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

Fixing Canada's Access to Medicines Regime (CAMR): 20 Questions & Answers

In this document:
Questions 1 to 4 give a quick overview of CAMR and why it needs to be fixed.
Questions 5 to 11 provide more in-depth, background information.
Questions 12 to 14 explain the solution for fixing CAMR.
Questions 15 to 20 respond to some of the main objections to reforming CAMR.

1. What is Canada's Access to Medicines Regime (CAMR)?

In 2004, Parliament passed a bill (known as the *Jean Chrétien Pledge to Africa*) that created what is now known as "Canada's Access to Medicines Regime" (CAMR). The stated purpose of this federal law is to help get medicines to patients in developing countries for public health needs, including HIV/AIDS, tuberculosis, malaria or other epidemic diseases. CAMR was passed by Parliament with unanimous support from all political parties in May 2004 and came into force in May 2005. The regulations that form part of CAMR came into force in June 2005.

2. Why does CAMR need to be fixed?

At the moment, developing countries that want to obtain less expensive, generic versions of patented brand-name drugs from Canada must wait until a Canadian generic manufacturer, under CAMR, can get a *compulsory licence* for a specific quantity of medicines for a limited period. A compulsory licence is a legal document that allows a generic manufacturer to produce and sell/export a less expensive, generic (i.e., non brand-name) version of a medicine without the consent of the company that holds the patent on the original product. Since CAMR was passed almost six years ago, it has only been used once — after years of work by non-governmental organizations (NGOs) and one generic company — for a single shipment of a single AIDS drug to a single developing country. In its current form, CAMR is unlikely to be used again due to the procedural requirements it places on developing countries and generic pharmaceutical manufacturers. The process is cumbersome and doesn't fit well with how countries purchase medicines or the business considerations facing manufacturers, meaning patients go without affordable medicines. This is why reforms to streamline CAMR are being proposed, including a "one-licence solution" (described more below in Question 12). If CAMR is reformed, Canada's largest generic pharmaceutical manufacturer, Apotex Inc., has committed publicly that it will make a desperately needed three-in-one AIDS drug (a "fixed-dose combination") that is suited for children in developing countries. Currently, only a very small percentage of children with HIV have access to paediatric formulations of medicines. This makes the need for reforms even more urgent.

3. Isn't compulsory licensing just stealing the property rights of the patent-holder?

No, compulsory licensing is not theft. In exchange for receiving a *compulsory licence*, the generic manufacturer must pay a royalty to the company that holds the patent (e.g., a percentage of the value of the contract it has to sell the generic medicine). The company that holds the patent still has the right to make and sell the original product. The compulsory licence merely authorizes competition by the generic manufacturer (or manufacturers) in exchange for a royalty. Nothing in CAMR, either currently or in the proposed reforms, prevents brand-name pharmaceutical companies from competing to supply their patented product to developing countries.

4. How can issuing a compulsory licence help people in developing countries get better access to essential medicines?

Compulsory licensing can bring down the prices of medicines by limiting the monopoly of the patent-holder and creating greater competition. For example, competition from some generic manufacturers has been critical to bringing down the prices of AIDS medicines for developing countries by more than 95 percent. This has made it possible to increase dramatically the number of people able to get these medicines. Compulsory licensing is a legal tool used regularly in many countries in various sectors. For many years, compulsory licensing was part of Canadian law, including for medicines; a royal commission and other investigations concluded that it helped stimulate a generic pharmaceutical industry in Canada and saved Canadian patients and their insurers (government and private plans) hundreds of millions of dollars. Compulsory licensing has been recognized by countries the world over, including in agreements at the World Trade Organization (WTO), as a key policy tool that governments have the right to use to offset the negative effects of allowing monopolies on medicines through patents.

