



National Office/Siège social
317 Adelaide St. W., suite 500
Toronto, ON M5V 1P9

Tel./Tél.: (416) 967-1611
Fax/Télé.: (416) 967-9078
E-mail/Courrier électronique:
info@cciorg.ca

Website/Site internet
www.cciorg.ca

Regional Offices
Bureaux régionaux

**Atlantic Office/
Bureau de l'Atlantique**
1657 Barrington St., suite 131
Halifax, NS B3J 2A1

Tel./Tél.: (902) 422-2933
Fax/Télé.: (902) 423-0579
E-mail/Courrier électronique:
atlantic@cciorg.ca

**Quebec Office/
Bureau du Québec**
5083, rue Saint-Denis
Montréal, QC H2J 2L9

Tel./Tél.: (514) 528-5363
Fax/Télé.: (514) 528-5367
E-mail/Courrier électronique:
quebec@cciorg.ca

**Ontario Office/
Bureau de l'Ontario**
317 Adelaide St. W., suite 500
Toronto, ON M5V 1P9

Tel./Tél.: (416) 967-0801
Fax/Télé.: (416) 967-9078
E-mail/Courrier électronique:
ontario@cciorg.ca

**Western Office/
Bureau de l'Ouest**
119 West Pender St., suite 103
Vancouver, BC V6B 1S5

Tel./Tél.: (604) 734-4677
Fax/Télé.: (604) 734-4675
E-mail/Courrier électronique:
west@cciorg.ca

Charitable No./No d'oeuvre de charité
(129814570 RR0001)

Douglas Clark
Director
Patent Policy Directorate
Industry Canada
clark.douglas@ic.gc.ca

Brigitte Zirger
Director
Therapeutic Products Directorate
Health Canada
bpsip_info_bpspi@hc-sc.gc.ca

Re: Canada's Access to Medicines Regime

January 23, 2007

Dear Mr. Clark and Ms. Zirger:

Thank you for the opportunity to inform the government's review of Canada's Access to Medicines Regime. Canada has been a global leader in the fight against AIDS. While we commend the government's leadership in introducing Canada's Access to Medicines Regime (CAMR), to date, it has failed to deliver. Access to less expensive generic medicines is essential to the success of Canada's development program and immediate steps must be taken to fix the legislation.

Canadian Crossroads International (CCI) is an international development agency founded in 1958 that actively involves Canadian volunteers in Canada's development program. We work directly with civil society organizations in West Africa, Southern Africa and South America. Our projects focus on poverty reduction through economic development, women's rights and HIV/AIDS. A key priority for Crossroads and our partners is to mitigate the impact of AIDS globally.

The need is great. Over 75 per cent of people in need of lifesaving HIV treatments are not receiving them. Last year, three million people – mostly living in developing countries – died unnecessarily of AIDS-related illnesses. HIV attacks women and men in their most productive years. Worker shortages are devastating communities and economies. Young people whose lives are cut short by HIV/AIDS cannot take their rightful place as economic and social agents of change in their countries. And, their orphaned children will be ill-equipped to provide leadership in the future if they are deprived of basic needs, including parents to raise them.

Canadian Crossroads International is actively supporting African civil society organizations on the front lines of this pandemic. Our AIDS projects are helping build the capacity of organizations to implement education and prevention programs. Voluntary testing and counselling is critical to these prevention programs. However, there is little incentive to be tested if there is no treatment available.

For Crossroads' partners and the people they serve, affordability is a key barrier to access. In Togo, for example, the vast majority of people living with HIV do not know their status and do not have access to information or testing. Of those who know their status and require treatment, less than 20 per cent are taking anti-retroviral therapy, as the cost of treatment for one year exceeds the annual earnings of most citizens. Even in countries such as Ghana where some government subsidy programs exist, the cost of anti-retroviral treatment for one month can range from 40 per cent of the average monthly wage to four times the average monthly wage.

Failure to get affordable drugs to countries burdened by AIDS threatens to undermine all of our development efforts. The success of Canada's development program depends on increasing access to less expensive anti-retroviral treatment. We are confident that with the government's continued leadership we can meet our international commitments to get affordable Canadian generic drugs to countries that need them. Following are concrete steps the government must take to make Canada's Access to Medicine Regime work.

1. **Provide authorizations to export which are not limited to a single drug-order for a single country.** The current process is cumbersome, long and expensive. Canada should simplify the process by a standing statutory authorization permitting export of generic medicines to eligible countries or by granting a single, open-ended licence of any given drug.
2. **Remove unnecessarily restrictive and time-consuming steps in the licensing process.**
 - a) Eliminate the time limit on licences granted. The two-year time limit on licences is not required by the WTO. It constitutes a significant barrier to generic companies who are forced to re-initiate the long approval process to continue exporting a drug beyond the two-year period and prevents them from guaranteeing supply to purchasers beyond two years.
 - b) Limit the requirement of negotiating with a patent-holder before seeking a compulsory license. These negotiations are unwieldy and expensive causing unnecessary delays. For public non-commercial use and to address national health emergencies there should be no requirement to negotiate a voluntary licence.
 - c) Eliminate the list of eligible drugs. The process of adding necessary drugs to the list is time consuming. The WTO agreement does not require it and it has created unnecessary delays.
 - d) Remove the requirement for Health Canada approval. Again, this is not required by the WTO agreement, nor do other drugs require Health Canada approval for export. Canada should accept Health Canada or WHO pre-qualification as sufficient to permit export of a generic drug under a compulsory licence.
 - e) Eliminate patent-holders' extra litigation rights. Existing legal recourse under the Patent Act should be sufficient.
 - f) Eliminate the requirement that NGOs get the permission of the importing country government. This is not required by the WTO and is redundant with the

existing requirement that the medicine be approved for use by the importing country's drug regulatory authority.

g) Eliminate double standards that apply to some countries. Currently, developing countries that do not belong to the WTO face additional barriers to importing generic medicines from Canadian producers such as the requirement to declare a national emergency or similar situation. Access to medicines should not depend on WTO membership.

On behalf of Canadian Crossroads International's partners and volunteers, I thank you for your consideration of our submission. Should you require any additional information, or if I can be of further assistance, please do not hesitate to contact me at 416.967.1611 ext 333 or karen@cciorg.ca. We look forward to your report in May on how Canada will get less expensive generic Canadian drugs to the countries most burdened by HIV and AIDS.

Sincerely,

A handwritten signature in black ink that reads "Karen Takacs". The signature is written in a cursive, flowing style.

Karen Takacs
Executive Director