

## Briefing from the EQUINET Secretariat

### WORLD TRADE ORGANISATION AGREEMENTS: TIME TO MAKE PUBLIC HEALTH A MORE CENTRAL CONCERN

In 2000 EQUINET co-published a policy paper (Policy Series 4) with the Southern African Development Community (SADC) Health Sector Co-ordinating Unit noting the demands that global trade rules now place on southern African states to implement policy, legal and institutional measures to sustain essential drug access, meet public health obligations and protect equity in access to health care. This primarily relates to

- Restrictions on options for lower cost access to newly patented pharmaceutical drugs, and
- Reduced regulation of international private health sector providers.

The most high profile agreement recently has been the WTO agreement on **Trade Related Aspects of Intellectual Property (TRIPS)**, which establish standards for intellectual property rights. The patents arrangements under TRIPS exclude third party use, offering for sale, selling or importing of such products for a minimum of 20 years from the date the patent application is filed. This stops production of generic copies for at least 20 years, reducing competition in that time and thus enabling high prices.

Before TRIPS, many developing countries did not recognise patents for pharmaceuticals. This allowed countries to make copies of new drugs. TRIPS obliges all WTO member states to implement product patent protection for all drugs patented after 1995. Least Developed Countries (10 out of 14 SADC states are LDC states) have to make their patent law TRIPS compliant by 2006.

Currently, most essential drugs are not patented. TRIPS is thus less of an issue for the vast share of **existing** essential drugs than it is for **new and future** essential drugs, patented after 1995. Increased costs of new patented drugs for HIV/AIDS, resistant Tuberculosis, Malaria etc places a burden on the public health budget.

Where drugs are patented, TRIPS allows certain public health "safeguards":

- Article 31 of the Agreement allows member states to grant drug licenses without the approval of patent holders, on the grounds that the drugs will be allocated to non-commercial use, or that they are required to meet an "emergency";
- When a patented product is marketed at a lower cost in another country, countries may "**parallel import**" that drug from that country where the same manufacturer sells it at a lower price, if they have enabling provisions in their patent law.
- Countries may insert "**compulsorily license**" clauses in their national law. This allows a government, under certain circumstances, to import or produce a more affordable generic copy of the patented product, and pay a royalty to the patent holder. These exceptions are, however, time limited, and conditional.
- In some instances member states are permitted to waive patent rights in order to curb "abuses" of monopoly positions maintained by patent holders, with abuses including aspects of unfair or unreasonable pricing;
- In order to benefit from lower priced generic drugs immediately after patent expiry, governments can insert "**Bolar**" or "early working" clauses in the patent act. These allow generic companies to develop and test (but not stockpile for sale) generic drugs in the last years of a patented drug.

Countries can also seek non legal remedies, such as:

- voluntary price reductions / donations from industry
- price controls (not regulated under TRIPS)
- voluntary license from patent holders for local production / transfer of technology, emergency use.

The recent withdrawal of the legal challenge by pharmaceutical manufacturers to the South African government's 1997 amendments to its Medicines and Related Substances Control Act is an advance in that it reinforces the right of states to take measures such as parallel importing or issuing of compulsory licenses to meet public health needs.

International pharmaceutical companies are, however, still taking up a legal challenge to Brazil's patent law as being non compliant with TRIPS and to Brazil's price controls on medicines. The legal challenge has, according to Oxfam, been backed by threats of withdrawal of investment, trade sanctions, and a request for a WTO dispute settlement panel to rule on the alleged violations of the TRIPS agreement.

There is widening pressure that access to medicines should not be left to isolated legal challenges, but should be dealt with through a more systematic review of global trade rules. In response to this, World Trade Organisation (WTO) members will hold a special meeting, primarily at the instigation of African nations, to discuss the impact of global patent rules on access to medicines on 20 June at the WTO in Geneva.

*Oxfam UK note " It is not surprising that the TRIPS Agreement is fast becoming the epicentre of a battle which pitches some of the world's most powerful pharmaceutical companies, backed by rich governments, against some of the world's most vulnerable people. More widely, there is a growing sense that the Agreement is fundamentally unfair and unbalanced – a fact which threatens to bring not only the patent system but also the whole multilateral rules-based system into disrepute, and which policy makers ignore at their peril".*

On 14 May 2001, the EU Council of Ministers passed a resolution on communicable diseases endorsing governments' use of the public-health safeguards within TRIPS.

The EQUINET regional conference in September 2000 called for stronger and more unambiguous provisions to give meaning to the "public health safeguards" permitted under the TRIPS (Article 8) and other WTO agreements. Advocacy is now growing for amendments to trade rules and procedures to

- give governments the option of reducing the length and scope of pharmaceutical patenting on public health grounds,
- ease the conditions for compulsory licensing, and to
- develop fast-track procedures for public-health purposes.

There are also calls for a moratorium on trade disputes with developing countries over TRIPS compliance until a review of TRIPS is concluded, and the concerns of developing countries about its implementation are addressed.

The EQUINET secretariat draws the attention of the public health community to the June 2000 meeting and to the 4th WTO Ministerial in Qatar. The outcomes of the debates at these platforms will have a significant impact on public health and access to essential drugs. Oxfam GB has recently issued a policy briefing on the meeting. Please let us know of any other such positions, or views you have on strengthening the public health safeguards in TRIPS. We will disseminate these.

The EQUINET policy series also drew attention to another WTO agreement, the **General Agreement on Trade and Services (GATS)**, which provides for the opening up of countries' domestic markets to foreign suppliers of hospital and medical services. Such provisions, still under negotiation, were not part of previous global trade agreements. Depending on their application, they may further restrict the rights of national governments to regulate liberalisation and manage resources in the best interests of public health, particularly if foreign private health providers are able to challenge local subsidies and other state spending on public and not-for-profit health services. On the basis of the TRIPS experience, and given that essential drugs demand an equitable health infrastructure, it is equally important that the public health impacts of and safeguards in this agreement be given attention.

*EQUINET Policy Series #4 on WTO and Public Health in SADC is available in hardcopy from the EQUINET secretariat at TARSC, 47 Van Praagh Ave, Harare, email [tarsc@mweb.co.zw](mailto:tarsc@mweb.co.zw) or as a downloadable pdf file from our website at [www.equinet.org.zw](http://www.equinet.org.zw). If you have input or comments on this issue please email these to the secretariat to [rloewenson@healthnet.zw](mailto:rloewenson@healthnet.zw).*