Fixing Canada's Access to Medicines Regime: What you need to know about Bill C-398

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. So far, it has delivered only one medicine to one country since Parliament created it more than 8 years ago (in May 2004). CAMR is clearly not working; it needs to be reformed to address the unnecessary deficiencies and limitations that have rendered it cumbersome and user-unfriendly for both developing countries and the manufacturers of lower-cost, generic medicines — the two parties that need to make use of CAMR if patients are to get the medicines they need.

In the last Parliament, the House of Commons passed another bill (Bill C-393) that would have made key changes to CAMR to make it work, including enacting what has been called the "one-licence solution." The bill was passed by a large majority in early March 2011 with strong support from MPs belonging to all parties. However, Bill C-393 did not proceed through all the necessary stages in the Senate before Parliament was dissolved for a federal election a few days later; therefore, the bill died on the order paper and did not become law.

In the current Parliament, a new bill — Bill C-398 — was introduced in February 2012. This bill reintroduces the core reforms to CAMR that were already endorsed by the strong majority of MPs with the last bill. Bill C-398 gives Parliament a second chance to pass the changes needed to streamline CAMR. Yet opponents of CAMR reform have continued to spread misinformation about the proposed reforms, in an effort to block Bill C-398. Below, we identify some of the key claims being made by those who oppose CAMR reform and explain why these are incorrect and misleading. By streamlining CAMR, Parliament can deliver on its promise to people in developing countries struggling with the burden of such public health problems as AIDS, tuberculosis, malaria and other diseases.

A number of key points should be remembered in the debate over fixing CAMR:

- Market competition among drug companies is critical to ensuring affordable prices for medicines for developing countries, and CAMR is a mechanism aimed at encouraging such competition.
- Independent experts on international law have repeatedly indicated that the "one-licence solution" that has been proposed (and is included in Bill C-398) is consistent with WTO rules on patents. It aims to make workable a mechanism that all WTO members have already agreed, back in 2003, should be available to developing countries needing lower-priced medicines.
- The proposed reforms would not weaken measures aimed at ensuring the delivery of quality medicines to patients. All medicines exported under CAMR would still be reviewed by

Health Canada and all of CAMR's existing safeguards against illegal diversion of medicines would remain unchanged.

- Streamlining CAMR does not jeopardize pharmaceutical research and development (R&D) because it does not affect markets in wealthy countries that drive brand-name companies' profits and their decisions on R&D.
- The proposed reforms offer value for money. The changes cost taxpayers nothing. In fact, making CAMR work would make Canadian foreign aid more effective, because limited resources could purchase more medicines. Greater access to medicines for AIDS and other public health problems is a necessary part of Canada's commitment to maternal and child health.
- Fixing CAMR helps address high prices for medicines, a key barrier to access. This is a necessary part of larger action to improve treatment access; it complements and supports efforts to strengthen health systems and infrastructure in developing countries.
- There is nothing to be lost by reforming CAMR with the proposed "one-licence solution," but there is much that could be gained in saving many lives.

MYTH: Proposed reforms to CAMR would weaken current safeguards aimed at ensuring medicines are not diverted and illegally resold.

FACT: These claims are simply false, as an examination of Bill C-398 quickly reveals. All the requirements already contained in CAMR — such as disclosing the quantities of a medicine being shipped, and to which countries — are also preserved. These safeguards were already deemed satisfactory by Parliament when it first created CAMR. In fact, Bill C-398 includes an additional change to CAMR, which did not appear in the last bill (Bill C-393). This change further clarifies and strengthens the provisions aimed at ensuring transparency in the use of CAMR (so as to prevent diversion), and means that CAMR would *conform even more closely to WTO rules than it currently does*. It specifies that Canadian generic manufacturers exporting under CAMR must post online both (1) "the quantities being exported to each country or WTO Member" under their licence and (2) a copy of the written notification the importing country has made to the WTO (if a WTO Member) or to the Government of Canada (if not a WTO Member). That notification sets out the importing country's "expected quantities" of the pharmaceutical product, which the generic manufacturer is then authorized under its licence to supply.

MYTH: Proposed CAMR reforms would remove measures to ensure the quality of medicines being supplied to developing countries.

FACT: This claim is simply not true; again, this is easily verifiable by looking at what Bill C-398 would change — and what it would not change — in the current CAMR sections of the Patent Act. Under Bill C-398, Health Canada review would continue to be required for all drugs exported pursuant to licences issued under CAMR.

MYTH: Proposed amendments to CAMR would violate Canada's obligations under the WTO treaty on intellectual property rights.

FACT: This is simply incorrect as a matter of law, as confirmed by careful analyses by some of the world's leading legal experts on the subject.

