

Health Partners International of Canada
Comments Regarding
The Review Of Canada's Access to Medicines Regime

Submitted to Industry Canada & Health Canada

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Health Partners International of Canada (HPIC) is a Canadian non-profit medical aid agency that is having a significant impact by providing needed essential medicines, medical supplies and vaccines to people in many of the poorest countries. We have worked over the years in partnership with Canadian physicians and non-governmental organizations, and a number of government departments, including CIDA, to help those who suffer needlessly from preventable or treatable illnesses and diseases. The medicines and supplies that we provide are donated by Canada's health-care industry. Since 1990 HPIC has safely and effectively distributed essential products to 116 countries. Total wholesale value of this assistance exceeds \$210 million.

HPIC is pleased that the Government of Canada is taking a closer look at the workings of the Access to Medicines Regime to help prevent death and alleviate suffering related, in particular, to the shocking effects of the HIV/AIDS pandemic. We unequivocally support the aim of the Regime, namely to get aid to the people who so desperately need it.

Since the International AIDS Conference in Toronto in August 2006, most Canadians have come to know about the HIV/AIDS situation, particularly as it affects the poor in sub-Saharan Africa. Many have seen, through the media, the devastation caused by this affliction. Anyone with eyes to see their desperate plight, ears to hear their horrifying stories, and a heart to feel compassion, must be moved to help in whatever way they can.

We applaud the federal government's commitment to ensure the delivery of affordable essential medicines to some of the poorest regions of the world. We were delighted to hear the Minister of Industry emphasize the Government's "continued commitment to being a global leader in improving access to medicines in developing and least-developed countries." It was also heartening to read the Minister of Health's acknowledgement that CAMR is only part of

Canada's broader response to fighting public health problems such as HIV/AIDS, tuberculosis, malaria and other epidemics.

HPIC stands ready to work with our partners to deliver Canadian-sourced anti-retroviral drugs to regions of greatest need in Africa by whatever mechanism the government deems appropriate. Already, we provide needed products that deal with opportunistic infections related to HIV/AIDS. These volumes, however, need to be greatly increased.

One doctor in South Africa who runs a clinic that assists people suffering with AIDS illustrates the point well. Dr. Margie Hardman writes, "All five of our doctors were here seeing just over 125 patients yesterday...I think this was the most important statement; 'almost nobody dies from HIV; they always die of an opportunistic infection.' Our death rate has dropped from one a day to three a month with the advent of ARVs but the most difficult and most expensive exercise is to treat patients infected with opportunistic infections when they have low CD4 counts. The difficulty is that even with a low CD4 count, many patients have a good quality of life and only ever go to seek western medical help when they are very sick. The most common problem is TB and the co-epidemic has serious ramifications for public health."

We are also very much aware that HIV/AIDS drugs must be delivered in a coordinated framework that includes patient counselling, home-based care, trained medical professionals, blood testing laboratories, and the consistent supply of ARVs, other medicines and medical supplies. HPIC thereby assists in improving the general health of people who would die, were it not for the medicines and supplies that are generously donated to us by the Canadian health-care industry.

It is our belief that Government policy should enable Canadian aid organizations such as ours to be the outstretched hand of Canadians in a way that is both reasonable and responsible. We are aware, however, that this Review must resolve practical policy and regulatory issues regarding to whom medicines are sold and in what conditions. And we trust that people with a heart to do so will find workable and equitable solutions.

We also understand that there is much work to do to ensure that vital medicines are delivered and used in ways that are intended by the legislation, known previously as C-9. Proven Canadian organizations such as ours can serve to ensure that this does happen. For millions of people in impoverished countries, the desire to help on the part of caring Canadians is their only real hope. Many of them are counting on the will and ingenuity of men and women in the industrialized world to bring practical solutions to bear in alleviating so much needless suffering and to prevent an alarming situation from deteriorating even further.

HPIC's recommendations

HPIC understands that problems associated with HIV/AIDS are complex and daunting. We are concerned that many advocates present a somewhat simplistic picture of the problem and, therefore, propose naïve solutions. We do not presume to understand all of the issues involved but do have sufficient experience and expertise in providing effective medical aid to be confident that we can make an important contribution to this Review.

Following are recommendations that we offer. We would be pleased to discuss these at the Committee's request.

