

CAFTA & Public Health: Will poor people have access to medicines?

Summary: Intellectual property measures in the Central America Free Trade Agreement (CAFTA) will limit the ability of Central American governments to make affordable medicines available to their populations.

Background: Chapter 15 of the CAFTA agreement requires Central American governments to enact more stringent intellectual property laws related to pharmaceutical products. In general, the measures in CAFTA are designed to delay or limit the introduction of generic competition and shift the balance of intellectual property systems toward patent holders and against broader societal interests and public health.

Generic competition has proven effective in reducing drug costs in a sustainable way. Cheaper drugs can mean life and death, most notably in the case of AIDS medicines where prices in developing countries dropped from \$10,000 to \$300 a year per patient over the past few years. In Costa Rica, where 85 percent of the population has formal health insurance, the public health system relies on generics to keep costs down and maintain widespread coverage. In other Central American countries, where less than one-fifth of the population has health insurance, patients must buy drugs out-of-pocket. For these patients, patented drugs are too expensive and patent rules that limit the availability of affordable generics prevent them from obtaining life-saving medicines. Even though these poor countries do not represent a significant market for the pharmaceutical industry, the US has insisted on stringent new requirements that will limit poor people's access to medicines.

All of the CAFTA countries are WTO members and are therefore signatories to the intellectual property treaty known as the TRIPS Agreement, which requires countries to institute high levels of intellectual property rights. The TRIPS Agreement's application to pharmaceutical products has come under scrutiny in recent years; in some controversial cases, the agreement threatened to prevent developing countries from providing cheap AIDS medicines to patients. In recognition of the potentially devastating impact of higher prices on poor patients' access to medicines, WTO members unanimously adopted the "Doha Declaration on the TRIPS Agreement and Public Health" in 2001. The Declaration affirmed that TRIPS provisions should be interpreted so as to prioritize public health over patent rights.

CAFTA undermines the Doha Declaration and public health: In August of 2003, members of the WTO agreed to provide new mechanisms under the TRIPS Agreement for countries to provide medicines for public health purposes. Unfortunately, CAFTA would extend patents beyond what is required under TRIPS by eliminating or weakening the public health safeguards contained in TRIPS.

Extending patents and limiting the government's ability to introduce generic competition is particularly damaging to poor patients in developing countries who buy medicines out-of-pocket. When drug prices rise, the poor make difficult sacrifices to buy drugs. More often, they do without and suffer or die unnecessarily. Central America has the second highest death rate from communicable diseases in Latin America. Nearly 165,000 people are living with HIV/AIDS and 30,000 cases of full-blown AIDS have been reported in the region.

The following provisions in CAFTA's Chapter 15 raise concerns:

- **Obstacles to the use of compulsory licenses.** Under the TRIPS Agreement, governments may issue a compulsory license to obtain cheaper generic drugs by temporarily overriding a patent. Compulsory licensing is an important tool for governments to protect the public interest or to remedy anti-competitive behavior. The threat of a compulsory license has been used as negotiating leverage by developing countries such as Brazil to negotiate price reductions with drug companies, and the US uses it to regulate anti-competitive behavior. Yet CAFTA includes a new provision that appears to make compulsory licensing pointless by prohibiting generic suppliers of patented drugs from obtaining marketing approval at any point during the patent period. As a result, governments would be effectively forbidden from making cheaper versions of patented medicines available to the public, even during a health crisis.
- **Restrictions on use of test data to block the introduction of generic products.** CAFTA requires governments to guarantee exclusive use of test data for pharmaceutical products for five years. This would deny generic manufacturers critical information necessary to prove the safety and efficacy of their products. Usually generic producers simply prove their product is bio-equivalent to an already approved, patented product, relying on the test data of the original product to prove safety and efficacy. CAFTA would prohibit generic competitors from relying on this data for five years from the time the data is first submitted. Furthermore, the agreement mandates protection of test data that has been submitted in countries not covered under CAFTA. A patent holder could protect itself from generics competition for up to ten years -- five years prior to entering a CAFTA-country market and an additional five years following marketing approval in the CAFTA country. This provision would also impede the use of compulsory licenses for public health.
- **Patent extension.** CAFTA requires extension of the patent term beyond the standard 20 years under the TRIPS Agreement to compensate for delays in granting the patent or regulatory approval. Each additional day a drug patent is extended is one more day in which drug prices may be out of reach for poor people.
- **Obstacles and delay for generic competition.** CAFTA would forbid generic producers from seeking approval for drugs in advance of the expiration of a patent. Generic producers often do this in order to be ready to sell their product immediately upon patent expiry. In addition, drug regulatory authorities must notify the patent holder when another company seeks approval for a generic version of its product. Similar provisions in US law have been abused by the pharmaceutical industry to block competition. These provisions are likely to result in delaying the availability of affordable generic medicines.

While the US will have little trouble complying with the intellectual property requirements of CAFTA, the Central American countries will be forced to impose new, more stringent patent protections that could seriously reduce or delay the availability of affordable generic drugs and competition in the pharmaceutical market. Oxfam believes that Central American countries should be able to make full use of safeguards provided under the TRIPS Agreement, assuring the primacy of public health over patent rights.