

Editorial

WTO deadlines: why developing countries must act now to protect access to medicines

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Within the next 12 months there are intellectual property deadlines looming for developing countries that could have a significant impact on their future access to medicines. These relate to the World Trade Organisation's (WTO) Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement. This Agreement outlines the intellectual property obligations for all 144 WTO members, including intellectual property over medicines. It was negotiated during the Uruguay Round from 1986 to 1994. Under TRIPS, inventors can apply for a minimum of 20 years' patent protection for a new drug.

The first deadline comes in July of this year, when part of the TRIPS Agreement will be amended. The amendment will take into account debate that has occurred since the creation of the TRIPS Agreement and which has further defined how and when the Agreement should be used to address public health needs. This has important implications for the future access to medicines by the developing world.

To understand these implications, first some background. There has been much debate since the creation of the TRIPS Agreement as to whether medicines sit comfortably next to all other products when it comes to patent regulation. On one hand, the inventor of a new medicine needs to be able to protect their right to recoup the investment on research as well as profit from their invention. On the other hand, shouldn't the public health needs of a population take precedence over the need to protect intellectual property rights?

In Doha, Qatar, in November 2001, WTO members agreed 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'.¹ The Doha Declaration confirmed, among others things, that member states could grant permission, using a 'compulsory licence', to allow the production or importation of generic medicines for that country without the consent of the patent holder. This provision is so-called 'compulsory' as the patent holder has no say in whether the patent is overridden, but nevertheless receives adequate compensation. The existence of generic competition has

been a key way of driving down the price of medicines, thereby overcoming a significant barrier to drug access. For example, since the introduction of generic competition, the internationally available price for an antiretroviral (ARV) triple-combination has fallen from US\$10 000 in 2000 to US\$132 in late 2003 — representing a 98% decrease in price.² This drastic reduction in ARV prices has increased the feasibility of governments and donors providing treatment for hundreds of thousands of people living with HIV/AIDS in the developing world. The use of compulsory licensing to ensure generic competition, which in turn results in lower-priced drugs, is only one example of how the 'safeguards' that exist under TRIPS, can reduce a major barrier to drug access.

However at more recent WTO meetings, countries such as the United States, under heavy pressure from the US proprietary pharmaceutical industry, have sought to place additional stipulations on how the TRIPS Agreement will be amended. These stipulations seek to create many additional bureaucratic barriers to overcome in order for developing countries to produce, import or export generic medicines.

Thus, in the lead-up to the deadline for an amendment of the TRIPS Agreement in July (this may be extended), it is up to both developing and developed countries to test if the TRIPS 'safeguards' and the proposed amendments to the Agreement, really will ensure practical, sustainable and affordable access to medicines. For example, if the price of a patented medicine in a country puts it beyond the reach of a majority of the population, can a government easily issue a compulsory licence to access a more affordable generic version? This question was almost put to the test in October last year, when the South African Competition Commission ruled that GlaxoSmithKline and Boehringer-Ingelheim were charging excessive prices for their antiretrovirals. This ruling created the possibility that a compulsory licence could have been issued to allow generic production of the drugs. However before this occurred, the two companies agreed to allow generic production of the antiretrovirals.³ Meanwhile in another test of the proposed amendments to the TRIPS

Agreement, the Canadian Government recently debated how to incorporate these amendments into its Patent Act so as to allow the country to export generic medicines to the developing world.⁴ Unfortunately the resulting bill caved in to patent-holder pressure, placing several restrictions on the production and export of generic medicines to developing countries. These restrictions are above and beyond what is contained in the proposed amendments to the TRIPS Agreement and include a limited list of medicines that may be exported.⁵ The South African and Canadian examples illustrate how WTO members should be asking themselves *now*, whether they are *really* able to overcome the barriers for importing and exporting generic medicines that are slated for inclusion into the TRIPS Agreement when it is amended later this year. Experiences in trying to overcome these barriers and use the 'safeguards' should be fed back into the process of amending the TRIPS Agreement, so that the Agreement *really does* ensure access to medicines for the poor.

The second deadline comes on the 1 January 2005. Under the TRIPS Agreement there is a timetable by which all WTO member states must become fully 'TRIPS compliant' and introduce into their national legislation a patent law system which complies with all TRIPS requirements. While developed countries are already TRIPS compliant, developing countries such as India have until the 1 January 2005 to fully comply with the Agreement, and least developed countries, such as Myanmar and Bangladesh, have until 2016. Up until now, countries such as India have been able to develop a sophisticated generic pharmaceutical industry, because of their lack of national patent legislation for pharmaceutical products. For example, India has been able to manufacture and supply generic antiretrovirals for HIV/AIDS treatment to developing countries worldwide, which would have been impossible if the country had had pharmaceutical product patents. However, this ability to produce and export generic medicines may be compromised after 1 January 2005, when India will become fully TRIPS compliant.

Many developing countries have already amended their patent law to be fully TRIPS compliant prior to the deadline. However those that have yet to do so should ensure that as their patent laws are developed, they include the provision to use the 'safeguards', such as compulsory licensing, available under the TRIPS Agreement. If necessary, countries should seek unbiased technical advice to ensure that these safeguards are incorporated correctly into national law so that they are easily used in the future. This advice could be provided by developed country governments — as long as it is given in a balanced and transparent way. The relevant health authorities in developing countries should be included in the process of drafting patent laws to ensure that the access to medicines issue is properly addressed.

The deadlines for the amendment of the TRIPS Agreement and the requirement that developing countries be fully TRIPS compliant are fast approaching. It is up to health practitioners in developing countries to be aware of these deadlines and to encourage their governments to ensure the 'safeguards' permissible under TRIPS are enshrined in national legislation *and used* when required. This would include urging governments to make use of compulsory licences when necessary to foster generic competition so that prices for medicines are reduced to levels that are affordable for the local population. Health practitioners in developed countries can encourage their governments to provide unbiased technical support to countries that need to incorporate the TRIPS safeguards into their national legislation. In all WTO member countries, healthcare providers, community-based organisations and advocates can encourage their governments to support amendments to the TRIPS Agreement at the WTO that are workable, sustainable, economically viable and that will clearly ensure 'access to medicines for all'.

For more information about these issues, visit the following websites:

Medecins Sans Frontieres: Access to Essential Medicines Campaign

www.accessmed-msf.org

Consumer Project on Technology

www.cpt.org

Health Action International

www.haiweb.org

Third World Network

www.twn.org

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