1. *Take an integrated approach to dealing with HIV/AIDS*

The current fixation on anti-retroviral therapy impacts significantly other necessary strategies ranging from prevention, through treatment and care, to the mitigation of the numerous adverse effects of the disease. In particular, where ARVs haven't reached, agencies that can alleviate suffering in other ways deserve support and guidance. As exciting as the prospect of ARV therapy may be, a holistic approach is necessary, as is the coordinated collaboration of numerous agents offering a range of other medical services as well as social and spiritual ones. Making ARVs available is an urgent issue of international justice, but HPIC aligns itself with those who advocate that the application of a broader strategy is needed to achieve optimal results.

HPIC recommends that the government as well as aid agencies, industry and civil institutions ensure that there is a balance in funding and allocation of other resources to all aspects of the battle against HIV/AIDS, including treatment of opportunistic infections, and other public health initiatives that support of HIV/AIDS interventions.

2. *Simplify the process as much as possible and ensure that information regarding CAMR is clearly communicated to countries that could benefit*

Eligible countries are not always aware of the legislation itself or not sufficiently familiar with rules and procedures regarding authorization that can be sought under the Patent Act and the Food and Drugs Act. Canada's legislative initiative, while not unique, is innovative and promising, but it cannot achieve results without the initiative and active participation of countries wishing to benefit from it.

While HPIC is not advocating changes to the existing legislative framework, we are all aware of concerns expressed about the practical application of certain provisions. A forum such as the one that this statutory review offers is a privileged opportunity to take into account the varied views of the numerous stakeholders seized by the tragedy that continues to devastate most of sub-

Saharan Africa. Various perspectives are important, including those of the African nations that we all seek to help. We believe that serious consideration of their concerns is necessary to ensure that CAMR's overarching principles are properly applied.

Ultimately, this Review should ensure that the process is simple to understand and streamlined for the intended beneficiaries. The objective ought to be the effective and efficient application of rules to achieve the goals envisaged at the outset.

HPIC recommends that the government undertake programs to facilitate access to essential medicines through Canada's Access to Medicines Regime by involving developing countries (especially sub-Saharan Africa), by encouraging use of its provisions and by making adjustments if necessary.

3. Favour practical solutions of manageable scale

The situation urgently calls for new approaches and strategies to consolidate Canada's humanitarian response in a determined and sustained manner. We are confident that Canadians have a heart to encourage their government to do this. Our suggestion would be to focus on practical solutions that can be refined and tested before they are coded into policy and shaped into far-reaching programs. What countries crying out for help need from Canada is less rhetoric, less bureaucracy and more healing. The former merely create cynicism and despair; the latter fills them with hope and the prospect of a brighter future. Mammoth programs seem impressive at a glance, but they are in reality difficult to manage efficiently. Modest initiatives, on the other hand, are often those that reach deepest into the fabric of the targeted community. They cause lasting change because the community must take responsibility for their sustainability.

A number of health-care facilities in the least developed countries of the world have demonstrated the ability to act effectively but lack the resources to ramp-up their current capacity. In our view, a cautious approach that focuses on some of these would facilitate the development of an appropriate template for effective support of others.

Ultimately, the objective is for all infected people in the world's least developed countries to enjoy sustainable access to essential medicines that are needed to deal with the pandemic. Meanwhile, there is a need for interim strategies that bridge the widening gap between the desperate situation in which these struggling nations currently find themselves and the benefits of long-term development programs. In the mix of solutions, medical aid is necessary and the need for it is urgent.

HPIC recommends that the government focus on support of suitable facilities with the supply of ARVs and other appropriate medicines from Canadian sources in order to develop a template for the effective treatment of HIV/AIDS, particularly in sub-Saharan Africa.

4. *Protect the anti-diversion provisions of the current regime*

Everyone benefits from Canadian programs achieving the greatest possible impact for intended beneficiaries with the least risk of inefficiency or erosion. In effect, the possibility of black-marketing is a constant concern for aid organizations and the reason why HPIC has adopted such stringent policies and practices regarding the security and safety of our shipments.

Failure to protect or even strengthen anti-diversion provisions could jeopardize support for the program and make it difficult to launch similar initiatives in the future.

HPIC recommends that the government take all reasonable steps to ensure that medicines originating from Canadian sources not be diverted from their intended consignee.

5. *Adopt HPIC's Medical Aid Incentive proposal*

HPIC proposes an innovative donation incentive that encourages the private sector to provide and, if necessary, manufacture medical aid products that are most urgently required, perhaps with the inclusion of desperately needed antiretroviral drugs for Africa. It must be noted that there is currently no economic incentive for companies to give gift-in-kind donations out of inventory.

The objectives are these:

1. To help meet Canada's foreign aid policy objectives in the area of health at a minimal and highly leveraged incremental net cost to the federal treasury, and
2. To better enable Canadians to bring health and hope, by delivering high quality medical aid to millions of needy children, women, and men, suffering needlessly from treatable illnesses and conditions in the poorest places of our world.

