

# Will they deliver treatment access?: WTO rules and Canada's law on generic medicine exports

More than two years since Canada enacted the *Jean Chrétien Pledge to Africa*, no generic medication produced under compulsory license has yet been exported from Canada. In this feature article, Richard Elliott describes attempts by two Canadian generic pharmaceutical companies to navigate the complicated and unwieldy processes established under the Act, and, noting the government's pledge to review the law and fix it to make it work, prescribes a number of ways in which the process should be streamlined.

## Introduction

Many developing countries cannot afford patented brand-name medicines, but also lack the industrial capacity to manufacture their own less expensive generic products, which means they rely on imported medicines. Under the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS), countries belonging to the World Trade Organization (WTO) must grant exclusive patent rights on medicine, but also retain the right to grant compulsory licences that legally authorize the production of lower-cost, generic versions of patented drugs in exchange for royalties. Breaking the monopoly of patent-holders allows market competition, which brings down prices.

However, TRIPS also states 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 great pressure from developing countries and treatment activists, on 30 August 2003 WTO members adopted an ostensible "solution" to this problem by relaxing this restriction to allow compulsory licences in one country to produce lower-cost generic drugs for export to developing countries in need.<sup>1</sup>

In May 2004, Canada's Parliament unanimously enacted the *Jean Chrétien Pledge to Africa*, legislation that amended the *Patent Act* and the *Food and Drugs Act* to implement this WTO decision.<sup>2</sup> While Canadian civil society organizations belonging to the Global Treatment Access Group (GTAG) succeeded in obtaining significant improvements to what the government of the day had introduced, they warned that the remaining flaws could hinder the usefulness of the legislation. They also said that they would support efforts to use it, notwithstanding its limitations.<sup>3</sup>

## Taking stock: what has happened with Canada's initiative?

### An FDC ARV for HIV?

In May 2004, shortly after the law was passed, Médecins Sans Frontières (MSF) publicly committed to testing it by placing an order for medicines needed for its field projects.<sup>4</sup> In August 2004, MSF identified to Health Canada and representatives of the Canadian generic pharmaceutical industry five drugs that were urgently needed to treat its patients.

Finally, in December 2004, Apotex Inc., a privately-held Canadian generic pharmaceutical company agreed to produce a three-in-one antiretroviral combination of zidovudine, lamivudine and nevirapine (AZT+3TC+NVP), drugs which represent one of the first-line treatment regimens for HIV recommended by the World Health Organization (WHO). At the time, those drugs were not available in the form of a fixed-dose combination (FDC), a product that would simplify treatment significantly and help with the global effort to scale up treatment.

Apotex developed an active prototype of the FDC by April 2005. However, this FDC was not on the list of products eligible for compulsory licensing for export in Schedule 1 of the *Patent Act*. The addition of a new product to the schedule requires a decision of the federal Cabinet, following the recommendation of both the Minister of Industry and the Minister of Health.

In September 2005, after further pressure, the Cabinet made the requisite order amending Schedule 1. In late 2005, Apotex submitted to Health Canada an application for approval, as required under the legislation (a step not required under the WTO 2003 decision), at which time MSF began discussions with potential importing country authorities. The Health Canada review process took seven months; the product received approval in July 2006.

In August 2006, shortly before the XVI International AIDS Conference, the WHO Prequalification Project, having reviewed the dossier submitted to Canadian drug regulators, also gave its stamp of approval, a precondition upon which many developing countries insist when making procurement decisions.

During the XVI International AIDS Conference, a representative of the Clinton Foundation HIV/AIDS Initiative indicated the Foundation would be willing to place an order for the Apotex FDC product as the basis for a compulsory licence application.<sup>5</sup> Brokering a large-scale, multi-country order, in addition to the outstanding commitment by MSF to purchase an initial smaller quantity of the product, could provide significant pressure that could break the seeming logjam in this first effort to use Canada's legislation.

However, as of the time of writing, Apotex remained tied up in ongoing negotiations with the companies holding the relevant Canadian patents, even though in theory Canada's law requires only 30 days of such negotiations before the way is legally clear for an application to be filed for a compulsory licence. It remains unclear if or when a voluntary licence will be issued or if Apotex will proceed with a compulsory licence application.

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#### **Pandemic influenza: might the JCPA help?**

There has been another effort to use the Canadian legislation, to respond to another emerging global health concern. It, too, remains an effort in progress. There is considerable concern about the possibility of a future global influenza pandemic, highlighted most recently by outbreaks of avian influenza and the fear that at some point a variant of this or another animal flu virus could be transmitted from human to human.