5. How does CAMR relate to the World Trade Organization (WTO)'s TRIPS Agreement?

Compulsory licensing laws such as CAMR are allowed under the WTO's *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS). TRIPS is a treaty that binds all WTO members, including Canada. TRIPS sets out minimum standards for intellectual property protection that all WTO members must meet within specific timeframes. This includes granting 20 years of patent protection on pharmaceutical products. During the time the patent is in force, the company that holds the patent has a monopoly on making and selling that medicine. Monopolies raise the price of patented medicines, rendering them unaffordable for many people, particularly those living in developing countries.

In order to offset this negative impact of the treaty on developing countries, TRIPS provides for "flexibilities" in patent rules. These flexibilities include, among other things, the *compulsory licensing* of patents. Although CAMR strives to take advantage of flexibilities in the WTO's rules on patents, it has many additional restrictions that are not required by the WTO that make it difficult to use. It also does not take full advantage of all the flexibility that can be found in WTO rules. Therefore, it is possible to reform CAMR to make it easier to use, while still respecting WTO rules.

In November 2001, WTO member countries unanimously adopted the *Doha Declaration on TRIPS and Public Health*. The Doha Declaration specifically addressed some of the controversy over the TRIPS rules on patents that make it harder for countries to access affordable medicines. In the Doha Declaration, WTO members, including Canada, agreed that the TRIPS Agreement "does not and should not" prevent countries from protecting public health, and that it "should be interpreted and implemented" in ways that let countries do this. They agreed that every WTO member has the right to use the flexibilities in the TRIPS Agreement to protect public health, and in particular "to promote access to medicines for all." These flexibilities include issuing compulsory licences on patented medicines to deal with public health problems, whether a short-term problem or a long-lasting situation such as the HIV/AIDS pandemic. The Doha Declaration reaffirmed explicitly that countries are free to determine for themselves the grounds on which compulsory licensing may be done. Contrary to what some have claimed, the wording of the Doha Declaration is explicit that it is *not* limited to just emergencies or public health crises or epidemics (although the AIDS pandemic is certainly an ongoing global crisis).

6. What is the WTO's "August 30th, 2003 Decision" and how does it affect CAMR?

In the 2001 Doha Declaration, WTO member countries recognized that there was a problem with the section in the TRIPS Agreement (Article 31) that limited the use of compulsory licences "predominantly" for the purpose of supplying the domestic market of the country where the licence was issued**.** Thus, Article 31 restricted the quantity of drugs that could be exported under a compulsory license. This effectively prevented developing countries with insufficient manufacturing capabilities from getting affordable generic medications, since countries with such manufacturing capabilities were limited in their ability to export generic drugs to these countries needing to import generic medicines. On August 30th, 2003, WTO members issued a temporary waiver, which allows countries to use compulsory licenses on pharmaceutical products to export affordable medicines to nations that have insufficient capacity to manufacture them. This waiver is sometimes referred to as the "August 30 Decision." CAMR is an implementation of the August 30th Decision. A few other countries have also passed laws implementing the August 30th Decision.

7. Some people have pointed out that Canada is the only country that has used the WTO's August 30th, 2003 Decision (by exporting an AIDS medication to Rwanda under CAMR). If it has worked, why amend CAMR?

It is true that Canada is the only country that has seen a successful use of the 2003 WTO Decision — i.e., the one licence issued under CAMR that has allowed the export of one AIDS drug to Rwanda. However, the law is supposed to be an "expeditious" (i.e., fast) solution that helps developing countries make "effective use" of compulsory licences to get more affordable medicines. The purpose of CAMR, as stated in the law passed by Parliament, is "… to address public health problems afflicting many developing and least developed countries." Issuing one licence to export only one drug to only one country in all the years since the law was passed in 2004 is not the fast solution that WTO members agreed was needed, especially against the backdrop of millions of people needing medicines for HIV or other public health problems. Developing countries have been reluctant to make use of CAMR (or the similar laws adopted by

a few other countries that are essentially the same as CAMR), and so far no generic manufacturer has been willing to use CAMR again in its current form.

