

Canada's Access to Medicines Regime: Promise or Failure of Humanitarian Effort?

Le Régime canadien d'accès aux médicaments :
promesse ou échec d'un geste humanitaire?



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Abstract

There is often a gap between promises made politically and the will to implement these promises meaningfully. One example is Canada's Access to Medicines Regime (CAMR). CAMR was enacted following a WTO decision that changed global intellectual property rules, allowing countries to issue compulsory licences for the production and export of domestically patented medicines to countries without pharmaceutical manufacturing capacity. Ideally, CAMR would be a vital part of Canada's international assistance. However, in the three years since CAMR was implemented, this attempt to improve medicines access by the world's neediest appears instead to be largely a failure of Canadian humanitarian efforts.

Résumé

Il y a souvent un écart entre les promesses politiques et la volonté de les concrétiser. Le Régime canadien d'accès aux médicaments (RCAM) en est un exemple. Le RCAM a été décrété suite à une décision de l'OMC qui modifiait la réglementation mondiale quant à la propriété intellectuelle, afin de permettre aux pays d'émettre des licences obligatoires pour la fabrication et l'exportation de médicaments brevetés localement vers les pays qui ne sont pas dotés d'une industrie pharmaceutique. Idéalement, le RCAM serait un élément contribuant à l'aide internationale offerte par le Canada. Cependant, depuis la mise en place du RCAM, il y a trois ans, les efforts pour améliorer l'accès aux médicaments par les plus nécessiteux semblent plutôt se traduire par un échec du geste humanitaire du Canada.

AS A CONDITION OF MEMBERSHIP IN THE WORLD TRADE ORGANIZATION (WTO), member countries agreed to implement common standards for all intellectual property, including pharmaceutical patents and products under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Pharmaceutical patents create market monopolies for a limited time for companies that hold patents and thus limit the availability of cheap generic drugs. Even though TRIPS restricts generic drug production until patents expire, it also contains public health provisions that allow countries to override patents. For example, a country can issue a compulsory licence for public health reasons. This licence permits a country the discretion to allow generic production of a patented drug by a third party without the patent holder's consent, while the licensee pays the patent holder a reasonable royalty. Because this provision was originally permitted only for predominantly domestic use, a poor country without manufacturing capabilities was unable to benefit from it.

The WTO's (2003) Decision on the Implementation of Paragraph 6 of the Doha

Declaration on TRIPS and Public Health clarified the issue of how compulsory licences could be used to provide countries without a domestic manufacturing capacity access to medicines. The “Paragraph 6 decision” allows countries with manufacturing capacity to produce and export generic versions of domestically patented products under a compulsory licence to those countries without.

With much fanfare, Canada amended both its patent law and the Food and Drugs Act in May 2004 to take advantage of this new provision so that it could issue compulsory licences and export generic versions of patented medicines to countries in need. Royal assent was granted in May 2005 and the implementing regulations were published on June 1, 2005. The legislation adds a section to the Canada Patent Act entitled “Use of Patents for International Humanitarian Purposes to Address Public Health Problems” and is now known as CAMR.

In discussing CAMR and its implementation, we focus on access to medicines for HIV/AIDS for two reasons. First, millions of people in developing countries still do not have access to treatment. Second, while generic versions of first-line therapies are now available at low cost, in the range of USD\$120 per person per year, the same situation does not apply for second-line therapies. There is significant need to generate generic competition for these medicines to bring prices down from current levels of USD\$700 to \$1,700 per person (Flynn and Palmedo 2007). We note, though, that the situation is equally desperate for the treatment of many other diseases.

The Problems

Because CAMR’s failure to improve access to medicines has already been analyzed by many (Attaran 2007; Cohen and Esmail 2007; Elliott 2006; Canadian HIV/AIDS Legal Network 2007), here we highlight provisions of the legislation that particularly affect the likelihood that Canadian generic medications will be exported in a timely way. Some of the difficulties arise from the original Paragraph 6 decision because it itself is administratively demanding. However, CAMR adds extra layers of complication.

