



CANADA'S LAW ON COMPULSORY LICENSING FOR EXPORT

UPDATE December 3, 2009

On the evening of December 2, 2009, in a victory for treatment activists, Canada's House of Commons voted narrowly (143 in favour, 127 against) to move forward with a private member's bill that would streamline "Canada's Access to Medicines Regime" (CAMR), the law originally passed in 2004 to implement the WTO General Council Decision of August 30, 2003 on compulsory licensing of patented pharmaceutical products for export.

In more than 5 years since it was passed, CAMR has been used to issue only one compulsory licence, which authorized the export of 15.6 million tablets of the fixed-dose combination product Apo-Triavir (AZT + 3TC + NVP) to Rwanda by Apotex, Inc., Canada's largest generic pharmaceutical manufacturer. (The ultimate price of the tablet supplied to Rwanda was US\$0.195 per tablet, comparable to the price offered by other generic manufacturers at the time.)

The bill in the House of Commons, Bill C-393, was introduced by New Democratic Party MP Judy Wasylycia-Leis. Following yesterday's vote, it will now proceed to a House of Commons committee for further study. A virtually identical bill, Bill S-232, was introduced earlier this year by Liberal Senator Yoine Goldstein and is now sponsored by Liberal Senator Sharon Carstairs. It is currently before a committee of Canada's Senate, which wrapped up hearing from witnesses just two weeks ago and is expected to proceed next to a clause-by-clause debate on the bill.

Both bills are facing stiff opposition from the patented pharmaceutical industry. The lobby group Rx&D - Canada's Research-based Pharmaceutical Companies, and companies such as GlaxoSmithKline and Boeringer Ingelheim, have testified in Parliament against the proposed reforms, and have been advancing numerous objections to them, including the inaccurate claim that the reforms are not in compliance with Canada's obligations as a WTO Member.

The Canadian HIV/AIDS Legal Network has been spearheading the campaign for reform, and a broad range of civil society organizations and concerned individuals have been mobilized to press the case, including UNICEF Canada, Canadian Crossroads International, Grandmothers to Grandmothers Campaign, RESULTS Canada, Universities Allied for Essential Medicines, student groups, and others. Treatment activists will continue campaigning in support of the proposed reforms.

Generic drug manufacturer Apotex, Inc. has made the public commitment that, if the current law is streamlined along the lines proposed by the two bills before Parliament, it will produce a paediatric formulation of Apo-Triavir which it will seek to export under compulsory licence to eligible importing countries: <http://www.apotex.com/global/about/press/20090918.asp>.

Both bills reflect heavily the amendments originally proposed in April 2007 by the Canadian HIV/AIDS Legal Network during a Parliamentary review of Canada's legislation. Both of them would implement, among other reforms, a "one-licence solution". Instead of the current country-by-country, order-by-order process of compulsory licensing currently found in CAMR, a reformed law would require only one licence on a patented pharmaceutical product. That one licence would authorize exports to any of the developing

countries covered by the current law and without limiting the quantity to a pre-determined "maximum quantity". As a condition of the licence, the generic manufacturer would still pay royalties to the patent-holder(s) based on the sales of the generic product. (The existing formula in CAMR for calculating royalties that must be paid on any given contract is perfectly adequate and provides clarity and certainty to all involved, including the generic manufacturer getting the licence.)

The full text of the Legal Network's brief regarding the proposed reforms (as submitted to the Senate committee that has already held hearings on Bill S-232) is available at: <http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=987>.

For more information, see the materials available at www.aidslaw.ca/camr, including:

"Fixing Canada's Access to Medicines Regime: 20 Questions & Answers"
<http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=965>

Results of a nation-wide poll recently conducted show very strong public support for fixing CAMR (<http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=994>), and this week we released an open letter to all Parliamentarians, signed by the former Prime Minister and dozens of other eminent Canadians, calling on them to move forward with the bills to reform CAMR (<http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=996>).

Below is a statement issued yesterday by the Legal Network following the vote in the House of Commons, as well as a list of selected media reports (with links) in recent months on the campaign to reform the legislation — including favourable editorials in some of the country's leading newspapers.

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CANADIAN HIV/AIDS LEGAL NETWORK

For immediate release

IMPORTANT STEP FORWARD IN VOTE ON BILL C-393 *Statement from Richard Elliott, Executive Director of the Canadian HIV/AIDS Legal Network*

December 2, 2009, Ottawa — “Today’s vote in favour of sending Bill C-393 to Committee is an important step towards providing medicines to children and adults dying of treatable diseases in developing countries. Parliament now joins experts and advocates in the fields of science, academia, public service and the arts, newspaper editorial boards, and according to a recent poll, 80 percent of Canadians, in support of reforming Canada’s Access to Medicines Regime [CAMR].