CAMR is seriously flawed. The legislation is layered with restrictions and regulatory requirements which go beyond what is required in the WTO's August 30th, 2003 Decision. The many conditions within CAMR make it impossible to fulfill the stated intent of the legislation. As the first country to enact detailed legislation to implement the WTO decision, and the only country to export one shipment of a desperately needed medicine, Canada is well-positioned to show leadership in acknowledging that the current approach, while an important initiative by Canada and a few other countries, does not offer the rapid, flexible, sustainable solution that is needed and that was promised.

8. If the need for medicines is so critical, why aren't developing countries coming forward to use CAMR?

Since CAMR was passed in 2004, no developing countries other than Rwanda have come forward to use the law to get much-needed medicines for their people. Nor has any country sought to use the laws similar to CAMR that have been passed by a few other countries. Why? Part of the reason is that these laws are cumbersome and too difficult to use. The process for a generic drug manufacturer in Canada to get a compulsory licence under CAMR, in order to supply developing countries, doesn't reflect procedures that developing countries need to go through when procuring medicines. There are too many hurdles that developing countries have to jump before they can place an order and receive the medicines. As it stands now, the law contains over 100 clauses. Simply understanding the law requires legal training. In developing countries — as is the case in most developed countries — doctors, not lawyers are the ones who place orders for drugs. For more than a decade, developing countries have been dissuaded from using compulsory licensing through threats of trade sanctions from the multinational brand-name pharmaceutical industry and some high-income countries (e.g., the United States, European Communities). These added disincentives make it all the more important that legislation such as CAMR be as simple, straightforward and risk-free as possible for developing countries.

9. If it took only two weeks for Canada's Commissioner of Patents to issue the compulsory licence to export the Apotex drug to Rwanda, why did it take so long for Apotex to send the first shipment of medicines to Rwanda?

The issuing of a licence by the Commissioner of Patents is only the last step in a long process. While the approval of the licence itself can take place quickly, getting to the point of applying for a licence under CAMR is a cumbersome, drawn-out process. A number of preliminary procedures need to happen before submitting an application for a compulsory licence.

Currently, the procedural requirements include trying first to negotiate a possible *voluntary* licence from the company that holds the Canadian patent on the brand-name product. This process includes disclosing in advance the importing country and the quantity of the medicine to be made and exported from Canada in generic form if a licence is obtained. This information must be shared with the brand-name company and will certainly end up being shared with other governments, including those that have pressured developing countries to avoid using compulsory licensing. Moreover, in order for a generic manufacturer in Canada to go through

the CAMR process, it needs first to reach an agreement with a country about supplying a fixed, "maximum quantity" of a particular medicine — only *after* this can the process of trying to get a licence to supply that medicine get underway under CAMR. But, generally, good procurement practices mean that governments should not strike such one-off arrangements, and should instead put out a tender calling for bids from potential suppliers of medicines before awarding such a contract. This illustrates how CAMR's current requirements don't fit well with the process by which developing countries normally purchase medicines and are a disincentive. Proposed reforms to CAMR would cut through these requirements to streamline the process.

In the single example of how CAMR worked, the process leading up to the two-week approval actually required over three years of work, including trying to convince developing countries to take the steps required under CAMR. Eventually Rwanda initiated that process in mid-2007. As with many governments' processes for purchasing goods and services, Rwanda (the importing country) used a tendering process to procure medicines. First, Rwanda had to determine the scope of the tender (how much medicine it needed and what type). Then, Rwanda had to issue the tender and wait for interested pharmaceutical companies to respond with a bid to fill the order. Rwanda had to review the bids and decide which was successful and award the contract. Apotex, the only Canadian generic drug company to apply for a compulsory licence under CAMR, could not participate properly in the tendering process to fill the order *until* the compulsory licence was granted, because until then it had no legal authorization to supply the medicine if it were selected by Rwanda as the supplier. However, in order to get the licence, Apotex had to identify in advance the specific country (Rwanda) and the quantity of the drug to be exported — even though it hadn't yet been awarded the contract. As soon as Apotex was granted the compulsory licence, it submitted a bid in the internationally competitive process, which was eventually successful after review by Rwanda. After Apotex was awarded the tender from the Rwandan government for the generic triple fixed-dose combination AIDS drug (Apo-Triavir), it arranged for export of the drug according to the timetable requested by Rwanda. While these logistics of the shipment, after the licence was issued, are separate from CAMR, we can and should streamline the part of the process that *is* governed by CAMR — including the current requirements that create major disincentives for countries and generic manufacturers to even try to use the process in the first place.

