



## CANADA'S ACCESS TO MEDICINES REGIME

### UPDATE May 7, 2008

Today it was announced that the Government of Rwanda has, after a competitive international tendering process, chosen to purchase a generic fixed-dose combination AIDS drug from Toronto-based generic pharmaceutical manufacturer Apotex, Inc., using the provisions of Canada's 2004 law on compulsory licensing of patented pharmaceuticals for export to eligible developing countries. This clears the last major hurdle to the first use of "Canada's Access to Medicines Regime", and the first use anywhere of the August 30, 2003 decision of the General Council of the World Trade Organization (WTO).

Last July, the Government of Rwanda filed with the WTO a notification of its intent to use the mechanism under the 2003 WTO Decision to import generic medicines (WTO Doc. IP/N/9/RWA/1). Rwanda's notification stated that it anticipated importing up to 260,000 packs of the Apotex product "ApoTriavir" (AZT/3TC/NVP). This combination is one of those recommended by WHO as a first-line regimen.

Rwanda's notification was a necessary precondition for Apotex to pursue the process under Canadian law for obtaining a licence to manufacture the product legally for export. Efforts to negotiate a voluntary licence with each of the patent-holders involved were unsuccessful, and the generic manufacturer applied for a compulsory licence. In September 2007, the Commissioner of Patents issued a compulsory licence to Apotex, authorizing the production of the quantity notified by Rwanda, amounting to 15,600,000 tablets. (The treatment regimen consists of 2 tablets daily.) In October, Canada notified the WTO of this compulsory licence having been issued (WTO Doc. IP/N/10/CAN/1).

Rwanda subsequently initiated an international tendering process. Apotex submitted a bid quoting a price of US\$0.195/tablet, meaning treatment with this regimen would cost US\$146 per patient per year. This is lower than the lowest price from a generic source (US\$176 per patient per year) reported publicly in the most recent edition of "Untangling the Web of Price Reductions", 10th ed. July 2007, last updated March 2008; <http://www.accessmed-msf.org/main/hiv-aids/price-guide-to-aids-drugs>.

Below are the press releases issued today by Apotex and by the Canadian HIV/AIDS Legal Network. Also below is a list of other background material about the Canadian legislation and civil society's criticisms of it and proposed reforms.

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## **APOTEX, INC.**

Attn: Health and News Editors  
For Immediate Release  
May 7, 2008

### **Canadian Company Receives Final Tender Approval From Rwanda For Vital AIDS Drug**

Toronto, ON. -- Apotex Inc., Canada's largest generic pharmaceutical company has successfully bid and been awarded a tender from the Rwandan Government for the life saving triple combination AIDS drug "Apo Triavir". Apotex is the first company to provide this medicine to Africa under the provisions of the Canadian Access to Medicines Regime (CAMR).

The CAMR provides a mechanism for developing countries to address critical healthcare needs by importing less expensive generic versions of patented drugs. Following the process it has taken Apotex over three years to get to this point where a drug can go to thousands in Africa.

Apotex is the only company in Canada to have worked through the complicated CAMR process. The Generic Pharmaceutical Industry has recommended that the Federal Government simplify the process of getting urgently needed drugs to Africa.

Apo Triavir is a combination of 300 mg Zidovudine, 150 mg Lamivudine and 200 mg Nevirapine and was evaluated and approved under the provision of the CAMR by Health Canada. Triavir fully conforms to all Health Canada regulations and requirements for marketing a drug in the Canadian healthcare system. As per Canadian regulations, the product can only be exported to eligible countries under CAMR and cannot be sold in Canada until the relevant patents expire.

Apotex is producing Apo Triavir at cost, with the price quoted in the Tender at 19.5 cents per tablet. The three separate AIDS brand products would cost around \$6.00 per dose if bought individually.

"If other critical medicines are to go to Africa in a reasonable timeframe, the Federal Government must change the CAMR Legislation. CAMR is unworkable as it now stands. Apotex decided to do this because it was the right thing to do for the people dying from AIDS in Africa", stated Jack Kay, Apotex President and COO.

