



## **FIXING CANADA'S ACCESS TO MEDICINES REGIME: CAMPAIGN FOR LIFE-SAVING TREATMENT AT CRITICAL STAGE**

**UPDATE  
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The campaign in Canada's Parliament to fix **Canada's Access to Medicines Regime (CAMR)** — so that more affordable life-saving medicines can get to developing countries — continues and is now at a critical juncture.

On November 1, 2010, the Parliamentary committee studying Bill C-393 voted, by the slimmest of majorities, to strip the bill of its “one-licence solution”, the key provision to streamline the current cumbersome regime. Now the bill is back in the House of Commons, where this damage can be reversed if Members of Parliament take action. If Bill C-393 is to make meaningful reforms to Canada's Access to Medicines Regime, the “one-licence solution” (described further below) must be restored. Fixing CAMR in this way would help supply access to affordable life-saving medicines to people in the developing world.

Debate on Bill C-393 is currently scheduled to start on **Monday, January 31, 2011**, the first day that Parliament reconvenes after the holiday break. But the bill faces three challenges, all of which can be overcome if the political will is mobilized in Parliament:

### **1. A new sponsor for Bill C-393 in Parliament**

The MP who originally introduced Bill C-393 is no longer in the House of Commons. Therefore, while debate on the bill can proceed in Parliament, the bill eventually needs a new sponsor in order to be brought to a final vote. There are MPs who want to take the bill forward to a vote, but making this minor procedural change requires unanimous support in the House of Commons. Three of four parties in the House of Commons — the New Democratic Party, the Liberal Party and the Bloc Québécois — have committed that they will respect the spirit of Canadian democratic debate and allow Bill C-393 to go to a vote with a new sponsor. But the Conservative government has not yet given this commitment — even though they have been asked repeatedly and this procedure has been done on numerous occasions before. In fact, Prime Minister Stephen Harper has himself benefitted from this courtesy in Parliament: before his party was elected and he became Prime Minister, he had his own private member's bill in the House of Commons and when he stepped down as an MP, the House agreed unanimously to transfer the bill to a new MP. Given statements by some MPs, including Conservative MPs, there are real concerns that the government will block a motion to accept a new MP as sponsor of Bill C-393.

### **2. Restoring the “one-licence solution”**

Bill C-393 needs to have the “one-licence solution” restored and the bill, including this clause, must then be supported by a majority of MPs in the House of Commons when it comes to a vote. A motion to reinstate the “one-licence” clause of the bill has been introduced and will be part of the upcoming

debate when Parliament resumes. There is solid support for the “one-licence solution” but Big Pharma is lobbying hard against it. MPs need to hear from their constituents that they want and expect them to vote in favour of restoring this essential clause to Bill C-393, and to then vote in favour of the bill itself.

### 3. Efforts to limit the duration of any reforms to CAMR: the proposed “sunset clause”

The Bloc Québécois has recently put forward a motion to limit the changes to CAMR by Bill C-393, including the “one-licence solution”, so that they will last for only 4 years. After that time, the reforms would automatically expire, and the law would revert to the existing cumbersome rules of the current CAMR. This is certainly not in the best interest of those in desperate need of life-saving medications: if we already know that the current CAMR has failed, why would we return to it after fixing its key flaws? The Bloc Québécois motion does allow that the changes to CAMR could be further extended, but only if the federal government adopts a resolution to do this, which must then be supported by a majority in both the House of Commons and the Senate. These would be difficult hurdles to overcome, particularly in the face of guaranteed opposition from Big Pharma to any extension of the changes to CAMR. There is no sound rationale for such a “sunset clause” that would limit the changes improving CAMR to such an arbitrary and short timeframe. But such a time limit would likely have the effect of creating, yet again, a disincentive to using even a streamlined CAMR. It limits the economies of scale and commercial viability needed for generic manufacturers to participate in any significant way, and it does not give developing countries the certainty they need about longer-term, sustainable sources of supply from those manufacturers.

## Background

Canada’s Access to Medicines Regime (CAMR) was a unanimous pledge by Parliament to help people dying in developing countries because they lack access to affordable medicines; it is Canada’s implementation of a 2003 agreement negotiated by all countries of the World Trade Organization (WTO). This agreement was to create more flexibility in rules on pharmaceutical patents so that lower-cost, generic versions of expensive, brand-name patented drugs could be exported to countries with insufficient capacity to manufacture their own.