10. Is there a limit on the length of a compulsory licence under CAMR? Can a licence be renewed?

Under CAMR, a compulsory licence for exporting is only valid for up to two years. The licence can be extended for up to another two years *only* if necessary to complete delivery of the initial amount of the medicine authorized by the compulsory licence. The renewal *cannot* be used to ship additional quantities of the medicine.

11. Once a compulsory licence is issued using CAMR, can a developing country increase the quantity of the drug needed?

No. When it first tries to negotiate with the patent-holder for a voluntary licence, and then when it applies for a compulsory licence, the generic drug company must state the "maximum quantity" of the product that will be exported during the two-year licence. To increase the quantity of medicines, the process would have to begin anew. This is unfortunate because

increased needs and or capacity to distribute additional drugs often cannot be correctly identified during the initial process to order the drug. In fact, after the licence was issued to Apotex to authorize export of a certain quantity of the AIDS medication to Rwanda, the Rwandan government later determined that it wanted to purchase more of the same medicine to keep scaling up its AIDS treatment program. If it wants to purchase more from Apotex, both Rwanda and Apotex must go through the process all over again.

12. How do we fix CAMR? What is the "one-licence solution"?

CAMR could be fixed by introducing a "one-licence solution." CAMR currently requires a country-by-country, order-by-order process of compulsory licensing. A better law would require just one licence on a patented medicine, at the beginning of the process, which would authorize the generic manufacturer to supply any of the countries covered by the law and supply those countries with the quantities of that medicine they notify as being necessary. "One process, one licence" would be easier and more flexible for developing countries and for suppliers of generic medicines, and therefore better for patients who need life-saving medicines. As a condition of this single licence, the generic drug manufacturer would still pay royalties to the company (or companies) holding the patent (or patents) on the drug. These royalties would be based on the sales of the generic product, just like the existing formula in CAMR. Everyone gets their fair share — the generic companies if they are successful in securing a contract to supply an eligible importing country, and the brand-name drug companies for creating the original formula of the medicines.

13. What would it cost taxpayers to fix CAMR?

Nothing. CAMR can easily be fixed if there is the political will in Parliament to pass the necessary amendments. It does not require the government to spend any money. The point of simplifying CAMR is to make it more user-friendly for developing countries (the purchasers of medicines) and generic manufacturers (the suppliers), and thereby permit competition in the marketplace to force prices of medicines down and keep them down. The costs of using CAMR are borne by these parties. Streamlining CAMR would create *no additional costs* to Canadian taxpayers. In fact, it would allow developing countries to make *more efficient use of donor aid*: the less expensive the medicines they need to purchase, the more patients they can treat with available resources, including aid provided by Canada. Fixing CAMR would make Canadian foreign aid more effective, something all political parties say they support.

14. Is it easy to amend CAMR? What's being done?

Yes. As a result of efforts by NGOs and some parliamentarians, new legislation is currently before Parliament that would streamline CAMR. In March 2011, a large majority of the House of Commons passed a private member's bill to do just this. Bill C-393 had strong support from Members of Parliament from every political party. However, the bill 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. It needs to pass fully through both the House of Commons and the Senate in order to become law.

15. Will Canadian generic manufacturers who are issued a compulsory licence under CAMR be able to compete with generic manufacturers in other countries, such as India?

