



## **FIXING CANADA'S ACCESS TO MEDICINES REGIME: Bill C-393 up for final vote in House of Commons in early March**

**UPDATE  
February 2011**

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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.

### **Where do things stand now? And what needs to happen?**

Thanks to intense advocacy by civil society groups, all political parties in the House of Commons agreed, on February 2, to let MP Paul Dewar (NDP, Ottawa Centre) become the new sponsor of Bill C-393, so that it can move forward to a vote once debate in the House of Commons concludes. **The final hour of debate on Bill C-393 is scheduled for Thursday, March 3 and the final series of votes — including voting on amendments — will take place on the evening of Wednesday, March 9.**

But Bill C-393 still faces challenges, including opposition from Big Pharma (i.e., Canada's Research-Based Pharmaceutical Companies, or Rx&D, and their member corporations), which is actively lobbying MPs. If Bill C-393 is to be passed in a form that makes meaningful reforms to CAMR, we still need to mobilize political will in Parliament.

Several amendments are currently before the House as part of the debate and will be voted on before Bill C-393 itself, as amended, is put to a final vote. Below is an outline of key issues at stake in the upcoming votes.

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

Last November, 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. The House of Commons can reverse this damage. If Bill C-393 is to truly transform CAMR into workable legislation, the “one-licence solution” (further described below) must be restored. Fixing CAMR in this way would help supply access to affordable life-saving medicines to people in the developing world. Indeed, a motion to reinstate the “one-licence” clause of Bill C-393 is before the House of Commons, and there is good support for the “one-licence solution.” But there is also some strong opposition, including from Big Pharma, because it will mean CAMR gets used again to issue compulsory licences for export — which is indeed the very point of Bill C-393. **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.**

## 2. Removing arbitrary, unnecessary limits on medicines that can be supplied under CAMR

CAMR currently includes a limited list of medicines (Schedule 1) that can be produced as generics for export to eligible countries. There is an amendment before the House of Commons to replace this limited list with a broader definition of “pharmaceutical product” to address public health problems. The proposed definition is exactly in line with the language already agreed to by Canada and all other countries at the World Trade Organization (WTO) when they negotiated this kind of flexibility in patent rules for this express purpose. The opponents of this reform to CAMR are simply wrong when they claim it would violate WTO rules. **MPs need to hear from their constituents that they should live up to this WTO agreement and should not arbitrarily limit the scope of CAMR and the drugs available under it.** It is both unethical and bad public health policy for Canada to tell developing countries that CAMR can only be used to get certain medicines for certain public health problems.

## 3. Resisting efforts to limit the duration of CAMR reforms: the Bloc Québécois’ 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 four 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 for a possible extension of the changes to CAMR, but only if the federal government adopts a resolution to this effect, which must then be supported by a majority vote in both the House of Commons and the Senate. These would be extraordinarily difficult (and needless) 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 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. There is no “sunset” on AIDS or other public health problems, so why should the changes that will make CAMR work be “sunsetting”? **MPs, including those belonging to the Bloc Québécois, need to hear from concerned Canadians that this proposal should be changed into a four-year review of the CAMR reforms — not an automatic revocation of the changes.**

Contrary to the claims by Big Pharma and some MPs, with the proposed amendments, Bill C-393 retains the current CAMR provisions aimed at ensuring the quality of medicines being exported (i.e., requiring Health Canada approval). It also retains the current CAMR requirements for packaging and labeling the medicines in certain ways to prevent them from being diverted to unauthorized countries. Also, Bill C-393 does not extend the list of countries eligible to import Canadian-made generic drugs beyond those already found in the current CAMR or agreed upon by countries at the WTO. *It is important to be aware of these aspects because of inaccurate claims that Bill C-393 weakens these elements.*

## Background to Canada’s Access to Medicines Regime and Bill C-393

Canada’s Access to Medicines Regime 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. 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 seven 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.aidslaw.ca/EN/camr/documents/ApotexLetter-Submission2010-ENG.pdf>.

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, Canadian Labour Congress, l’Association québécoise des organismes de coopération internationale (AQOCI), student groups, local and national AIDS organizations and others. 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.aidslaw.ca/camr](http://www.aidslaw.ca/camr) for more information. You can find “Fixing Canada’s Access to Medicines Regime (CAMR): What You Need to Know About Bill C-393” at <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>.
2. Contact your Member of Parliament by email, phone or regular mail to let them know that you want them to vote in support of Bill C-393, with its “one-licence solution” restored and without any “sunset clause” or prohibitively short timeline.
3. Join the Facebook group ([www.aidslaw.ca/facebook](http://www.aidslaw.ca/facebook)) focused on reforming CAMR for important updates, including action alerts in the weeks ahead.
4. Watch a short video on why CAMR needs to be fixed, featuring interviews with the Legal Network, UNICEF Canada and African grandmothers and AIDS activists, at [www.aidslaw.ca/camr](http://www.aidslaw.ca/camr).

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