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The Jean Chrétien Pledge to Africa Act and its Impact on Improving Access to HIV/AIDS Treatment in Developing Countries

Introduction

The introduction of antiretroviral therapy (ARV) in high income countries has reduced deaths from AIDS by over 70%. Yet millions of people in the developing world still lack access to medicines they need, be it anti-retroviral drugs that fight the virus' effect on the immune system or drugs to prevent and treat opportunistic infections that can be painful and deadly. There are many reasons for the lack of access to ARVs and other medicines, but high drug prices are one significant barrier.

Prohibitive drug prices result, in part, from strict rules on intellectual property that allow drug companies holding patents on medicines to charge higher prices because of the monopoly granted by the patent. The prices of the first line of ARVs, used in combination to treat people living with HIV/AIDS, have come down significantly, thanks to competition between brand-name companies and generic producers. This competition became possible in part because pharmaceutical patents were not recognized in all countries, thus allowing for the production of lower-cost generic drugs and their export to other countries where these drugs were also not patented. However, countries that were able to produce generic medicines for export have recently had to conform to the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This has meant losing some of this flexibility. It is now more complicated to produce generic drugs, particularly newer ARVs and other increasingly essential drugs, including for export to other developing countries.

The cost of treatment remains a major concern for developing countries facing the pandemic. The different initiatives aiming at improving access to less expensive treatment are therefore watched with great interest. Canada's *Jean Chrétien Pledge to Africa Act*, brought into force in May 2005, is such an initiative. This legislation implements a 2003 WTO decision that allows countries with pharmaceutical manufacturing capacity to override patents in order to make generic drugs for export to eligible developing countries that need less expensive medicines.

This document assesses some of the measures taken recently to improve access to more affordable ARV therapy in developing countries. It provides a synopsis of the key WTO rules and developments, and of the Canadian law, the concrete benefits of which have yet to be realized.

WTO patent rules and access to treatment

TRIPS

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is a treaty of the World Trade Organization adopted in 1994 when the WTO was created. TRIPS requires all WTO member countries to adopt certain rules on intellectual property, including granting patents on pharmaceuticals. Until TRIPS, some countries, including some key developing countries with the industrial capacity to manufacture generic medicines, did not allow patents on pharmaceuticals. But under TRIPS, all WTO member countries must grant such patents, for a minimum of 20 years from the date of filing the patent application. High income countries had to ensure their laws complied with TRIPS by 1996. Developing counties and certain economies in transition had to comply by 2000, although in the specific case of pharmaceuticals they could wait until 2005 to grant patents if their law did not already provide for patents in this area. The original deadline for least developed countries (LDCs) to comply with TRIPS was originally 2006, but this has been extended to 2013 (and to 2016 in the case of patents on pharmaceuticals).

The Doha Declaration

As a general rule, it is illegal to copy any drug that is still under patent. However, at the WTO Ministerial Conference in Doha, Qatar in November 2001, WTO member countries adopted a Declaration in which they agreed that TRIPS should not prevent members from taking measures to protect the public health of their citizens. The Doha Declaration repeats the "flexibilities" contained in TRIPS that countries may use to overcome the barriers posed by patents. For example, through a practice known as "parallel importing", a country may import patented drugs from another country where the patent-holding manufacturer sells them for less.

"Compulsory licensing" is another flexibility permitted under TRIPS, and is central to current global efforts to scale up access to medicines. A compulsory licence on a patented drug authorizes a generic drug manufacturer to make a version that is therapeutically equivalent but less expensive. Under TRIPS, countries are free to decide the grounds on which compulsory licensing can be done. For example, this could be done in case of a national emergency, but contrary to misrepresentations by some governments and pharmaceutical companies, TRIPS does not limit compulsory licensing just to emergency situations. Another basis for compulsorily licensing a patented invention could be to compensate for anti-competitive practices by the company holding the patent. Compulsory licensing may also be done on purely "public interest" grounds. It is up to each country to decide whether and how it will make compulsory licensing possible under its laws.

TRIPS says that usually a generic company must first seek a voluntary licence from the company holding the patent, in exchange for some sort of remuneration (e.g., a royalty fee). However, if no agreement can be reached with the patent-holder "on reasonable commercial terms and conditions" and within a "reasonable period of time", then a compulsory licence allows the generic company to make the drug without the patent-holder's consent (although the patent-holder still must be paid "adequate remuneration"). In some cases, such as the situation where a compulsory licence is issued because of a national emergency, there is no need to try negotiating first with the patent holder for a voluntary licence.