A Canadian generic company has to attempt to negotiate a voluntary licence from the patent holder for 30 days. Only if these negotiations fail to produce an agreement on “reasonable terms and conditions” can the company apply for a compulsory licence (Patent Act 1985). The legislation does not specify what constitutes “reasonable” terms and conditions and thus can potentially lead to unnecessary delays and, from a company’s perspective, high costs such as legal fees. Moreover, CAMR stipulates that the time window starts only once a generic company has identified a would-be importer. This stipulation creates a 30-day period during which the patent holder and others, such as the United States Trade Representative, could try to pressure the importing country not to use the compulsory licence route. Equally important, even if a generic company is granted a compulsory licence, and then enters into a contract to export,

CAMR allows the compulsory licence to last for only two years. Further, the contract must specify the volume of drugs to be shipped during the two years. The compulsory licence is renewable only if the contract is not fulfilled within the period, that is, if the agreed-upon volume has not been supplied. Otherwise, should generic companies want to continue to supply the original purchaser or to supply new customers with the same product, they are then required to undertake the entire contractual process again (Patent Act 1985).

Additionally, one of the strongest criticisms levelled at CAMR by those who believe that patents and the availability of generics are not significant factors in the lack of access to HIV/AIDS medications in developing countries is that it ignores the realities of the global generic industry. Critics claim that Canadian generic producers come from a price point that is typically not competitive (Attaran 2007), meaning that production and shipping costs can make the cost of most Canadian contracts unattractive. Claims about Canadian-made generics being uncompetitive have been shown to be inaccurate because international non-governmental organizations, such as the Clinton Foundation, have been able to reach agreements to reduce prices with the companies that supply the active ingredients for generic medications; these lower prices are passed on to companies such as Apotex (personal communication, generic company representative 2008). Still, what holds is that the effective use of CAMR is limited by bureaucratic constraints and transaction costs for both developing countries and generic companies. We illuminate this point below.

Despite Apotex's receiving Health Canada approval for Apo-TriAvir[®], a fixed-dose combination antiviral medication, in August 2006, it could not enter into the voluntary licensing procedure, much less apply for a compulsory licence, because no country had requested the product (Apotex Group 2007). Once Rwanda notified the WTO in July 2007 of its intent to import 260,000 packs of Apo-TriAvir[®] (WTO 2007a,b), Apotex responded that it would work towards meeting this order (Talaga 2007). After Apotex's negotiations for voluntary licences with the patent holders failed, a compulsory licence was granted on September 20, 2007, and Canada notified the WTO of this authorization on October 4, 2007 (WTO 2007b), at the same time that Rwanda started an international tender process to supply its needs. On May 7, 2008 Apotex announced that it had won the tender to provide Rwanda with Apo-TriAvir[®] under CAMR with the winning bid price of 19.5 cents per tablet (priced at cost) (Apotex Group 2008). Apotex sent the first shipment of medicines to Rwanda on September 24, 2008 (CBC News 2008). Seven months of the 25-month delay between Apotex receiving its approval from Health Canada and the shipment of the first batch of drugs can be accounted for by Rwanda's tendering process, which has nothing to do with CAMR. A much longer period, 13 months, was due to a combination of waiting for a country to apply to the WTO and negotiations between Apotex and the patent holders. (The remaining five months were a function of the time it took to manufac-

ture and arrange to ship the drug.)

This is the first test case for CAMR, which has come at no small price, so far, to Apotex. Apotex estimates that it has invested CAD\$3 million to develop this product (Kay 2007), with most of the costs going towards acquiring the active ingredients for the medication and legal fees related to licence negotiations costs with patent holders. One of the most significant obstacles exposed by this process has been CAMR's requirement that a country be named in order for the licensing process to proceed, rather than allowing interested generic producers to commence the licensing process prior to negotiations with a recipient country having been concluded and the recipient country named. Jack Kay, President and Chief Operating Officer of Apotex, points out: "If other critical medicines are to go to Africa in a reasonable timeframe, the federal government must change the CAMR legislation significantly. CAMR is unworkable as it now stands" (Apotex Group 2008).

Shortly after CAMR was passed, Médecins sans Frontières (MSF) started working on its practical implementation, but it has taken almost four and a half years from that point and nearly three and a half years since Apotex first indicated a willingness to use the legislation to get to where a single drug has actually been exported. Although we now have an example of CAMR's use, its implementation has been a practical failure and risks damaging Canada's reputation for humanitarian action. Between 2004 and 2007, before CAMR produced any results, an estimated 8.3 million children and adults in Sub-Saharan Africa alone died from AIDS-related illness (Joint UN Programme on HIV/AIDS and WHO 2007).