The mechanism proposed includes a deduction from taxable income, of the cost of the inventory (or cost basis), plus one half of the gain that would have been realized if the inventory had been sold at its fair market value on the date of the contribution, up to a maximum of twice the donated inventory's cost basis. This is similar to the tax incentive provided in the United States.

To implement this incentive, the incremental federal tax cost represents only 4 to 5.4 per cent of the fair market value of the medical aid that Canada will deliver overseas. This would provide a return on incremental investment of 18.5 - 25 times. Concretely, this means that \$10 million of incremental tax cost to the Treasury would generate approximately \$185 to \$250 million of needed medical aid donated by the Canadian health-care industry.

The backgrounder for this Review provided by the government rightly states that one part of Canada's multi-faceted approach to dealing with HIV/AIDS, tuberculosis, malaria and other diseases in developing countries is by "supporting Canadian organizations in global health." Canadian NGOs and health-care companies are among these and, with sufficient incentives, are capable of playing an even greater role.

HPIC recommends immediate implementation of a Medical Aid Incentive to encourage Canada's health-care industry to increase its participation in the war against HIV/AIDS, tuberculosis, malaria and other opportunistic and infectious diseases in the least developed countries of the world.

A challenge for Canada

What lies under all of the projects that HPIC has supported through its 16-year history is a landscape of suffering. Though we must never lose sight of all the wonderful things happening in Africa, what seizes our heart is the plight of the poorest of the poor.

According to UNAIDS, every minute of every day, a child under the age of 15 becomes infected with HIV. In most cases, the virus is transmitted by the HIV-infected mother; transmission can occur in the womb, during birth or through breastfeeding. Ninety per cent of the more than 5 million children who have been infected were born in Africa. In addition to the 5 million children who have been infected with the HIV virus, some 15 million children under age 18 have lost one or both parents to AIDS. The vast majority—more than 12 million—are in sub-Saharan Africa, where the weight of numbers puts an enormous strain on the traditional family safety net.

Women comprise about half of all people living with HIV worldwide. In sub-Saharan Africa, they make up 57 per cent of people living with HIV, and three quarters of young people infected on the continent are young women aged 15-24.

By targeting predominantly young and middle-aged adults who are the mainstay of the economy and the principal support of their families, the epidemic destroys the very fabric of societies. Particularly in places where HIV prevalence is high, it hamstring economic growth and makes the provision of social services more

difficult. And in a vicious twist, by exacerbating poverty it makes populations more vulnerable to the spread of HIV.

It is often said that bringing an end to this horrible devastation is a matter of political will. But political will is not just the concern of politicians. It is the will of a nation. The will of all people – both in government and in civil society – is needed in the nations affected as well as the nations that must become a part of the solution. We cannot do this without political will among African nations. But African nations cannot meet the tremendous needs that they face without political will in nations such as ours.

Canada has a brilliant reputation as a prosperous land and as a land of compassionate people. The whole world knows that kindness is a hallmark of Canadian culture. The problems associated with AIDS in Africa are too big for kindness or even compassion alone. They also call for the mobilization of all developed countries and all segments of society.

Solving these problems will require us to be more efficient and effective in what we are already doing but – more importantly – to bring to bear resources that are currently not available.

Can we ignore the cry of the people living with AIDS in Africa? To answer this question, which we might prefer to ignore, we must refute stubborn myths.

1. The situation of AIDS in Africa is not the same as AIDS in North America. Dealing with HIV/AIDS in Africa for Canadians takes understanding, sensitivity, and the willingness to adjust to what Africans truly need rather than what Canadians might assume is needed.
2. The situation is not hopeless. Provided we muster the will and the resources and stay focused on the solutions long enough, we can help turn the tide of devastation. We have all heard about wonderful things already happening, particularly at the grass-roots level. There are thousands of stories like these across Africa.
3. There is no silver bullet, no instant solution. Beating this disease that threatens the very foundations of civilization will take a lot of hard work by a lot of people working on many fronts over a long period of time.
4. For optimal effect, projects must be networked as part of a comprehensive solution that is integrated and resource-efficient.

Many Canadians ask, what more can we do? And, how can we do it in a smarter and more effective way? The stakes are high. But failure to respond in a timely fashion to this monumental challenge will needlessly cause millions of deaths. It will also cause such economic and political instability in many countries that peace and security will be threatened. If the will to make a difference needs to start somewhere, and it does, let it be here ...beginning now.