January 24, 2007

Brigitte Zirger
Director
Therapeutic Products Directorate
Health Canada

Dear Ms. Zirger,

As representatives of four leading child-focused organizations we are pleased to attach our submission in response to the consultation paper on Canada's Access to Medicines Regime (CAMR) released by the federal government. We trust that these recommendations will improve the effectiveness of the bill particularly in relation to the needs of children living with HIV and AIDS.

Sincerely,

Plan Canada

Save the Children Canada

UNICEF Canada

World Vision Canada

CANADA'S ACCESS TO MEDICINES REGIME (CAMR)

Submission to the Government of Canada
January 2007

1.0 INTRODUCTION

1.1 Children and AIDS

The AIDS pandemic has reached endemic proportions in many regions of the world and is redefining the very meaning of childhood for millions of children. In the 25 years since the onset of this pandemic, the world's response to stopping the spread of HIV and AIDS has been woefully insufficient – particularly for children. Currently, 2.3 million children and young people under the age of 15 are infected with HIV; 15.2 million children and young people have lost either one or both of their parents to the disease. Children who are infected or affected by HIV and AIDS face human rights abuses and are vulnerable to poverty, homelessness, school drop-out, discrimination, loss of opportunity, early death, and increased vulnerability to neglect, abuse and exploitation.

HIV and AIDS directly affects millions of children, adolescents and young people, especially in the 54 countries where adult HIV prevalence has reached more than 1 percent of the general population. Because of death and illness, those countries face system-wide shut downs: the illness and death of doctors and nurses, as well as increasing use of medical services, have led to decreased health-care capacity; schools are becoming dysfunctional, losing their teachers to illness and death; men and women are becoming too sick to work and spending increasing amounts on health care while becoming poorer – as a result, children are working in their place or are forced to sell family assets.

In 2006 alone, it is estimated that 530,000 children were newly infected by HIV mainly through mother-to-child transmission. In many cases, contraction of the virus could have been prevented through anti-retroviral (ARV) treatments provided to HIV positive mothers. A recent report found that 1 out of 10 young pregnant women in Sub-Saharan African cities is HIV positive; yet only 1 out of 10 pregnant women with HIV in low- and middle-income countries is receiving ARV prophylaxis treatments, which could reduce the risk of antenatal transmission to their children. As a result of the lack of access to these critical drugs along side other preventative measures, 1 out of 3 children born to these mothers will contract the virus. Of those children who do contract HIV, only 10% currently receive anti-retroviral therapies. Further, at most, 4% of children born to HIV-infected mothers receive cotrimoxazole prophylaxis to prevent opportunistic infections that can be fatal– the rest face bleak and short-lived futures - one out of two will die before their second birthday.

Ensuring that children and mothers have access to low cost medical treatment to prevent the spread of HIV and AIDS through parent-to-child-transmission and to improve the health of those children who are already infected, would go a long way to reducing the suffering of millions of children and their families worldwide. As organizations with a mandate to improve the lives of children around the world, Plan Canada, Save the Children Canada, World Vision Canada, and UNICEF Canada urge

you to examine this legislation with an eye to protecting the world's future generations. This legislation has the potential to assist in making this the last generation of children to grow up infected by HIV and AIDS. Collectively, we have an obligation to ensure that it does just that.

Why CAMR is so important for Children

Although some progress has been made in treating adults living with HIV, children are hardly getting the medicines that can prolong their lives. Without treatment, the progression of HIV infection in children is particularly aggressive and more than half the children do not live past their second birthday. HIV care, support and treatment for children is crucial to secure their future and CAMR can address the current challenges that prevent children from accessing treatment such as:

- Antiretroviral drugs for children are twice as expensive as the adult drugs, and are frequently unavailable in appropriate form for children, in some cases the few available require refrigeration or tend to be foul-testing
- Fixed-dose combination for adults, which simplify treatment to a single pill, is still largely unavailable for children
- Tools for diagnosing HIV in infants are expensive and unaffordable in resource-poor settings

Children living with HIV and AIDS are clearly disadvantaged in their access to medicine. CAMR has the potential to address these concerns and ensure that children in low-and medium-income countries enjoy life in all its fullness just like their peers in high-income countries. Studies show that effective services for Prevention of Mother-To-Child Transmission (PMTCT) could preclude an estimated 315,000 children from paediatric HIV infection annually. They also show that paediatric HIV is entirely preventable. It has been virtually eliminated in high-income countries because of the availability of prevention, testing and treatment services

In order to ensure that this legislation fully benefits children and their families around the world, we the undersigned call on the Government of Canada to make the following changes to the legislation:

2.0 REVIEW OF THE CONSULTATION PAPER

In 2004, when the Patent Act, Bill C-9, was amended, Canada became the first country to implement a World Trade Organization (WTO) agreement to allow the export of generic versions of patented medicines to poor countries. The new law meant that drug manufacturers could produce generic medicines that would help prolong the lives of people suffering from HIV and AIDS. Brand name medicines to treat HIV and AIDS are out of reach for many people in developing countries and this bill was expected to provide safe and quality pharmaceutical products at a cheaper price than the brand name products.

However, nearly three years since the act was passed, no generic medicines have been exported by any Canadian company as a result of this legislation.