The Apotex Group has 6,000 employees in Canada and exports close to 300 quality lower cost medicines to 115 countries. It is the No. 1 pharmaceutical company in Canada for R&D with planned expenditures of \$2 Billion over the next 10 years.

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# CANADIAN HIV/AIDS LEGAL NETWORK

For immediate release

## CANADA FINALLY POISED TO DELIVER ON PROMISE OF AFFORDABLE MEDICINES TO DEVELOPING COUNTRIES?

*But law must be streamlined to ensure it will be used again*

**Toronto, May 7, 2008** — The Canadian HIV/AIDS Legal Network welcomed today's announcement that Rwanda's government, after a competitive tendering process, has chosen to purchase a low-cost AIDS drug from Ontario-based generic pharmaceutical manufacturer Apotex, Inc. — meaning that Canada's Access to Medicines Regime should soon deliver for the first time on its promise of affordable medicines for developing countries.

However, this represents the first success in four years since the law on exporting generic medicines was passed, confirming that the Regime must be simplified if Canada is to play an ongoing role in helping developing countries with access to AIDS treatment or other medicines they need.

"This is great news, and we hope supplies will start moving soon. But Canada's law is riddled with unnecessary hurdles," said Richard Elliott, Executive Director of the Legal Network. "Getting this far has required an extraordinary amount of work by one company and various non-governmental organizations. This is not sustainable. How many lives could have been saved in the meantime if this law had worked smoothly the way it should and could?"

Last year, the Legal Network presented the government and Parliament with a submission containing 13 concrete amendments they could pass immediately in order to make the law truly workable. But in December of last year, the Minister of Industry tabled a long-overdue report in Parliament indicating the government had no plans to make any changes.

"We did their homework for them," said Elliott, "but so far the government has refused to act. What we need is a straightforward system that is user-friendly for both developing countries and for generic manufacturers in Canada. Instead of requiring separate negotiations and a separate licence for each country and each order of medicines, we need a simple 'one-licence solution' such as the one we've proposed."

Based on an agreement hammered out at the WTO in 2003, Canada's Access to Medicines Regime was created by legislation passed unanimously in Parliament in May 2004. It is meant to allow compulsory licensing of patented medicines, so that generic drug companies in Canada can legally produce and export lower-cost versions of patented, brand-name medicines to developing countries. The deal between the Rwandan Government and Apotex, Inc. marks the first use anywhere in the world of this mechanism.

For more information on the Legal Network's proposed amendments to the legislation, see "Getting the Regime Right", the 2007 brief to Parliament, available at [www.aidslaw.ca](http://www.aidslaw.ca).

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*Disponible en français*

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## ADDITIONAL MATERIAL OF INTEREST

"Getting the Regime Right", Legal Network brief with recommended amendments, submitted to the Parliamentary committee reviewing Canada's Access to Medicines Regime (April 2007)

<http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=705>

Access to Medicines and Intellectual Property: An International Expert Meeting on Canada's Access to Medicines Regime, Global Developments, and New Strategies for Improving Access (19-21 April 2007)

<http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=792>

Notifications to WTO by Rwanda and Canada available via:

[http://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)

"Time to Deliver (or not)" - Commentary by the Canadian HIV/AIDS Legal Network on needed reforms to Canada's legislation on compulsory licensing for export (November 2006)

<http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=610>

"Neither Expeditious, Nor a Solution: The WTO August 30th Decision is Unworkable – An illustration through Canada's Jean Chrétien Pledge to Africa" (briefing paper by Médecins Sans Frontières)

[http://www.msf.ch/fileadmin/user\\_upload/uploads/communiques/images\\_2006/pdf/came\\_Neither\\_expeditious\\_nor\\_a\\_solution\\_-\\_August\\_30\\_and\\_the\\_JCPA\\_single\\_page.pdf](http://www.msf.ch/fileadmin/user_upload/uploads/communiques/images_2006/pdf/came_Neither_expeditious_nor_a_solution_-_August_30_and_the_JCPA_single_page.pdf)

"Medicines for all? Commitment and compromise in the fight for Canada's law on compulsory licensing for export", in *The Power of Pills: Social, Ethical & Legal Issues in Drug Development, Marketing and Pricing* (Pluto Books, 2006)

<http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=679>

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