All countries at the WTO, including Canada, have repeatedly and explicitly agreed that issuing compulsory licences on patented medicines to facilitate exports of lower-priced, generic medicines is entirely consistent with WTO rules. They agreed in the 2001 Doha Declaration that the WTO *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) "can and should be implemented and interpreted" in ways that support WTO members in protecting public health, including in promoting "access to medicines for all". In the same Doha Declaration, they also explicitly agreed that developing countries need to be able to "make effective use of compulsory licensing" to this end. This is the very purpose of CAMR in the first place. Bill C-398's "one-licence solution" simply eliminates the unnecessary bureaucratic impediments to using the system, so that the licensing system is simple and flexible in order to address the evolving needs of developing countries.

Independent international legal experts have confirmed that the "one-licence solution" complies with WTO law. This includes one of the world's leading experts, Professor Frederick Abbott, who co-authored the leading international text on this subject and was actively engaged in negotiating the very decision by the WTO General Council in 2003 that is the basis for CAMR. He has twice testified before Parliament that the one-licence solution is WTO-compliant. In 2010, the UN Development Programme convened an international consultation with legal experts who reviewed the reforms proposed to CAMR and concluded the one-licence mechanism was consistent with WTO rules. The director of the Intellectual Property Division at the WTO Secretariat has also twice testified before Parliament (both the Senate and the House of Commons), emphasizing that WTO Members have insisted on maintaining their flexibility when it comes to their national legislation on intellectual property issues.

MYTH: The proposed reforms to CAMR authorize "unfair" competition for brand-name pharmaceutical companies.

FACT: This claim makes no sense. The proposed "one-licence solution" does not, as some inaccurately claim, create unfair competition for brand-name pharmaceutical companies. To be clear: nothing in any proposed changes to CAMR would prevent brand-name pharmaceutical companies from competing to supply their patented products to developing countries. Rather, the proposed reforms simply aim to enable competition by generics to also supply those eligible countries. Bill C-398 does not change the requirement that generic manufacturers pay royalties to patent-holding pharmaceutical companies in the event of any compulsory licence being issued. Those royalties would still be calculated according to the existing formula in CAMR. Bill C-398's reforms to CAMR are aimed at making workable something already endorsed by Parliament.

Competition in the global marketplace has been the single most important factor driving down the prices of medicines to bring them within reach of developing countries. These dramatically reduced prices have made it possible to scale up AIDS treatment, such that 8 million people in low- and middle-income countries are now receiving life-saving medicines. (However, this is still

only 53% of the 15 million currently in need of treatment according to the World Health Organization, and in the case of children with HIV, access to treatment is even worse: as of December 2010, WHO estimated that only 23% of children in low- and middle-income countries who needed antiretroviral drugs were getting them.) CAMR is supposed to enable such competition, which is increasingly important as it becomes more challenging for developing countries to obtain the Indian-made generic medicines which have been central to treatment successes so far.

Encouraging such competition is the very function of a mechanism such as CAMR — it permits compulsory licensing of patented medicines for the limited purpose of exporting lower-cost, generic medicines to eligible countries. All WTO member countries have already repeatedly endorsed compulsory licensing for this purpose, including in the 2003 WTO General Council decision on which CAMR is based.

MYTH: Canadian generic manufacturers will not be able to supply medicines at prices competitive with generic manufacturers elsewhere, such as India.

FACT: This claim is simplistic and unfounded. Indeed, the goal of treatment advocates making the case for CAMR reform is not to get business for Canadian companies; the goal is to get quality medicines at the lowest possible price for as many patients in developing countries as possible. But it makes no sense to simply assume that Canadian generic pharmaceutical companies cannot compete globally — they often do already.

Indeed, in the one case to date in which CAMR has been used, the Canadian generic drug company supplied the medicine to Rwanda at the same price being offered by Indian generic manufacturers (19.5 US cents/tablet or 39 cents per daily dose of two tablets) and won the contract through a competitive bidding process. Rwanda has since purchased more of this medicine from Indian generic manufacturers at essentially the same price, showing that the price offered by Canadian manufacturers can be competitive — but the hurdles in the CAMR process impede its use.

Furthermore, the simpler it is for developing countries and generic manufacturers to use CAMR to supply multiple developing countries, the greater economies of scale and the lower the costs of production that can be achieved by generic manufacturers in Canada — making them more competitive. As it stands, CAMR impedes effective competition by Canadian generic companies. Those who support greater competition in the market, including by Canadian companies, should support the “one-licence solution” proposed by Bill C-398, since it would make it easier for Canadian companies to compete globally to supply medicines at the lowest possible price — and more competition ultimately benefits developing countries that need to purchase medicines and hence the patients in those countries.

MYTH: Streamlining CAMR would undermine incentives for brand-name pharmaceutical companies to research and develop new medicines.