To date, CAMR has delivered only one medicine to one country (Rwanda) since Parliament created it in May 2004, almost 7 years ago. CAMR is clearly not working.

Bill C-393 was introduced in the House of Commons in May 2009 to address the unnecessary deficiencies and limitations in CAMR that render it so weak. **Bill C-393 aims to put in place a “one-licence solution” as a way to remove the current practical barriers to making use of CAMR.**

The current CAMR includes a cumbersome case-by-case approach with lots of red tape and disincentives for both developing countries and generic drug-makers. Instead of the 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. The one-licence solution originally proposed by Bill C-393 would let a generic drug-maker get a single licence allowing a medicine to be exported to any of the countries already in the current law, and to supply the quantities of medicines required by countries as their needs evolve over time (rather than a pre-determined and fixed “maximum quantity”), without having to go through drawn-out and uncertain processes every single time.

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.)

By streamlining CAMR, Bill C-393 makes the entire system more user-friendly and allows Canada to follow through on Parliament’s promise to help developing countries gain access affordable medicines for AIDS and other urgent public health needs.

Without this change, CAMR will continue to languish unused. But if this change is adopted, there is already a public commitment from Canada's largest generic drug manufacturer that, as a first next step, it will make a child-friendly version of the three-in-one AIDS drug that is urgently needed for export. This product is one of the "fixed-dose combinations" (i.e., products combining multiple medicines in a single dose) that is needed for treating children and infants with HIV. Apotex Inc. has committed to producing a paediatric formulation of this product which it will seek to export under compulsory licence to eligible importing countries: <http://www.apotex.com/global/about/press/20090918.asp>.

But Bill C-393 is facing stiff opposition from the patented pharmaceutical industry, and especially the lobby group, Canada's Research-based Pharmaceutical Companies (Rx&D). 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 International Federation of Pharmaceutical Manufacturers Associations (IFPMA), the global lobby group for "Big Pharma", has also lobbied against Bill C-393, testifying against it before a Parliamentary committee.

Results of a nationwide poll show very strong public support for fixing CAMR ([www.aidslaw.ca/publications/publicationsdocEN.php?ref=994](http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=994)). Numerous prominent Canadians, including the former Prime Minister whose government enacted the original CAMR law, have called on Parliament to move forward with Bill C-393 ([www.aidslaw.ca/publications/publicationsdocEN.php?ref=996](http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=996)).

The Canadian HIV/AIDS Legal Network has been spearheading the campaign for CAMR reform, and a broad range of civil society organizations and concerned individuals have been mobilized to press the case. These include the Grandmothers to Grandmothers Campaign, Dignitas International, the Interagency Coalition on AIDS and Development, UNICEF Canada, Oxfam Canada and Oxfam Quebec, Canadian Crossroads International, RESULTS Canada, Universities Allied for Essential Medicines, l'Association québécoise des organismes de coopération internationale (AQOCI), student groups, local and national AIDS organizations and others. Treatment activists will continue campaigning in support of the proposed reforms — and in support of saving lives.

#### **For more information and to take action...**

1. Visit [www.LetParliamentVote.ca](http://www.LetParliamentVote.ca) to take urgent action to demand that the respect our democratic process and allow Bill C-393 proceed to a final vote, rather than derail an important humanitarian initiative on a procedural technicality.
2. More information can be found at [www.aidslaw.ca/camr](http://www.aidslaw.ca/camr), including this important overview, "Fixing Canada's Access to Medicines Regime (CAMR): What You Need to Know About Bill C-393" <http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=1149>. You can also find other key documents, including the full text of the **Legal Network's brief to the Parliamentary committee** that studied Bill C-393 and the submissions from numerous other experts at <http://www.aidslaw.ca/EN/camr/index.htm#Documents>.
3. Watch a short video on why CAMR needs to be fixed, with interviews with the Legal Network, UNICEF Canada and African grandmothers and AIDS activists, at [www.aidslaw.ca/camr](http://www.aidslaw.ca/camr).
4. Join the Facebook [www.aidslaw.ca/facebook](http://www.aidslaw.ca/facebook) group on reforming CAMR for more important updates.

If you have any questions or require additional information, please contact our Outreach Coordinator, Lindsey América-Simms, at [lsimms@aidslaw.ca](mailto:lsimms@aidslaw.ca).