The New Focus of the Canadian Government

Many activists have suggested changes to CAMR, such as accepting alternatives to Health Canada approval of a generic product (e.g., pre-qualification by the World Health Organization), as a precondition to exporting the product and eliminating the requirement to first attempt negotiating for a voluntary licence from a patent holder (Canadian HIV/AIDS Legal Network 2007). But the political will to reform the legislation is lacking. In 2007, the minister of industry tabled a report on the findings of the regulatory review of CAMR carried out by Industry Canada and Health Canada. It recommended a focus on non-legislative measures to improve access to medicines to the developing world "until a more definitive assessment can be made" (Government of Canada 2007). The conclusions are essentially a commitment to do nothing with respect to CAMR. Interest groups, like the Canadian HIV/AIDS Legal Network, have pressured the government effectively to make CAMR work better. Most recently, this push to reform CAMR resulted in Bills S-232 and C-393, which were introduced on March 31, 2009 and May 25, 2009, respectively, and which aim to significantly streamline the requirements in the legislation.

The current Canadian government is focusing its contributions on other global health initiatives. Some are laudable, such as the 2008 commitment of a further CAD\$450 million to the Global Fund to Fight AIDS, Tuberculosis and Malaria (Department of Finance Canada 2008). Other measures, while potentially helpful, seem to place more emphasis on ensuring that the interests of the research-based pharmaceutical companies are not upset than on improving access to medicines in countries without manufacturing capacity. For example, in its 2007 budget, the government created an additional tax incentive for drug donations (Department of Finance Canada 2007). It offers pharmaceutical companies a tax write-off as long as donations are in line with WHO best practices and are administered by registered Canadian charities. Most recently, this push to reform CAMR resulted in private member Bills S-232 and C-393, which were introduced on March 31, 2009 and May 25, 2009, respectively, and which aim to significantly streamline the requirements in the legislation. Bill C-393 received Second Reading on December 2 2009 and is promisingly proceeding through Parliament.

The Way Forward

It took almost three and a half years, after publication of CAMR's implementing regulations, to reach the point where a single life-saving medicine was exported to a single country, and that contract will last for only two years. When the legislation was first introduced into the Canadian Parliament, the minister of international trade was quoted as saying, "It is a priority for us to implement the WTO agreement that will ensure that poor countries have access to medicine to combat pandemics such as AIDS, malaria and tuberculosis" (Scofield 2003). In rhetorical terms, CAMR promised an elephant, but so far the legislation has delivered little more than a mouse.

The recent shipment of drugs to Rwanda seems to show that Canadian generic manufacturers can compete on price with companies from low-cost countries such as India. Further, there is the issue of competition: the more generic companies that are able to compete, the lower the prices (Campaign for Access to Essential Medicines 2008). Adding Canadian generic companies potentially increases the level of competition, especially in the case of second- and third-line therapies that currently have no generic versions. If Canadian generic versions of these drugs are available, they may stimulate competition from generic companies in other countries and ultimately lead to lower prices. Finally, even if in some cases Canadian prices are higher than others, the quality of Canadian generics may be superior (Scofield and Chase 2003).

There are two approaches that should simultaneously be undertaken by the Canadian government to improve access to medications in developing countries: legislative reform of CAMR and non-legislative initiatives. Competition and quality support the argument that, in principle, CAMR is worth keeping. However, even correcting its

deficiencies that we highlighted earlier will not be sufficient to fulfill Canada's stated intention of helping to address the lack of access to essential medicines. Norway, the Netherlands, India, China and the European Union have also taken the same route as Canada and have amended their legislation to allow the export of medicines under compulsory licences. These initiatives have all, to date, led to no exports. In the face of these failures, it may be that the use of national legislation and legal provisions, such as compulsory licensing, while potentially helpful, are not enough on their own, and that other measures must be undertaken to increase global access to medicines.

Beyond legislative remedies, industrialized countries need to play to their strengths in moving forward to improve access. Canada has a highly developed generic industry that is in the forefront of innovative manufacturing processes. The government should be investigating economically viable policies that would transfer the technology to formulate generic drugs to countries that need it. Canada also has a significant research and development capacity in both the generic and patent-protected pharmaceutical sectors. The government could adopt initiatives, perhaps through the tax system, to encourage research in and production of paediatric formulations of medications and formulations that would be better able to withstand the severe climatic conditions in many developing countries.

Intentions are only as good as their results. If Canada is truly interested in improving access to essential medicines, then a reformed CAMR may be of value. Even so, it still needs to be combined with larger, more sustainable measures that move beyond rhetoric to achieve meaningful results, as measured by the speed and volume of medicines that move from Canada to populations in need.

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