Leading public health authorities have warned there is a risk of a global pandemic of avian flu that could, in some scenarios, lead to the death and suffering of millions. Such a pandemic would likely take the greatest toll in regions where significant

numbers of people are already immunocompromised as a result of HIV, TB and other illnesses. The WHO has already released a report that recommends, among other things, stockpiling antiviral drugs,<sup>6</sup> and the Canadian government has recognized the threat.<sup>7</sup>

Oseltamivir phosphate — marketed under the brand name Tamiflu — is an oral antiviral medicine used for both treatment and prophylaxis of influenza, including the H5N1 variant of avian flu that has provoked global concern, and is of considerable and growing interest given its possible beneficial use in the event of outbreaks. But very few developing countries have stockpiled oseltamivir in anything remotely close to the quantities recommended, which means they lack one of the tools for treatment or prevention of avian flu, should such a pandemic occur.

In December 2005, Canadian pharmaceutical company Biolyse Pharma announced it had developed an alternate process for producing oseltamivir, and that it wished to obtain a non-exclusive compulsory license to produce and export the medicine to developing countries at a reduced cost. However, the medicine was not included on Schedule 1 of the *Patent Act*, the list of pharmaceutical products eligible for compulsory licensing for export.

In February 2006, Biolyse submitted a formal request to the Ministers of Health and Industry to add oseltamivir phosphate (in both capsule and powder form) to the list of products eligible for compulsory licensing for export in Schedule 1 of the *Patent Act*.<sup>8</sup> The multinational pharmaceutical company Hoffmann-La Roche, Inc. (Roche), which holds the relevant Canadian patents on oseltamivir,

has opposed the compulsory licensing of the product.

On 21 September 2006, the federal cabinet made the requisite order adding these two formulations of the drug to the list.<sup>9</sup> Biolyse has stated that it now plans to ramp up its production capacity to produce up to one million doses a day once its facility is fully operational,<sup>10</sup> on the assumption that it will line up purchase orders from eligible countries and then successfully proceed through the protracted process under the Canadian law for obtaining either a voluntary or compulsory licence allowing it to export to those purchasers.

## Conclusion

As of this writing, more than two years since Canada passed its law, no generic medication produced under compulsory license has yet been exported from Canada. During the XVI International AIDS Conference in Toronto, under sustained public criticism of the failed initiative, Canada's new Minister of Health pledged to review the law and fix it to make it work. By law, Parliament must review the legislation by May 2007, providing an opportunity to replace the current unwieldy process with a more effective legal regime.

Beyond the unnecessarily burdensome features added by the Canadian government, the experience has illustrated a more fundamental problem, namely the mechanism agreed at the WTO in August 2003 — witness the fact that more than three years have passed since the WTO adopted its “solution” and not a single country has filed the required notification that it intends to use the mechanism to import lower-cost medicines.<sup>11</sup> MSF's experience to date, particularly as illustrated through its hands-on

experience with the Canadian legislation, has prompted the organization to comment that the WTO's August 2003 decision is “neither expeditious, nor a solution.”<sup>12</sup>

**Canada needs to streamline the legal process so that developing countries and generic drug companies can and will use it.**

In order to put in place a legislative regime that stands a greater chance of delivering on the “pledge” originally made in 2004, Canada's law-makers will need to be willing to step away from the flawed WTO mechanism and enact a series of changes that will simplify and streamline the process of compulsory licensing for export. 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 as enacted by Canada, however, forces generic companies through unnecessary red tape to get a licence to manufacture and export each patented drug, and even then allows for export only in a pre-negotiated quantity and to a single country.

What is needed is for Canada to 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. (Generic producers would still be required to pay royalties to the patent holders, according to the sensible formula already contained in the existing law, which bases the royalty payable on any given contract on the level of development of the importing developing country.)

Such a process 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 members agreed that their 2003 decision did not preclude using other "flexibilities" in the WTO's TRIPS Agreement, and they have also said that TRIPS should be interpreted and implemented so as to promote access to medicines.<sup>13</sup> Under Article 30 of TRIPS, 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.

It remains to be seen whether the federal government — or perhaps Parliament as a whole, given that the opposition parties in the House of Commons jointly hold more seats than the minority governing party — has the political courage of the convictions all parties stated unanimously and solemnly when they originally enacted the legislation in 2004.

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<sup>1</sup> WTO General Council, Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc. IP/C/W/40 (30 August 2003). Available via <http://docs.wto.org>.