General Recommendations:
a) While the legislation is based on a desire to improve the health care for millions of vulnerable people around the world, it is not being used. In order to show true support of this legislation, the Government of Canada should be more proactive in communicating to Governments and relevant NGOs that this legislation exists and in providing assistance to Governments and pharmaceutical companies to move through the process as smoothly and quickly as possible.

b) Establish a formal committee to continuously monitor and evaluate the efficacy and implementation of the bill and advise the Ministers of Health and industry accordingly. Members of the committee should include civil society and other key stakeholders.

c) This bill gives the patent holder a lot of room to institute litigation. *The bill is supposed to open doors and reduce roadblocks. The risk of litigation dissuades generic pharmaceutical producers from entering into generic production under this legislation because of the high cost of potential litigation.*

4.0 Eligible Importers
The requirement in section 4 of the consultation paper, that NGOs undertaking humanitarian work must seek the permission of an eligible importing country in order to import generic drugs under CAMR is prohibitive. This is not required by WTO rules and creates unnecessary delays and bureaucracy.

Recommendation: *This additional requirement under CAMR should be removed.*

5.0 Eligible Pharmaceutical Products
Although Schedule 1 in section 5 of the paper was meant to provide clarity and transparency to what products are eligible under the regime, it effectively shut out many other essential products not on the list. The process of expanding the list is also cumbersome, a committee must advise the Ministers on the recommendations they make to the Governor-in-Council regarding any change to the schedule. Neither TRIPS nor WTO regulations require any limited list of eligible products. This kind of red tape eliminates the benefits envisaged under the bill, especially in production of paediatric formulations for children that are not on the list because it hinders Canadian generic manufacturers from responding to the emerging needs of the developing countries.

Recommendation: *Schedule 1 is unnecessary and should be eliminated. The WTO waiver covers all medicines, not just those in their model list.*
However, if the list must be adopted then:

- *It should be made comprehensive to include paediatric and prevention of antenatal transmission pharmaceutical products and formulations*
- *The advisory committee should convene immediately instead of 2008 and meet regularly and involve experts on paediatric issues, HIV&AIDS, TB, Malaria and other major diseases*
- *The Canadian government should consider facilitating the process for a country that has the ability to manufacture drugs with Active Pharmaceutical Ingredients (some developing countries have been licensed to assemble APIs)*

- *CAMR should allow the export of APIs*

6.0 Notification

Section 6 of the consultation paper mentions that WTO imposes several requirements and conditions to be met by eligible importers in order to qualify for the waiver, including names and expected quantities of the products needed, confirmation that it is a least developed country or that it has insufficient manufacturing capacity and has been granted a compulsory license. CAMR adds even more requirements, complicating the legislation further.

Recommendation: *The requirement for a certified copy of the intended importing country's requisite notice to be provided to WTO or to the Canadian Government should be eliminated and the process simplified with a clear time line to avoid bureaucratic red tape.*

Question 9 in section 6.0 addresses additional requirements for non-WTO members. Although CAMR allows both WTO and non-WTO members to import pharmaceutical products under license, additional requirements were introduced for non-WTO members. These countries are required to declare national emergency or other situations of extreme urgency; agree that the imported products will not be used for commercial purposes; and undertake to adopt anti-diversionary measures. These requirements are discriminatory and unduly burdensome on non-WTO members wishing to participate in CAMR. For instance, some countries may be unwilling to declare diseases like HIV and AIDS national emergencies, and may therefore not qualify even where there is critical need for affordable pharmaceutical products. Some countries like Ethiopia and Sudan are not WTO members yet in Ethiopia the prevalence rate of HIV in young pregnant women is about 15% and the country has a huge number of children living with HIV and mothers who are transmitting the virus to their infants. CAMR should be able to provide affordable paediatric and PMTCT pharmaceutical products to countries like Ethiopia without consideration of WTO membership

Recommendation: *This requirement is unnecessary and discriminatory. All countries should be treated equally under CAMR.*

7.0 Health Canada's Drug Review

Section 7 of the paper describes the requirement that pharmaceutical products be reviewed by Health Canada in accordance with the standards prescribed by the Food and Drugs Act. The requirement that all pharmaceutical products intended for export are reviewed by Health Canada creates unnecessary delay and barrier to export generic products to developing countries.

Recommendation: *This review should be made optional given that there already exists other bodies like the WHO with similar jurisdiction and importing countries often have their own approval processes. Should it be necessary for Health Canada to review the products, the process should be fast tracked and given a time line to avoid delays.*

8.0 The Application Process

Section 8 of the consultation paper explains the requirement that an applicant for a compulsory license include a declaration that it had sought a voluntary license 30 days prior on reasonable terms from the patentee. The applicant must identify the pharmaceutical product for which the license is sought, the quantity to be manufactured, the patent which protects it, the importing country, the purchaser and a copy of the notification the importing country provided to WTO or Canadian government as the case may be. These procedures are time consuming, bureaucratic and pose a serious barrier to the potential applicant. Potential producers of generic paediatric products would particularly be discouraged given the often short shelf lives of some of the products.

Recommendation: *The requirement is constraining and works against the principle of increased access and should be eliminated. In this regard, Canada should borrow from the Swiss, Norwegian and EU approach.*

9.0 Duration of the License

Under section 9 of the paper, a compulsory license issued under CAMR is valid for only two years and renewable for an additional two years in the event that a licensee is unable to ship the entire product within the stipulated time frame.

Production of paediatric formulations requires more investment to ensure that products are suitable for children. This includes drugs that do not require refrigeration to be used in resource-poor setting that lack such facilities and drugs that have taste acceptable to children. CAMR discourages investment in paediatrics because of the short two-year license duration. It does not make economic sense to invest in manufacturing a products for two years after which you must undergo a cumbersome and time-consuming process to renew the license. Other countries such as Switzerland and Korea do not give a specific upper or lower limit.

Recommendation: *The two-year period is an unnecessary disincentive and should be removed*.

Submitted by:

Plan Canada

Save the Children Canada

UNICEF Canada

World Vision Canada