda, Zambia and Zimbabwe** are taking the first steps to set up their own generic drug plants.

Both **Brazil** and **South Africa** have effectively lobbied pharmaceutical companies to get lower prices on a sustainable basis.

The **European Union** initially lobbied against the *South Africa Medicines and Related Substance Control Amendment Act* but changed its policy in 2000. The EU block has been very vocal against the US pushing TRIPS+ conditions in the FTA. That is positive. The EU allows its member states to produce generic drugs for exclusive export to developing countries. A member state such as the Netherlands (and also non-EU member Norway) is keen to produce generic drugs for exclusive export to the South. A request from a developing country, however, often doesn't reach the countries willing to export drugs. The procedure is either not started at all, or it is delayed as a result of the complexity of the procedure or the incapacity of the developing country to take the required action.

What can you do?

- ⌘ NGOs worldwide should lobby their governments for a **revision of the 1994 WTO TRIPS Agreement** in order to ensure and improve access to HIV- and other epidemics-related drugs for the world's poorest people;
- ⌘ NGOs should encourage governments in the South to **improve the relationship between the Ministry of Health and the Ministry of Trade** when dealing with TRIPS and FTAs;
- ⌘ In addition, NGOs should help create **awareness** of the impact of the 1994 WTO TRIPS Agreement for HIV-related medicines;

- ⌘ National and regional NGOs must:
 - identify **regional patent organisations** dealing with FTAs and TRIPS;
 - find out **when** patent applications are in process;
 - lobby regional patent offices to put the nation's health above the profit interests of pharmaceutical companies.
- ⌘ In their lobbying, NGOs could focus on four aspects of TRIPS+:
 - **Second use:** The TRIPS agreement requires protection for *novel* pharmaceutical products and processes, but not for *new* indications or *second use* of already-known molecules. Many FTAs, however, contain an obligation for developing countries to explicitly allow second-use patents, thus limiting their opportunities for distributing cheaper generic drugs. **NGOs in developing countries should persuade their governments to refuse second use patent applications and, if necessary, remove them from their patent legislation, as they are TRIPS+;**
 - **Patent extension over 20 years:** The TRIPS Agreement requires a *minimum* of twenty years patent protection. In the interests of public health, this is more than enough. Some FTAs, however, contain a provision to extend this minimum. **NGOs in developing countries should convince their governments that an extension is unacceptable;**
 - **Limits within compulsory licences:** The pharmaceutical companies are lobbying the US to negotiate a voluntary limitation for developing countries, so that compulsory licences are only granted for national emergencies, and anti-competitive or public sector use. **NGOs in developing countries should lobby their governments to resist voluntary restrictions to using flexibilities of the WTO TRIPS Agreement;**
 - **Early working clause:** To stimulate generic competition immediately after patent expiry, developed countries have drawn up 'early working' clauses which allow generic companies to develop, test and seek regular approval for their products (but not sell or stockpile them) a few years *before* patent expiry. **NGOs in developing countries should lobby their governments to resist any pressure in Free Trade negotiations to remove these early working clauses,** which are seen to be an obstacle for generic companies.

NGOs should lobby the governments of European countries about speaking out against the inclusion of TRIPS+ in regional Free Trade Agreements.

More information

- ⌘ AVERT (international AIDS charity), TRIPS, AIDS & Generic drugs, www.avert.org
- ⌘ For details on Free Trade Agreements, see: www.bilaterals.org
- ⌘ MSF, What to watch out for in Free Trade Agreements with the USA? www.accessmed-msf.org/documents/ftabriefingenglish.pdf
- ⌘ Ministry of Foreign Affairs, the Netherlands, *Trade, Health, Medicines & AIDS: TRIPS to development?* www.minbuza.nl
- ⌘ Canadian HIV/AIDS Legal Network, <http://www.aidslaw.ca>
- ⌘ DFID Health resource Centre. http://www.dfidhealthrc.org/publications/access_medicines.html
- ⌘ What happened in Hong Kong?, Oxfam Briefing Paper, December 2005, Oxfam International. http://www.oxfam.org/en/files/bp85_hongkong/download

Request for feedback

STOP AIDS NOW! has developed this fact sheet at the request of some of its partners and counterparts. This is not, however, the final version. It is a first attempt to provide you with some clear information about TRIPS, its impact and the things you can do about it. We would be happy to receive your feedback to help us write an improved, definite fact sheet. Please send your ideas, questions or criticism by e-mail to alopez@stopaidsnow.nl

