Canadian HIV/AIDS Legal Network | Réseau juridique canadien VIH/sida

Commentary
Commentaire

November 2006

TIME TO DELIVER (OR NOT)

Despite Prime Minister Harper's unfortunate statement that the recent XVI International AIDS Conference in Toronto (AIDS 2006) was no time for the government to make announcements about AIDS, one issue could not be avoided.

Two years ago, Parliament unanimously passed a law to ease access to lower-cost, generic medicines for developing countries confronting an ongoing tide of suffering and death. But so far not a single pill has left Canada. During AIDS 2006, federal Health Minister Tony Clement promised that the government would review the law and fix it to make it work.

So why hasn't it been used? And what can be done?

In 2001, the member countries of the World Trade Organization (WTO) unanimously recognized that countries have the right to grant "compulsory licences" that allow generic manufacturers to produce lower-cost versions of patented, brand-name drugs in exchange for royalties. Breaking the monopoly of patent-holders allows market competition, which brings down medicine prices.

Many developing countries can't afford patented, brand-name medicines and lack the industrial capacity to manufacture their own generic ones, meaning they rely on imported medicines. So, in 2003, WTO countries adopted a mechanism that would ostensibly allow for issuing compulsory licences in one country to produce lower-cost generic drugs for export to developing countries in need. The following year, Canada enacted legislation to implement this decision.

In theory, Canadian generic drug manufacturers can export lower-cost medicines to eligible developing countries. But when the previous government drafted the existing law, it sought to "balance the interests of all stakeholders." In other words, it bowed to pressure from the multinational pharmaceutical industry by building extra hurdles into an already cumbersome WTO framework. Canada should abolish the unnecessary barriers built into its law.

The more fundamental problem is the 2003 WTO decision on which Canada's law is based. The result: in the three years since the decision was adopted, not a single country has successfully used the WTO-approved mechanism.

The WTO decision embodied in Canada's law ignores the realities of both generic drug manufacturers and developing countries. Developing countries need simple contract processes that will ensure sustainable supplies of essential medicines or other pharmaceutical products; these contracts must be flexible enough to adjust to changing needs. The WTO decision enacted by Canada, however, forces generic companies through unnecessary red tape to get a licence to manufacture and export each patented drug, and only in a pre-negotiated quantity and to a single country.

What can Minister Clement do to fix this situation? He can streamline the legal process so that developing countries and generic drug companies can and will use it.

Generic manufacturers should be able to apply at the outset for a compulsory licence to manufacture and export any patented medicine, not just those on the limited list attached to the original legislation. With such a licence in hand, they should be able to negotiate multiple purchasing contracts with multiple developing countries — not just one-off agreements on a country-by-country, order-by-order basis for which a separate licence must then be obtained each time, as is currently the case.

There should be no arbitrary time limits on the length of the compulsory licence — currently, there is a two-year cap, limiting the economies of scale needed to make compulsory licensing viable for generic manufacturers and throwing into question for potential developing-country purchasers the long-term sustainability of supplies.

There should be no mandatory 30-day negotiation period between generic manufacturers and brand-name patent-holders — rather, getting the licence to produce for export to eligible developing countries should be automatic.

And, as is currently the case, generic manufacturers should be required to pay royalties to the patent-holders for each contract they negotiate with a purchasing country — the current law already contains a sensible formula for determining the applicable royalty, based on the level of development of the importing developing country.

Such a mechanism would give generic manufacturers and developing countries much more incentive to make use of the law and realize the goal of getting medicines to people who need them in developing countries. Canada has implemented the mechanism negotiated at the WTO in 2003; so far, it hasn't worked. But WTO countries also agreed their decision did not preclude using

other “flexibilities” in the WTO treaty on intellectual property, which they said should be interpreted and implemented so as to promote access to medicines. Under the treaty, countries can create “limited exceptions” to patent rights in their own laws. Canada can legislate the simpler, streamlined mechanism described above as one such exception. The question now is whether Minister Clement and his government will do so to deliver on the promise made.

Richard Elliott is Deputy Director of the Canadian HIV/AIDS Legal Network (www.aidslaw.ca), Canada's leading advocacy organization working on the legal and human rights issues raised by HIV/AIDS.