The WTO Decision of 30 August 2003 (the "paragraph 6 decision")

By adopting the Doha Declaration in 2001, WTO Members recognized some of developing countries' concerns about access to medicines and reaffirmed that TRIPS rules should not prevent countries from making effective use of compulsory licensing to get access to lower-cost, generic products. In paragraph 6 of the Doha Declaration, they also recognized a problem under WTO rules for countries that are unable to produce generic drugs domestically and

therefore need to import them. TRIPS says that products made under compulsory licences must be "predominantly for the supply of the domestic market". This limits the quantity of generic medicines produced under a compulsory licence that can be exported from one WTO member country to any other country. Therefore, even if a developing country needing less expensive medicines decided to import generics, this rule restricts other countries from supplying them. This undermines the ability of the importing country to use compulsory licensing effectively as a tool to get lower-cost treatment for patients.

Under pressure from health activists and countries unable to manufacture generic drugs domestically, WTO Members decided on August 30, 2003 to adopt an "interim waiver" of this restriction. This means that compulsory licensing may be done in one country to produce generics for export in significant quantities to countries needing medicines to address public health problems. While theoretically introducing some further flexibility into TRIPS, this "solution" was criticized by many activists and some developing countries because it requires a complex mechanism for granting compulsory licences needed to permit exports of generics to countries in need. The system requires order-by-order, drug-by-drug and country-by-country procedures, ignoring the fact that generic pharmaceutical manufacturers have little financial incentive to produce small volumes of drugs. To be competitive, generic companies need to take advantage of economies of scale and larger bulk orders, which could mean, in some cases, supplying several countries at a time. The "solution" is therefore procedurally cumbersome and also may not reflect the reality of the pharmaceutical market. In addition, the political reality is also such that countries taking measures such as compulsory licensing face considerable pressure from powerful countries, including threats of trade retaliation. In addition, countries such as the U.S. are undermining the possible use of this mechanism agreed at the WTO by negotiating with developing countries a range of bilateral or regional trade agreements that contain even more stringent patent rules, including on medicines.

In December 2005, the WTO General Council decided that this interim waiver would be converted into a permanent amendment to TRIPS. WTO Members agreed the amendment would take effect once it is accepted by two-thirds of WTO Members, and set themselves a deadline of December 2007 for this (although this could be extended further). The interim decision from August 2003 remains in effect until the permanent TRIPS amendment comes into effect. Health activists are concerned that the supposed "solution" first agreed in August 2003 has been made permanent as a TRIPS amendment even though it has not yet been tested and shown to be effective and efficient.

Canada's implementation of the 2003 WTO decision

The Jean Chrétien Pledge to Africa Act

In October 2003, under pressure from Canadian civil society and Stephen Lewis, the UN Special Envoy on HIV/AIDS in Africa, the Canadian government committed itself to implement the WTO decision from August 2003. The *Jean Chrétien Pledge to Africa Act* (JCPA) was presented as a legislative priority of the then Prime Minister and received all-party support in Parliament. During its drafting, brand-name pharmaceutical companies, generic manufacturers and civil society organizations were consulted by the government. These groups also made submissions before a Parliamentary committee reviewing the legislation before it was enacted.

In May 2004, the Canadian Parliament set a global precedent by enacting the JCPA. The legislation's stated objective is to facilitate "access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." However, it took some time before the legislation came into effect. After further pressure from civil society groups, the federal government finally proclaimed the JCPA into force on May 14, 2005 – exactly one year after it had been made law. The regulations accompanying the legislation were published on June 1, 2005. Canadian NGOs have characterized the legislation as having both some positive features and as containing several flaws that undermine its possible effectiveness.

Negative aspects of the legislation

Limited list of pharmaceutical products for which a compulsory licence can be issued

The JCPA includes a list of drugs (Schedule 1) that can be produced under compulsory licence for export, even though such a list is not required by the August 2003 WTO Decision, which simply refers to any "pharmaceutical product". Any future change to Schedule 1 requires a decision by the federal Cabinet. This limits Canada's ability to adapt as quickly as required. For example, fixed-dose combination (FDC) formulations of ARVs are critical to scaling up access to AIDS treatment, as recommended by the World Health Organization. However, any such product would need to be added to the list before a generic manufacturer could get licences to make it for export. Having a limited list creates an additional hurdle to using the legislation, delay while a request for an amendment is considered, and opportunities for pharmaceutical companies holding patents on medicines to lobby against any new drug being added to the list. During the final Parliamentary debate before passing the legislation, after being lobbied by the pharmaceutical industry, the government voted against proposals to add new medicines which all parties had already agreed to during parliamentary committee discussions. As a result, Bayer's patented pneumonia drug, moxifloxacin, was kept off the list of medicines.

