DELIVERING ON THE PLEDGE:

REFORMING CANADA'S ACCESS TO MEDICINES REGIME

Submission to the Government of Canada

January 2007

Canada's Access to Medicines Regime (CAMR) is failing to meet its goals. The legislation aims to make it possible for Canadian companies to obtain "compulsory licences" that would authorize the manufacture and export of lower-cost, generic versions of patented drugs needed by people in developing and least-developed countries.[1] The legislation is based on a World Trade Organization (WTO) decision adopted on August 30th, 2003.[2] Since Canada passed its law in May 2004, not a single drug has been exported. The World Health Organization estimates that over the same period, more than 25 million people have died because they did not have access to existing medicines and vaccines.[3]

Most people living with HIV/AIDS continue to be denied life-saving treatment, in part due to the high costs of patented drugs. The need for affordable medicines is clear; and Canada must ensure that the CAMR fulfills its humanitarian goals.

The federal government is currently reviewing the legislation, and is required to report to Parliament by May 2007. There is an urgent need to make this legislation effective for those in need of life-saving drugs. The current processes, however, are unnecessarily long and expensive, greatly limiting the legislation's potential for responding to public health needs. We, the undersigned, call on the Canadian government to take the following steps:

GLOBAL TREATMENT ACCESS GROUP GTAG

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

Interagency Coalition on AIDS and Development | Coalition interagence sida et développement

Canadian Crossroads International | Carrefour Canadien International

Oxfam Canada

Canadian Labour Congress | Congrès du travail du Canada

The North-South Institute • L'Institut Nord-Sud

Results Canada | Résultats Canada

care

CPAR

Students Against Global AIDS

CCIC CCCI

CANADA'S COALITION TO END GLOBAL POVERTY
ENSEMBLE POUR ÉLIMINER LA PAUVRETÉ DANS LE MONDE

Canadian Society for International Health | La Société canadienne de santé internationale

World Vision

The Global Treatment Access Group (GTAG) is a working group of international development, human rights, humanitarian, and AIDS service organizations, trade unions, student groups and faith-based groups seeking to improve access to essential medicines and other aspects of HIV prevention and care, treatment and support for people living with HIV/AIDS in developing countries.

1. Provide authorizations to export which are not limited to a single drug-order for a single country.

This can be done in a number of ways:

[a.] Create a standing statutory authorization permitting export of generic medicines to eligible countries: Parliament could enact legislation that authorizes the manufacture of generic versions of any drug patented in Canada for export to any eligible country specified in the legislation. The law would also require that any generic manufacturer exporting under this statutory authorization periodically disclose the dollar value of the contracts it has negotiated with various importing countries and remit to the patent-holder the required royalties, following the formula in the existing Canadian law. This approach is much simpler and more direct than the cumbersome process found in Canada's current law and in the WTO Decision of 2003, and still complies with Canada's WTO obligations.[4]

[b.] On any given drug, grant a single, open-ended license to a given manufacturer: Instead of requiring a generic manufacturer to apply for a separate licence to satisfy every separate order of a drug, the law could grant that manufacturer one initial compulsory licence on a drug. The licence would authorize the company to export that drug to any eligible country specified in the legislation, on the condition that the generic company pay royalties to the patent-holder, following the formula in the existing law. This approach would also be more streamlined than Canada's current law and, just like option [a], would comply with WTO rules.

[c.] Introduce a simple, fast process for licenses additional to the first license: Even if the law were still to require a separate licence for every single drug order, it should at least provide for a simple, rapid process for amending or supplementing the original licence to authorize the export a) of additional quantities of the drug, b) to additional eligible countries, or c) for an extended period of time. This would be a more streamlined implementation of the WTO Decision of 2003 on which Canada's current legislation is based.

2. Remove unnecessarily restrictive and time-consuming steps in the licensing process.

The legislation underpinning the CAMR creates procedural steps not required by the WTO Decision or prior Canadian law. The following changes would address this:

[a.] Remove the time limit on licenses granted: Licenses should cover the duration of the remaining patent term on the drug to be exported. The current time-limit of 2 years is arbitrary and not required by the WTO Decision of 2003. This measure constitutes a major barrier to the participation of generic companies, since they must re-initiate the long approval process to continue exporting the product beyond a 2-year period. This also prevents generic companies from guaranteeing to purchasers that they will be able to continue supplying after two years.

