Fact Sheet: Changes to India's Patents Act and Access to Affordable Generic Medicines after January 1, 2005 • contact: info@healthgap.org • tel: +1 (267) 475 2645

Background

India faces a deadline of January 1, 2005 to comply with WTO requirements, set out in TRIPS (the Agreement on Trade-Related Aspects of Intellectual Property Rights) that it protect product patents on medicines (TRIPS Art. 65.4). India has not protected product patents on medicines for the last 35 years. Competitive domestic manufacturers have kept medicine prices low in India, for domestic and export markets.

According to the WHO, India ranks 4th in the world in production of pharmaceuticals by volume and is the world's leading supplier of generic medicines, with 66.7% of its exports going to developing countries. In the case of antiretroviral medicines to treat HIV, Indian generic production has slashed prices by as much as 98%—from approximately $10,000 per year to as little as $140 per year for an initial three-drug combination.

When India begins to protect patents on medicines next year, the world's supply of new affordable generic medicines will essentially disappear. In addition, many products that have already been on the Indian market since 1995 in generic form will be evaluated for patentability and could become patent protected after January 1, 2005. If patents are granted on those older drugs, generic versions would be withdrawn from the market or face litigation from brand name companies (see **"Which drugs will be affected?"** below).

Unless the Government of India takes action to prioritize the protection of public health, both for Indian consumers and consumers in importing countries, drug prices will rise and lack of access to treatment for public health problems will worsen.

Which drugs will be affected?

Two categories of drugs will be affected—first, medicines that will be invented after January 1, 2005. If a medicine is patentable, the patent holder will be granted a 20-year monopoly from the date of filing as a result of the new rules. Without a compulsory license, generic versions will not be permitted on the market for the life of the patent. In other developing countries that have begun protecting patents on medicines in accordance with WTO rules, the vast majority of medicines patent filers in developing countries are multinational drug companies based in industrialized countries.

The second category of medicines that will be affected by the change in India's Patents Act are those that have been patent protected outside of India since January 1, 1995. According to WTO rules (TRIPS Art. 70.8), India was required to establish a "mailbox" where patent applications could be filed between 1995 and 2005. After January 1, 2005, the mailbox will be opened, and requests for patents considered by the Indian Patent Office.

Over the past ten years only a few hundred New Chemical Entities (NCEs) were identified, but approximately 4,000 patent applications for medicines are in India's mailbox. Experts assume, therefore, that most of those patent requests are for already known medicines that have been only slightly modified.

In the U.S., this process is known as "evergreening," which blocks generics from entering the market and driving prices down. Among the drugs presumed to be included in the mailbox are several used for AIDS treatment, such as Combivir (zidovudine/lamivudine combination), a medicine currently taken in generic form throughout Africa. If medicines like Combivir that are in the mailbox are granted patent protection after January 1, 2005, generic versions already on the market being will be withdrawn—or face litigation.

What impact will India's changes have on AIDS drug access in poor countries?

New patent monopolies in India will dramatically drive up the cost of medicines—for AIDS treatment as well as treatment for cancer, diabetes, heart disease, and other public health problems. This cost increase will burden poor people in India and in importing countries around the world.

An illustration of what will happen in India is provided by the case of the life saving anti-cancer drug Glivec (or Gleevec, imatinib mesylate). When Novartis was granted Exclusive Marketing Rights (EMRs) for Glivec in India, Glivec's price in India rose approximately ten times.

In the case of HIV treatment, new patent monopolies in India will prevent generic production of newer, more expensive combinations of antiretrovirals. These more costly combinations are needed when people living with HIV cannot tolerate "first line" treatment, or when they develop resistance to first line combinations. These older, first line drugs are as much as 21 times cheaper than "second line" treatment. Treatment is available to only 440,000 people with HIV in developing countries although 6 million people are in imminent need of medicines. As the number of people on treatment in poor countries grows, the number of people who need second-line treatment will also grow. The cost of AIDS treatment scale up will skyrocket in India and around the world—unless India commits now to using its rights to protect access to affordable medicines after new rules come into affect.

What are civil society groups in India recommending?
India fought for the passage of the historic Doha Declaration on the TRIPS Agreement and Public Health, which reaffirmed countries' rights to use flexibilities in WTO rules to prioritize access to affordable medicines ("Declaration on the TRIPS agreement and public health," WT/MIN(01)/DEC/2, 20 November 2001). However, the changes the government of India is considering are "TRIPS-plus"—they do not make full use of the flexibilities TRIPS provides, and in some cases they exceed the standard of patent protection that TRIPS requires.

Civil society groups in India, and in importing countries around the world, led by the Affordable Medicines and Treatment Campaign (AMTC), are demanding that the Indian government alter the Patents Act in the following, pro-public health manner:

- **Simplify and streamline India's compulsory licensing procedure.** Routine issuance of compulsory licenses after January 1, 2005 in India is critical if the rapid entry of generic versions of important pharmaceuticals is to continue. But compulsory licensing in India is considered cumbersome. The process must be changed to facilitate routine and expedited compulsory licensing of important medicines. A strictly enforced deadline of one to three months should be established for the grant of a compulsory license, and rights of appeal should not include permission for injunctive relief that would impede the use of the license.
- **Retain India's pre-grant opposition procedure.** India's pre-grant opposition procedure permits opposition to potentially frivolous patent applications, protecting consumers against high prices on non-innovative pharmaceutical products under consideration for patent protection.
- **Remove draft provisions for new-use or second-use patents, currently described in Section 3(d) of the Patents Act.** TRIPS does not require the granting of additional patents for new uses or new dosage forms for known medicines. New use or second use patents do not reward or encourage true innovation; they will however increase the cost of important medicines, compromise patient access, and extend monopolies over a longer period of time.
- **Fully implement the decision of the WTO General Council on the implementation of paragraph 6 of the Doha Declaration for countries that lack sufficient domestic pharmaceutical manufacturing capacity (the "August 30th Decision").** The draft amendment to the Patents Act would not permit export of compulsorily licensed medicines from India without a compulsory license granted in the importing country. If the importing countries does not have a patent for the compulsorily licensed medicine in force, it would not be allowed to import compulsorily licensed medicines exported by India, even though the August 30th Decision clearly permits this. Despite its flaws, the August 30th Decision should be implemented in as complete a manner as possible.