Additional hurdle in supplying ARVs in fixed dose combinations (FDCs)

The JCPA requires that any generic drug produced under compulsory licence for export must go through the same review process as if it were to be approved for sale in Canada. The standard practice is to do an abbreviated review based on the data submitted by the generic manufacturer showing that their product is equivalent to a brand-name product already approved. But in the case of FDCs, combining more than one medicine into the same tablet, there are few such products already approved. Health Canada's review system will need to be flexible enough to do an effective yet rapid assessment of a generic manufacturer's FDC that is needed for scaling up treatment in developing countries.

Double standard between WTO members and non-members

The JCPA allows Canadian-made generics to be exported under compulsory licences to countries that do not belong to the WTO. But in the case of developing countries that are not WTO Members (and that are not "least-developed"), it imposes unnecessary preconditions that will likely make the legislation of little benefit. For example, the JCPA requires that such a country declare a national emergency or "circumstances of extreme urgency" in order to be even eligible to import from a Canadian generic manufacturer. Moreover, the country must agree the imported generic drugs will not "be used for commercial purposes". But this term is not defined and it arguably limits the distribution channels in the importing country to only public facilities, even though it may be necessary, for example, to operate through private pharmacists. Neither of these conditions apply to developing countries

that belong to the WTO, so there is little justification for this double-standard.

Limited length of the licence

A compulsory licence granted under Canadian legislation is limited to two years. It may be extended for an additional two years, but only for the purpose of completing the export of the quantity of the medicine that was originally approved. After two years, the generic manufacturer must apply again for a new compulsory licence if it wants to export more of the medicine, to either the same country or another purchaser. This limitation is a significant flaw of the JCPA, especially because such restriction on the term of a compulsory licence is not required by any WTO rules. Generic manufacturers are concerned that the financial costs and risks associated with obtaining the required regulatory approvals and scaling up production will be greater than the short-term revenues that could be made under any contract that is limited in this way. The option to apply for a new licence is there, but this creates additional costs and opportunities for intervention in the interim by the company holding the patent, meaning this is just an additional disincentive for generic companies considering using the legislation.

Positive Aspects of the New legislation

Setting a precedent

The JCPA is the first detailed national law to allow compulsory licensing for the purpose of exporting generic pharmaceuticals to developing countries under the August 2003 WTO Decision. The fact that a high-income, G7 country took this initiative is politically important because it helps generate momentum for using compulsory licensing to improve access to medicines. In addition, the Canadian model is one that may be useful for other countries that might be considering similar initiatives, by learning from both its positive features and avoiding its limitations.

Clearly defined, low compensation royalties

TRIPS is vague on the question of compensation to patent-holders. In the event of negotiating for a voluntary licence, it simply refers to “reasonable commercial terms and conditions”. If no agreement on a voluntary licence can be reached, and a compulsory licence is issued, it simply states that "adequate remuneration" must be paid to the patent holder. The uncertainty as to the meaning of these requirements gives substantial power to the patent holder, who can drag out the negotiating process. As well, the possibility of having to litigate in court over whether a reasonable period of time for negotiations has passed, or as to what constitutes a reasonable royalty, is a major disincentive to any generic producer that might consider manufacturing medicines for export under a system like the August 2003 WTO decision.

By contrast, the Canadian law defines "adequate remuneration" by providing a clear formula for calculating in advance the specific royalty rate payable in any given situation. That formula links the royalty payable to the ranking of the importing country on the UN's Human Development Index (HDI), which is a comparative measure of well-being in countries, based on factors such as life expectancy, literacy, and income levels. According to the formula, the maximum royalty payable for the top-ranked country is 4% of the total value of the product to be exported under a licence. The figure is considerably lower in the case of most developing countries, given their HDI ranking. This part of the Canadian law creates a degree of certainty about the royalty, which is very important to generic producers if they are contemplating using the system.

Clear negotiation period for a voluntary licence

According to TRIPS, it is only when the generic producer has not managed to obtain a voluntary licence from the patent holder "within a reasonable period of time", that the competent

authority may issue a compulsory licence. Without any clear definition of what constitutes a reasonable period of time, it is open to the company holding the patent to extend negotiations and to reject reasonable proposals for remuneration from the generic manufacturer. There is, therefore, less incentive for a generic producer to try to get a licence. Fortunately, the Canadian law is much clearer: the period of negotiations over a voluntary licence has been fixed at 30 days. This means that after that period, if no agreement has been reached, the generic company can apply for a compulsory licence, which will be issued with the specific royalty rate that is clearly defined by law.

Concrete outcomes

The efficacy of the Canadian law remains to be seen. As of this writing, not a single patient from a developing country has received generic drugs exported from Canada under this law. This should not be a surprise. Bringing the generics to market under this legislation involves many steps: determining the formulation, seeking the different ingredients, preparing the drugs, packaging and different efficacy tests (control tests on intermediate products, control tests on finished product). For generic drugs, there is no need to go through the whole clinical trial process, as these trials have already been done for the brand-name drug. But bioequivalence tests are needed; these determine if the generic drug delivers the active ingredient in a way that is therapeutically equivalent to the original product.