[b.] Limit the requirement of negotiating with a patent-holder before seeking a compulsory license: These negotiations involve high costs and considerable delays. Canada's legislation should provide clear limits on the negotiations required. Following WTO rules, where the importing country wants to import the drug to address a national emergency or similar circumstance, or for public non-commercial use, there should be no requirement that the generic manufacturer first try to negotiate a voluntary licence.

[c.] Eliminate the list of eligible drugs: The WTO Decision does not require any limitation to specific drugs; this type of provision was debated and rejected at the WTO level. The list of drugs in CAMR (Schedule 1 of the *Patent Act*) has resulted in months of unnecessary delays.

[d.] Eliminate the absolute requirement of Health Canada approval: This measure is not required by the WTO Decision of 2003, nor do other drugs require Health Canada approval for export. Many developing countries will require "pre-qualification" of both the generic manufacturer and the drug in question by the World Health Organization before purchasing it. Requiring Health Canada approval of the generic manufacturer's product as an absolute precondition before the manufacturer can get a licence to produce for export can lead to duplication of effort and add months of unnecessary delay. Canada should accept either Health Canada approval *or* WHO pre-qualification as sufficient to permit export of a generic drug produced under a compulsory licence.

[e.] Eliminate patent-holders' extra litigation rights: In three separate provisions, the legislation underpinning the CAMR includes eleven separate grounds on which a patent-holder can start legal proceedings against the generic manufacturer at different stages (ss. 21.08(5), 21.14, 21.17). These are unnecessary additions to existing legal recourses under the *Patent Act*.

[f.] Eliminate the requirement that NGOs get the "permission" of the importing country government: Under Canada's current law, an NGO providing humanitarian relief in an eligible developing country has to get the "permission" of that country's government to import under CAMR. (This is in addition to the existing, sensible requirement that the medicine be approved for use by the importing country's drug regulatory authority.) Requiring this extra permission for NGOs to do their jobs is not required by any WTO rules, and creates an additional, unnecessary barrier to patients getting the medicines they need.

[g.] Eliminate double-standards that apply to some importing countries: Under the current law, if a developing country does not belong to the WTO, it faces additional barriers to importing generic medicines from a Canadian producer, such as the requirement to declare a national emergency or similar situation. These additional hurdles are not required under WTO rules of WTO member countries. Patients' access to more affordable medicines should not depend on whether their country belongs to the WTO.

Submitted by:

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AIDS Vancouver
Africafiles
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Canada Africa Community Health Alliance
Canadian AIDS Society
Canadian Association of Nurses in AIDS Care
Canadian Council for International Co-operation
Canadian Crossroads International
Canadian HIV/AIDS Legal Network
Canadian Labour Congress
Canadian Physicians for Aid and Relief
Canadian Society for International Health
Canadian Treatment Action Council
CARE Canada
Central Alberta AIDS Network Society
Human Rights Working Group on HIV/AIDS and Public Health, Faculty of Law, McGill University
Interagency Coalition on AIDS and Development
International Council of AIDS Service Organizations
KAIROS: Canadian Ecumenical Justice Initiatives
Marquis Project
McGill Global AIDS Coalition
Doctors Without Borders Canada
North-South Institute
Oxfam Canada
People's Health Movement (Canada)
RESULTS Canada
Students Against Global AIDS, National Committee
UNICEF Canada
United Church of Canada
Universities Allied for Essential Medicine
Western Aboriginal Harm Reduction Society
World Vision Canada
Youth Challenge International

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References

[1] The legislation which created the CAMR is commonly known as the *Jean Chrétien Pledge to Africa*. The goal of the CAMR and other features are described at http://camr-rcam.hc-sc.gc.ca.

[2] The WTO Decision can be seen at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

[3] World Health Organization (WHO). (2004) *Equitable access to essential medicines: A framework for collective action.* Geneva: WHO. Available at http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.4.pdf

[4] The WTO Decision of 2003 "is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31". Article 30 of TRIPS allows Canada to create "limited exceptions" to exclusive patent rights.

This briefing paper is available at www.aidslaw.ca/gtag.

Ce document est également disponible en français.