In the one case to date in which CAMR has been used, Apotex, the generic drug company who is supplying Rwanda with this medicine, is selling the drug (which needs to be taken twice a day) at a price of 19.5 cents (U.S.) per tablet (39 cents a day for the daily dosage of two tablets). This is basically the same price offered by Indian generic manufacturers. Streamlining CAMR to reduce the inefficiencies and costs of the current system would further encourage competitive prices. The simpler it is for developing countries and generic manufacturers to use CAMR with greater economies of scale, the lower the costs of production that can be achieved by generic manufacturers in Canada. This makes them more competitive in the global marketplace, against both brand-name pharmaceutical companies and other generic manufacturers. This ultimately benefits purchasing countries and patients in those countries through lower medicine prices.

16. It has been said that CAMR is "not a panacea" for developing countries. Will fixing CAMR improve access to life-saving medicines?

Yes. The claim that CAMR is "not a panacea" is a diversion from the core issue at stake. Nobody claims that CAMR, either in its current form or in a streamlined form as proposed by Bill C-398, is or would be a "panacea" for developing countries.

There are multiple barriers to access to medicines in the developing world, which vary from country to country and even within a given country. For example, in those parts of the developing world where there is limited or inadequate health-care infrastructure, this needs to be strengthened and scaled up. There is also a shortage of health-care workers, proper medical equipment or inadequate transportation.

But there is no disputing that the price of medicines prevents 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. Even in countries where well-developed infrastructure exists, if medicines are priced out of reach, they will not be available to patients in developing countries who cannot afford them. CAMR is one policy tool aimed at addressing the high prices of patented medicines. Streamlining CAMR could effectively assist developing countries in overcoming one of the major barriers to affordable treatment.

In fact, the use of CAMR to provide a needed combination AIDS drug at a significantly lower price allowed the Rwandan government to purchase a quantity of the medicine that would be enough to treat approximately 21,000 people with HIV for one year. It was the price of medicines, and not a lack of infrastructure, that was the barrier to getting treatment for these patients. CAMR cannot address all problems that limit access to medicines, and should not be expected to — but fixing it so as to help make medicines more affordable is part of a comprehensive solution.

17. Some opponents of Bill C-398, including parliamentarians, have said that the amendments to CAMR proposed in the bill would not comply with Canada's obligations under the trade treaties of the WTO. Is this correct?

No, these claims are not correct, as various international legal experts have confirmed — including in testimony before Parliament. As noted above (Questions 5 and 6), the TRIPS Agreement provides WTO members with some latitude in how they interpret and implement their obligations under TRIPS in their domestic laws. The WTO August 30th, 2003 Decision explicitly stated that the process laid out in the Decision was "without prejudice" to the "other flexibilities" found in TRIPS — meaning that WTO members such as Canada are free to try other approaches as well, using other "flexibilities" found in TRIPS, to achieve the goal upon which they all agreed. Also the *Doha Declaration on TRIPS and Public Health* reaffirmed that WTO members are free to determine for themselves the grounds upon which compulsory licences may be issued; they are also entitled to create "limited exceptions" in their domestic laws to exclusive patent rights. Finally, recall that WTO members unanimously agreed that 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."

The proposals put forward in Bill C-398 would increase access to medicines for all by making it simple and straightforward to use compulsory licensing to obtain lower-cost generic medicines in developing countries. The proposals preserve some of the positive features of the current CAMR and the underlying August 30th, 2003 WTO Decision, while streamlining the process for compulsory licensing in ways that still comply with TRIPS.

18. Some claim that diversion of medicines is a real problem. Should we be worried that medicines exported under CAMR won't get to patients in developing countries that need them?

During WTO negotiations, some member countries were concerned that generic drugs supplied under the August 30th, 2003 WTO Decision could be diverted from the market for which they are intended. In other words, they were concerned that drugs would be re-exported and sold to other countries (and particularly high-income countries), instead of getting to the patients for whom the order was originally placed. To date, these dire predictions have not been borne out by experience in developing countries where generic medicines have been made available, although it is regularly raised by the brand-name pharmaceutical companies in their opposition to simplifying CAMR. Even though there has been no evidence that diversion of lower-priced generic medicines is a significant problem, nevertheless this concern was resolved. Both the WTO Decision and CAMR contain anti-diversion measures that clearly distinguish between drugs made for export under legislation and brand-name drugs. These measures include: specific labelling; marking the generic drug with "XCL" to differentiate it from the brand-name product; and having the generic manufacturer create a website with information on the distinguishing features of the product, the quantity of the drug, the country to which the drug is being exported, and updating the website every time a shipment leaves for the intended country.

