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The fight over Canada's Access to Medicines Regime

Set up to deliver cheap drugs to the world's poor, few countries have used it. Is it broken or working just fine?

By Wanda O'Brien

Photo: Wanda O'Brien

Rwandan Darling Abandibakoblia has turned her life around thanks to anti-retroviral drugs.

Darling Abandibakoblia sits on her living room couch in Kigali, Rwanda, pen in hand, hunched over pages of notes. The 22-year-old social science student is studying for a test on Monday. This would have been an impossible task seven years ago.

When she was diagnosed with HIV at the age of 15, Abandibakoblia dropped out of school, unable to manage the workload as the virus took a heavy toll on her body.

"You are dying. You become a person who does not have value," Abandibakoblia says, reflecting on her reaction when the doctor told her she had tested positive. "[People] think that you can't do anything because you are the one who is sick."

Medication changed that. Ms. Abandibakoblia takes eight pills a day, four in the morning and four in the evening. She picks up her anti-retrovirals monthly from the health clinic closest to her.

"I've seen that my life can continue and I can go again to school," she says.

Access to that medication, however, has been endangered.

In July 2008, Rwanda became the first and only country to benefit from the much-vaunted Canadian Access to Medicines Regime (CAMR), a framework to allow developing countries to import cheaper generic versions of Canadian brand-name medicines to fight HIV/AIDS, tuberculosis, malaria and other diseases. A 15-million pill shipment to treat 21,000 patients was delivered in two batches. The final lot landed in Kigali this past September, with the previous amount arriving one year earlier.

However, unless changes are made to CAMR, the generic drug company that delivered the medication says the future export of medicines through the regime is unlikely as the current process is costly and complicated.

The government has refused to consider amending the regime. However, this week, two bills that would change CAMR will be debated before Parliament. Bill S-232, sponsored by Liberal Senator Sharon Carstairs, has been under study at the Senate Banking, Trade and Commerce committee this month. Meanwhile, NDP MP Judy Wasylycia-Leis's private member's bill, C-393, is set for second reading in the House on Friday.

The bills have been met with mixed reactions, including both strong support and opposition. Supporters say these bills would streamline CAMR and make it more effective, helping save poor people across the developing world. Opponents, including brand-name drug manufacturers and Canadian government officials, say the regime works well as is, and significant changes will open Canada up to trade litigation and undermine its brand-name pharmaceutical industry.

Pros and cons of reform

The anti-retrovirals Ms. Abandibakoblia takes are manufactured outside of Rwanda and brought into the country the same way as all consumable medicines—through Rwanda's national procurement and distribution agency. The agency puts out international tendering notices for foreign manufacturers to bid on. As a developing country that struggles to provide basic services for its citizens, price is an important consideration.

"Our objective is to treat as many patients who are in need of treatment. We have to choose effective drugs, yes, but at an affordable cost," says Dr. Jules Mugabo, head of the HIV, AIDS,

and sexually transmitted disease unit of Rwanda's national Centre for Treatment and Research on AIDS, Malaria, Tuberculosis and Other Epidemics in Kigali.

"Suppose we only have one manufacturer that is producing drugs—then the cost can be high. By having different companies, especially by having some companies in Canada because Canada is known for producing good quality drugs, that is an opportunity for Rwanda. And not only for Rwanda, but for most developing countries."

The Canadian Access to Medicines Regime, passed with all-party support in 2004. It followed a 2003 World Trade Organization verdict known as the August 30 Decision. As the benchmark for CAMR legislation and similar acts around the globe, the August 30 Decision allows generic drug manufacturers to obtain licences for patented drugs to create cheaper versions for export.

Under CAMR, developing countries must notify the WTO of their intentions to use the regime before a generic manufacturer can apply to the government for a compulsory licence. A compulsory licence enables a generics company to use a patented drug without the approval of the patent holder.

"A trigger point of this legislation is that a country needs to step forward and make a formal request to the WTO...and prior to that happening, nothing can move," says Bruce Clark, vice-president of regulatory and medical affairs at Canadian generic drug manufacturer Apotex.

In May 2006, with no importing countries coming forward, Apotex began discussions with patent-holders to try to get voluntary licences after NGO Médecins sans Frontières approached the generic drug company about its three-in-one anti-retroviral called Apo-TriAvir. Despite continuous efforts, brand-name drug companies refused to issue licences.

One year later, Rwanda became the first country to make a formal request under CAMR. Unlike in the effort to secure voluntary licences, where patent-holders were not compelled to respond to Apotex's request, the federal government issued a compulsory licence in 68 days—one month for the applications for the compulsory licences and one month for the Commissioner of Patents to grant them.

Government officials and the association that represents Canada's brand-name drug firms, Research-Based Pharmaceutical Companies (Rx&D), point to the quick turn-around as proof the legislation works.

"All these delays and all these complications that you're hearing about are outside CAMR," says Russell Williams, president of Rx&D. "We're prepared to work with the rules that are established. We do not believe it is a flawed legislation."

He says the regulations built into the system are safety measures that ensure the products go to the people they're intended for. "I see the benefit of having these checks and balances and I don't see the burden of going through the process of CAMR," he says.