<sup>2</sup> S.C. 2004, c. 23. The legislation was proclaimed into force one year later on 14 May 2005, and accompanying regulations came into force on 1 June 2005. See: "Food and drug regulations (1402 – drugs for developing countries," SOR/2005-141, *Canada Gazette (Part II)*, 139(11): 1112–24; "Medical devices regulations (developing countries)," SOR/2005-142, *Canada Gazette (Part II)*, 139(11): 1125–26; "Use of patented products for international humanitarian purposes regulations", SOR/2005-143, *Canada Gazette (Part II)*, 139(11): 1127–56, all at [http://canadagazette.gc.ca/partII/2005/20050601/html/index\\_e.html](http://canadagazette.gc.ca/partII/2005/20050601/html/index_e.html). For more information about what the government has since labelled "Canada's Access to Medicines Regime," see [http://camr-rcam.hc-sc.gc.ca/index\\_e.html](http://camr-rcam.hc-sc.gc.ca/index_e.html).

<sup>3</sup> For more detailed discussion, see: R. Elliott, "Pledges and pitfalls: Canada's legislation on compulsory licensing of pharmaceuticals for export," *International Journal of Intellectual Property Management* 1, 1/2 (2006): 94–112, available via [www.aidslaw.ca/gtag](http://www.aidslaw.ca/gtag); R. Elliott, "TRIPS from Doha to Cancún...to Ottawa: global developments in access to treatment and Canada's Bill C-56," *Canadian HIV/AIDS Policy & Law Review* 8, 3 (2003): 1, 7–18; R. Elliott, "Steps forward, backward and sideways: Canada's bill on exporting generic pharmaceuticals," *Canadian HIV/AIDS Policy & Law Review* 9, 3 (2004): 15–21; Canadian HIV/AIDS Legal Network and Interagency Coalition on AIDS and Development, *The Jean Chrétien Pledge to Africa Act and its Impact on Improving Access to HIV/AIDS Treatment in Developing Countries*, August 2006 (available via [www.aidslaw.ca/gtag](http://www.aidslaw.ca/gtag)).

<sup>4</sup> For a detailed analysis of MSF's effort to use the legislation to obtain this product, which is also one source of the information summarized here, see: MSF, *Neither Expeditious, Nor a Solution: The WTO August 30<sup>th</sup> Decision is Unworkable – An Illustration Through Canada's Jean Chrétien Pledge to Africa*, August 2006. At [www.accessmed-msf.org/documents/WTOaugustreport.pdf](http://www.accessmed-msf.org/documents/WTOaugustreport.pdf).

<sup>5</sup> Remarks of Anil Soni, Director of Pharmaceutical Services, Clinton Foundation HIV/AIDS Initiative at "Will it Deliver? WTO rules and Canada's law on compulsory licensing: the continuing challenge of scaling-up treatment access," satellite session, XVI International AIDS Conference, 15 August 2006, Toronto.

<sup>6</sup> World Health Organization, *Responding to the Avian Influenza Pandemic Threat: Recommended Strategic Actions* (Geneva: WHO, 2005). WHO/CDS/CSR/GIP/2005.8. At: [www.who.int/csr/resources/publications/influenza/WHO\\_CDS\\_CSR\\_GIP\\_2005\\_8/en/index.html](http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_GIP_2005_8/en/index.html).

<sup>7</sup> Information and news releases available on the Health Canada Website at [www.hc-sc.gc.ca/dc-ma/avia/index\\_e.html](http://www.hc-sc.gc.ca/dc-ma/avia/index_e.html).

<sup>8</sup> Letter from Biolyse Pharmaceutical Corporation, 14 February 2006 (at [www.biolyse.ca/news.asp?story=111](http://www.biolyse.ca/news.asp?story=111)). The Canadian HIV/AIDS Legal Network made the same request: letter from Canadian HIV/AIDS Legal Network, 14 February 2006 (at [www.biolyse.ca/news.asp?story=114](http://www.biolyse.ca/news.asp?story=114)).

<sup>9</sup> Order Amending Schedule I to the Patent Act (Oseltamivir Phosphate), P.C. 2006-996 (21 September 2006), SOR/2006-204, *Canada Gazette, Part II*, 4 October 2006. At <http://canadagazette.gc.ca/partII/2006/20061004/html/sor204-e.html>.

<sup>10</sup> A. Deslonchamps, "Canada to let Biolyse make generic version of Tamiflu", Bloomberg, 27 September 2006. At: [www.bloomberg.com/apps/news?pid=20601082&sid=a3iAW8wuUu84&refer=canada](http://www.bloomberg.com/apps/news?pid=20601082&sid=a3iAW8wuUu84&refer=canada).

<sup>11</sup> See the dedicated webpage for such notifications at [www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm).

<sup>12</sup> MSF.

<sup>13</sup> *Declaration on the TRIPS Agreement and Public Health*, WTO Ministerial Conference, Fourth Session, Doha (Qatar), 14 November 2001, WTO Doc. WT/MIN(01)/DEC/2, available via <http://docs-online.wto.org>, para. 4.