In Bill C-398, the CAMR requirements for marking and labelling a generic medicine produced for export in a way that distinguishes it from the patented brand-name product sold in Canada will be preserved while reforming CAMR to make it simpler to use and more effective, which is

the focus of the bill introduced in Parliament. The over-stated concern about diversion of medicines is easily addressed and should not divert attention from the need for CAMR reform, nor is it a legitimate argument against streamlining CAMR.

19. What about profits for brand-name companies that give them an incentive to research and develop new medicines? Doesn't compulsory licensing under CAMR undermine this incentive?

CAMR allows compulsory licensing only for the purpose of exporting lower-cost generic medicines to eligible developing countries. The current law already has a list — agreed on by all countries at the WTO — of which countries are eligible to benefit from these lower-priced medicines. Exports to the high-income countries in which brand-name pharmaceutical companies make almost all their profits are not authorized by CAMR. Developing country markets represent only a very small percentage of brand-name companies' profits; they have little or no impact on their investments in research and development (R&D). The entire continent of Africa, the hardest hit by the AIDS pandemic, represents less than 2 percent of global pharmaceutical sales. It is not credible for brand-name pharmaceutical companies to claim that enabling competition by lower-cost generic medicines in these markets in any way affects their R&D decisions — plus brand-name companies will receive royalty payments from generic companies for any sales in these countries, under the CAMR formula. None of this would change under proposed reforms to CAMR.

While both generic and brand-name drug companies sometimes make humanitarian contributions, they are private companies that seek to make a profit. The costs and returns of using CAMR will certainly be an important factor for a generic manufacturer to consider. This is another reason why CAMR needs to be as simple and straightforward to use as possible. It should also be remembered that the purpose of CAMR is to supply lower-cost generic medicines to countries with limited resources to pay high prices. Generic manufacturers competing to supply medicines to these countries will not be able to make more than quite limited profits at the most — and will have to pay royalties to brand-name companies on any such sales.

20. Isn't it premature to amend CAMR now?

No. People are dying every day. In a review completed in 2007 — already five years ago — the Canadian government concluded that "not enough time has passed and not enough evidence has accumulated to warrant making changes to CAMR." CAMR was created more than eight years ago. In that time, only one licence was requested and issued, which resulted in the shipment of a single order of one AIDS drug to one country. That breakthrough only came after years of pressure from NGOs and outspoken advocates, and thanks to the commitment of one generic company and considerable support and encouragement at the local level in Rwanda. This can't be sustained year after year — and it shouldn't be necessary. The single generic company that underwent the entire CAMR process is not likely going to try using it again in its current form. We don't need to wait yet more years to diagnose the problems. The limitations of the current regime have been identified repeatedly. Concrete solutions to streamline CAMR have been put forward so both developing countries and generic medicine manufacturers can more easily get affordable medicines to patients in developing countries.

Patients needing medicines can't afford the government's delay. Every day, thousands of people infected with HIV die from lack of affordable medicines. In the developing world, half of all children born with HIV will die before their second birthday because they don't have access to the medicines needed to prolong their lives. In its review of CAMR, the government said, "it does not rule out future amendments should circumstances change". Circumstances have indeed changed — for the worse. How many more caregivers have to go through the pain of holding and watching their children and grandchildren die before our government deems it is the right time to amend CAMR? As Canadians, we can no longer allow our government representatives to sit by while "monitoring" the situation and waiting for "enough evidence." It is time for us to insist our representatives uphold their commitment to improve access to medicines for the people in the developing world.

Access to life-saving medicines is not a luxury, but a human right. Fixing CAMR is one thing Canada can do to make that right a reality for patients in developing countries, including children and adults with HIV.