However, advocates note it took more than a year to get the medication to Rwanda—time that could have been saved if voluntary licences had been granted in 2006.

Another argument over whether to change CAMR or not is why more developing countries like Rwanda haven't come forward to use the regime. Government officials say goverments are turning to Indian drug manufacturers—which charge 17 cents per anti-retroviral pill compared with 19 for Apotex—to fulfil their needs.

However, advocates for change say developing countries are hesitant to use the legislation and approach the WTO as there is the potential for backlash from foreign trade markets with large pharmaceutical industries, such as the United States and the European Union.

"There are inhibitions by proposed recipient countries to request licences for fear of adverse effects on foreign aid and on trade," former senator Yoine Goldstein told Senate Banking committee members on Oct. 8.

In addition, there is the question of whether governments in developing countries—many of them corrupt or unable to dedicate resources to fighting disease—have even thought about using it.

"We always hope that countries will ensure that drugs reach the most disadvantaged, but we know that this is not always the case," Senator Carstairs, the sponsor of bill S-232, said the same day. "We do know that when NGOs purchase drugs, they do reach those most in need because that is their care group, but the present legislation prohibits their purchase of these drugs."

For those countries that are looking at using the legislation, the compulsory licences are only good for two years, meaning the entire process must be repeated over and over again to ensure a steady supply of medication—which must be taken for the rest of a patient's life. They

also stipulate a specific amount of medication, meaning the government has to guess how much will be needed by the time it is delivered.

A "one-licence system" is one of the reforms proposed in the private members' bills before the Senate and House. This would allow a generic manufacturer to obtain a licence for a patent without specifying a country—NGOs could apply instead—or a pre-determined amount of product. The two-year time limit currently placed on licences would be removed and countries would be able to increase the amount of drugs requested without forcing generics to re-apply for licences.

"The question we have is why would anyone not want to improve the legislation? We know the legislation is workable, but it needs some minor modifications to make it practical," says Mr. Clark of Apotex.

"You have to craft your legislation and the process it puts in place with an eye to how these things actually play out in the real world," says Richard Elliot, executive director of Canadian HIV/AIDS Legal Network, a civil society group that has been advocating legislative reform of CAMR. "And since we know that there are lots of disincentives for countries to actually make use of the regime, let's make it as easy as possible, as straightforward as possible, as risk-free as possible."

This approach would alleviate the pressure on a developing country to be singled out, says Mr. Elliot, but generics companies would still pay royalties on the products, as mandated through the WTO intellectual property agreements. Information on shipment location and quantity of product would be disclosed to patent-holders as products were exported, rather than being the cornerstone of access to patents. Instead, the compulsory licensing process could begin with a request from a region or an NGO.

Intellectual property, black markets

The root of the opposition to changing CAMR appears to revolve around the threat of diverting cheap, generic medicines from developing countries back to developed countries where they can be bought on the black market, the impact of the proposed changes on intellectual property rights, and possible conflicts with Canada's obligations under the WTO.

"This could have an impact, obviously, on Canada's compliance with international patent obligations," Colette Downie, director-general at Industry Canada, told the Senate Banking

committee on Oct. 8, "and it could also create a perception that CAMR would allow users to automatically infringe patents, which would have implications for the stability in Canada of our business environment for the provision of pharmaceutical products. It might perhaps also reduce incentives to actually sell pharmaceutical products here in Canada."

However, officials acknowledged that, at least when it came to whether the proposed reforms conformed with Canada's WTO obligations, they had not obtained a solid legal opinion.

Supporters of the bills say opposing arguments are ill-conceived, as CAMR would still contain anti-diversion measures and require royalties to be paid.

"All protections that are now envisaged for pharmaceutical companies would remain intact," former senator Goldstein said. "Royalties would be paid, the anti-diversion mechanisms would be remain in force, quality controls would assured, and compulsorily licensed products would not be distributed in Western countries currently served by these pharmaceutical companies, so there would be no competitive issues at all."

Yesterday morning, in advance of the debate in Parliament over the two CAMR reform bills, GlaxoSmithKline Inc., one of the world's largest brand-name pharmaceutical companies, issued a press release that said the company would "not object—through CAMR—to allow [Apotex] to continue manufacturing their drug for the treatment of HIV/AIDS in Rwanda." GlaxoSmithKline holds the patents on two molecules in Apo-TriAvir. However, the drug company said it "GSK believes that CAMR is simple, straightforward and efficient."

The release was clearly aimed at heading off concerns over the Canadian Access to Medicines Regime as debate heats up in Parliament. But advocates will undoubtedly push back just as hard.

"To treat this bill as a piece of technical legislation would truly miss the mark," Ms. Carstairs said on Oct. 8. "This bill is about people—people living primarily in sub-Saharan Africa, people who live in abject poverty, people whose opportunities to get treatment from malaria, tuberculosis and HIV/AIDS is virtually impossible. It is a bill about giving the chance of life to children, their moms and dads and their grandparents. It is about ensuring that a child receives treatment as soon as diagnosed, at a cost that is affordable."

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