After this first phase, which can take months, the generic producer must get Health Canada approval for the drug. This can also take several months. Under the JCPA, the generic manufacturer must also satisfy Health Canada that its product is sufficiently distinguished (e.g., through size, shape or colour, etc. as well as markings on the tablet itself) from the brand-name drug sold by the patent holder in Canada.

It is only after these steps have been completed, and when the product is ready to go to market, that the generic company can seek a compulsory licence (assuming that the patent-holder have not agreed to a voluntary one).

In addition, before a compulsory licence can be issued under the Canadian law, the generic manufacturer must tell the patent-holding company the name of the country that will be importing the generic product, as part of the effort to first negotiate a voluntary licence. This means that countries seeking to use the Canadian compulsory licensing law to get lower-cost medicines will likely face considerable pressure right away from the patent-holding company and likely other countries, such as the U.S., to refrain from such a step.

Given the duration of the manufacturing and approval process, and the apparent lack of strong financial incentives for generic manufacturers, and some developing countries' concerns about retaliation, it is not surprising that not a single medicine has yet been exported to any developing country under the JCPA.

Generic companies: will they use the JCPA?

The success of the JCPA requires action by the private sector. Is there a market for Canadian generic medicines in the developing world? The extent to which the JCPA will lead to Canadian generic companies supplying medicines needed for people living with HIV/AIDS or other health conditions remains to be seen. However, Canadian generic companies have proven they can compete globally in at least some markets. The Canadian Generic Pharmaceutical Association (CGPA), which represents Canada's generic drug companies, reports that 40% of sales volume of its member companies comes from exporting products to 120 countries (although a significant portion of this amount seems to

come from other high-income countries). However, there may be particular niche markets or classes of drug where Canadian generic drug manufactures will be competitive.

The World Health Organization estimates that, as of June 2005, more than 1.3 people living with HIV/AIDS in sub-Saharan Africa were receiving ARV treatment, but another 6.5 million were in need. With the growing mobilization of financial resources to scale up treatment access, and the need to use those resources most cost-effectively by relying, where possible, on lower-priced generics, this is a massive potential market. The possibility of gaining a foothold in this market, particularly if economies of scale could be achieved by negotiating large, multi-year and multi-country purchases, may help motivate generic producers in Canada to consider using the JCPA to produce ARVs for export.

However, this has not yet been the case. After the passage of the JCPA, in August 2004, Canadian government officials, the medical humanitarian organization Médecins Sans Frontières Canada (MSF), and representatives from the Canadian generic pharmaceutical industry met to discuss moving ahead with using the legislation once it came into force. MSF was asked to identify drugs they would require for use in their treatment programs in various countries. At MSF's request, Apotex Inc., the largest generic manufacturer in Canada, agreed in January 2005 to produce a fixed-dose combination antiretroviral drug containing the medicines zidovudine, lamivudine and nevirapine (AZT+3TC+NVP). At the time of writing, Health Canada had indicated the product had met its regulatory requirements, but no public announcement had yet been made regarding a possible licence for Apotex to export the drug for use in one or more developing countries. If this first attempt at using the JCPA proceeds successfully, it could encourage other generic companies to use the legislation to help respond to the public health needs of developing countries.

Conclusion

In the absence of concerted efforts by generic manufacturers and the federal government, there will be little concrete benefit to report when Parliament reviews the legislation in 2007.

We call on Canada to:

- Promote in developing countries the opportunity to obtain more affordable medicines from Canadian generic manufacturers.
- Broker exploratory meetings between Canadian generic manufacturers and health ministries in developing countries.
- Remove unnecessary red tape that dissuades generic drug manufacturers and developing countries from using the legislation.

We call on the generic drug industry in Canada to:

- Seek opportunities to export generic medicines to developing countries.
- Collaborate with developing country health ministries and NGOs in identifying medicines Canadian generic manufacturers can produce.
- Make special efforts to develop fixed-dose combinations and paediatric formulations of HIV/AIDS drugs.

Additional information

Canadian Generic Pharmaceutical Association
www.canadiangenerics.ca

Canadian HIV/AIDS Legal Network
www.aidslaw.ca

Consumer Project on Technology
www.cptech.org

Health Canada's new website on "Canada's Access to Medicines Regime",
http://camr-rcam.hc-sc.gc.ca/index_e.html

Intellectual Property Watch
www.ip-watch.org

Interagency Coalition on AIDS and Development (ICAD)
www.icad-cisd.com

MSF Campaign for Access to Essential Medicines
www.accessmed-msf.org

WTO "Frequently Asked Questions" brief on compulsory licensing:
www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

WTO TRIPS Agreement
www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm

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