FACT: This claim is not credible. Exports to high-income countries, in which brand-name pharmaceutical companies make the vast majority of their profits and on which they base their decisions about R&D, are not authorized by CAMR. CAMR only authorizes exports of generic versions of patented medicines to certain eligible countries — and these countries were already agreed upon by Canada and all WTO Members in 2003 and are already reflected in the current CAMR as created by Parliament in 2004. These countries represent a minor portion of total global pharmaceutical sales and the profits of brand-name pharmaceutical companies. For example, the entire continent of Africa, the hardest hit by the AIDS pandemic, represents roughly 2 percent of global pharmaceutical sales. As brand-name drug companies make little or no profit in developing countries, these markets have little or no impact on their investments in research and development (R&D). Leading Canadian academic experts in the economics of the pharmaceutical industry also testified to this effect before the House of Commons Industry Committee.

Furthermore, the brand-name drug companies are entitled to receive royalties on sales of generic medicines supplied under CAMR. The proposed "one-licence solution" does not change these limitations and requirements in any way; rather, it streamlines the licensing process so that CAMR is easy to use to supply more affordable medicines to the countries already agreed upon by Parliament.

MYTH: The barrier to greater access is not the price of medicines but rather widespread poverty and inadequate health systems.

FACT: There are multiple barriers to access to medicines in the developing world, which vary from country to country and even within a given country. But major progress has been made in increasing access to treatment, including by strengthening health systems. It is simply inaccurate to claim the quality of health or physical infrastructure in some developing countries presents an insurmountable challenge to delivering affordable medicines. For example, with determination and innovative approaches, AIDS treatment is being delivered effectively in some of the most resource-limited settings imaginable. In just a few years, millions of people have been put on life-saving AIDS drugs in developing countries thanks to both effective global investments in health systems (e.g., through the Global Fund to Fight AIDS, Tuberculosis and Malaria) and the use of generic medicines purchased at dramatically lower prices.

Every credible organization and expert recognizes the obvious fact that the price of medicines is a key factor affecting access to those medicines – and that the prices of medicines prevent many patients with HIV or numerous other conditions from accessing life-saving treatments. Prices are higher when medicines are only available from brand-name pharmaceutical companies that hold patents (i.e., monopolies) on those medicines.

Making medicines affordable, strengthening health systems and other initiatives to tackle poverty and improve health in developing countries are not mutually exclusive; rather, they are complementary and all are necessary. All the clinics, doctors and nurses in the world won't be able to help patients if medicines are priced out of reach. Streamlining CAMR could effectively assist developing countries in overcoming one of the major barriers to affordable treatment. The lower the prices of medicines, the more people can be treated with limited resources – and the more resources are freed up for investing infrastructure and other aspects of health care that are also needed in some settings.

Some have also suggested that fixing CAMR is not worthwhile because it does not solve all the health, poverty and infrastructure challenges of the developing world at once. Following this logic, progress on any one social or economic problem could only be pursued if the proposed solution resolved all problems. No one has suggested that fixing CAMR is a panacea. It is, however, a practical, tangible part of the solution that will realize positive results. Pointing to other challenges that must *also* be addressed is not a justification for failing to support CAMR reform.

MYTH: Brand-name pharmaceutical companies *voluntarily* gave licences to the Canadian generic manufacturer to supply a three-in-one AIDS drug to Rwanda, so there is no need for a compulsory licensing system such as CAMR.

FACT: This claim by the brand-name pharmaceutical companies is simply not true. The fact is that no voluntary licence agreement was ever reached between the brand-name companies involved and the generic manufacturer. Apotex ultimately filed an application for a compulsory licence, which is the purpose of CAMR. This is a matter of public record, with the compulsory licence issued by the Commissioner of Patents (in September 2007) and publicly available on the website of the Canadian Intellectual Property Office. If there had been a voluntary licence, there would have been no need for Apotex to apply for a compulsory licence.

MYTH: CAMR worked quickly once the first application for a compulsory licence was made, and therefore there are no delays or impediments in CAMR.

FACT: It is true that once the first application for a licence was filed, it was issued reasonably quickly. But it is not correct to claim that it only took 68 days from start to finish of the process, which is a claim often heard from the brand-name pharmaceutical companies. This ignores more than a year of lost time attempting to negotiate for a voluntary licence when the brand-name companies would not agree to any licence without a specific developing country being identified. As long as no specific country could be named, the licensing process was stuck in limbo and the possibility of exporting medicines was stalled. The “one-licence solution” proposed in Bill C-398 would avoid this hurdle by not limiting a compulsory licence to authorizing supply to just one specific country, but instead authorizing exports to any of the developing countries that are already recognized currently in the CAMR as being eligible importing countries.