“The Canadian HIV/AIDS Legal Network appreciates Members of Parliament rising in support of this legislation at Second Reading following debate that was characterized by hyperbolic misinformation from its opponents. We congratulate and thank them. The Legal Network looks forward to a reasoned debate at Committee, and the opportunity to further make the case that simplifying the licensing process of CAMR — to allow developing countries to access medicines more quickly and easily from Canadian generic drug makers — will save lives.

“We continue to maintain that this legislation is a win for patients in the developing world who need medicines, a win for Canadian generic companies that can supply those medicines, a win for brand-name drug companies that would receive royalties, and a win for Canada’s international reputation — all at no cost to Canadian taxpayers.

“Parliament made an important decision today but there is more work to do. We look forward to building upon the support of the MPs who voted to reform CAMR, and expanding this support to other MPs to ensure Canada successfully finishes what it started in 2004, when Parliament unanimously voted to bring in the regime.”

For details on CAMR reforms, please visit www.aidslaw.ca/camr.

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MEDIA COVERAGE

Globe and Mail, "Ottawa to debate bill that would open access to generic drugs" (December 3, 2009)
<http://www.theglobeandmail.com/news/politics/ottawa-to-debate-bill-that-would-open-access-to-generic-drugs/article1386291/>

Toronto Star, "MP 'ecstatic' after vote revives AIDS drugs shipments to Africa" (December 3, 2009)
<http://www.healthzone.ca/health/newsfeatures/article/733968--mp-ecstatic-after-vote-revives-aids-drugs-shipments-to-africa>

Globe and Mail editorial, "Living up to old rhetoric" (December 2, 2009)
<http://www.theglobeandmail.com/news/opinions/editorials/living-up-to-old-rhetoric/article1385121/>

Globe and Mail, "Liberal divisions imperil Canada's African pledge" (December 2, 2009)
<http://www.theglobeandmail.com/news/national/liberal-divisions-imperil-canadas-african-pledge/article1385131/>

Toronto Star editorial, "Help Africa Fight AIDS" (November 30, 2009)
<http://www.thestar.com/opinion/editorials/article/732339--help-africa-fight-aids>

CBC Power and Politics, "Dying for AIDS drugs" (December 1, 2009) [video]
<http://www.cbc.ca/video/#/News/Politics/ID=1347605850>

CBC Power and Politics, Question of the Day (December 1, 2009)
<http://www.cbc.ca/politics/insidepolitics/2009/12/question-of-the-day-1.html>

CBC, "Bill to help sale of HIV drugs gains support" (December 1, 2009)
<http://www.cbc.ca/canada/story/2009/12/01/aids-drugs-generic-bill.html>

Le Devoir, « Journée mondiale du Sida – Améliorer l'accès aux médicaments abordables » (1^{er} décembre 2009)
<http://www.ledevoir.com/societe/sante/278287/journee-mondiale-du-sida-ameliorer-l-acces-aux-medicaments-abordables>

CBC Radio, "The Current" — Canada's Access to Medicines Regime (September 28, 2009) [audio file]
<http://www.cbc.ca/thecurrent/2009/200909/20090928.html>

Intellectual Property Watch, "Last Cheaper AIDS Medicines For Rwanda Under WTO" (September 17, 2009)
<http://www.ip-watch.org/weblog/2009/09/17/last-cheaper-aids-medicines-for-rwanda-under-wto/>

Winnipeg Free Press, "Grannies say Canada failing HIV, TB patients in Africa" (November 30, 2009)
<http://www.winnipegfreepress.com/local/grannies-say-canada-failing-hiv-tb-patients-in-africa-78118597.html>

Canadian Medical Association Journal, "Prominent Canadians lobby for drug access reform" (December 1, 2009)
<http://www.cmaj.ca/earlyreleases/4theRecord.shtml>

Burlington Post, "Affordable medicine: a human right or a commodity?" (November 27, 2009)
<http://www.burlingtonpost.com/news/article/288142>

Ottawa Citizen, "Keeping our promise to Africa on access to AIDS medicine" (April 29, 2009) (4-part feature story)

<http://www.ottawacitizen.com/health/Part+solution/1545476/Keeping+promise+Africa+access+medicine/1545394/story.html>

Ottawa Citizen, "It shouldn't be hard to improve access to AIDS medicine" (October 6, 2009)
<http://www.ottawacitizen.com/business/shouldn+hard+improve+access+AIDS+medicine/2070197/story.html>

Georgia Straight, "Canada's Access to Medicines Regime needs reform" (September 14, 2009)
<http://www.straight.com/article-257071/goldis-chami-and-rebecca-goulding-canadas-access-medicines-regime-needs-reform>

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