

MERCK CAMR Submission

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Re: Canada's Access to Medicines Regime (CAMR) - Consultation Paper

Dear Mr. Clark,

Please be advised that Merck Frosst Canada supports Canada's Research Based Pharmaceutical Companies' (Rx&D) response to the CAMR - Consultation Paper. Inherent in this support is our belief that there are many potential reasons for the apparent lack of reliance on this legislation for the export of pharmaceuticals to date.

One is that the success of patentees' differential pricing policies in developing countries makes offers from generic producers under the legislation less enticing than expected. For example, Merck offers no profit pricing for HIV/AIDS products in developing countries hardest hit by the AIDS pandemic. Also, prices from the generic producers operating in developing countries are cheaper than those available from domestic/developed world manufacturers. It is unclear why developing nations seeking products would avail themselves of CAMR when differentially priced products or cheaper non-Canadian generics may already be available in their countries.

Despite the challenges, we believe that Canada has an opportunity to strengthen the effect of CAMR by moving beyond the current legislation to institute a more broad based approach to reaching Canada's humanitarian goals.

We encourage the Government of Canada to reach beyond current legislation and consider adding initiatives that will contribute to building health infrastructure. These could include ensuring appropriate warehousing facilities for storage of the medicines supplied, trained healthcare personnel who will ensure that the drugs supplied will be taken as needed for safety and efficacy, and building clinics and other healthcare facilities that will reach out to those in need through a broader access to medicines regime.

Merck & Co has 20 years experience dealing with pandemics such as HIV/AIDS, for which CAMR was designed, and we would welcome the opportunity to share our experience with the Canadian Government. In the African Comprehensive HIV/AIDS Partnership (ACHAP), the Merck Company Foundation and the Gates Foundation have each contributed US\$50 million, and Merck has also supplied free product, in a partnership with the Botswana government. This project has effectively supported the development of necessary health infrastructure, and Botswana has become one of the

few African countries that has reached its UN 3 by 5 goals for treatment with antiretroviral therapy. These and other public private and business to business partnerships of Merck are examples of approaches that make a difference in the lives of people in the developing world suffering with HIV/AIDS, and are described briefly in the attached document "Merck's Commitment to HIV/AIDS".

I hope these comments are helpful to the Consultation.

Sincerely yours,

Gregg Szabo
Executive Director, Policy & Reimbursement
Merck Frosst Canada Ltd.

Merck's Commitment to HIV/AIDS

HIV/AIDS is one of the greatest health challenges facing the world today. For more than 20 years, Merck & Co., Inc.,* has been at the forefront of the effort to respond to the HIV/AIDS pandemic through a three-pronged approach:

- Working to discover, develop and deliver breakthrough medicines and vaccines
- Developing long-term business models that help our products reach as many people as possible
- Promoting and participating in partnerships with governments, multilateral organizations, community-based organizations, other corporations and non-governmental organizations to help build infrastructure and address health and development challenges around the world

Through these and other pioneering efforts, Merck is making a substantial contribution toward meeting one of the most critical needs targeted by the United Nations Millennium Development Goals: halting and beginning to reverse the spread of HIV/AIDS.

Working to discover, develop and deliver breakthrough medicines and vaccines

Merck's HIV clinical research program began in 1985. Merck scientists were among the first to discover and develop medicines for the treatment of HIV/AIDS. In 1996, Merck introduced CRIVAN® (indinavir sulfate), a protease inhibitor, which was followed by the introduction in 1999 of STOCRIN® (efavirenz), a non-nucleoside reverse transcriptase inhibitor.

Today, Merck remains focused on developing new treatments for millions of individuals who are already infected with HIV, as well as on preventing HIV transmission through the development of a vaccine.

- Merck is in Phase III clinical studies for MK-0518, which belongs to a new class of **investigational antiretroviral therapy** agents called **integrase inhibitors** that inhibit the insertion of the HIV viral DNA into human DNA. Merck has established a worldwide expanded access program for MK-0518 for HIV/AIDS patients with limited or no treatment options.
- Merck scientists have been conducting research to develop an **HIV/AIDS vaccine** for nearly 20 years. Merck currently is testing vaccine candidates in phase I and phase II clinical studies.



Photo: Tom Maday © 2005

Developing long-term business models that help our products reach as many people as possible

Since our first HIV products reached the market a decade ago, Merck has worked to expand access to these medicines – particularly in the world's poorest countries and those hardest hit by the pandemic. Key efforts include:

- **The Accelerating Access Initiative:** Merck is a founding member of the UN/Industry Accelerating Access Initiative (AAI). Established in May 2000, AAI is a cooperative endeavor of UNAIDS, the World Health Organization, UNICEF, UNFPA and the World Bank, and several research-based pharmaceutical companies. Participants are committed to working with governments, international organizations and other stakeholders to find ways to broaden access while ensuring rational, affordable, safe and effective use of drugs for HIV infections and AIDS-related illnesses.

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Where patients come first  **MERCK**

- **Merck's HIV/AIDS Pricing Policy:** In 2001, Merck announced price reduction guidelines for our current HIV/AIDS medicines, CRIVAN and STROCRIN, based on the generally accepted United Nations Development Program Human Development Index and UNAIDS adult HIV prevalence data. Based on these guidelines, Merck makes no profit on the sale of its current HIV/AIDS medicines in the world's poorest countries and those hardest hit by the pandemic. For medium HDI countries with an adult HIV prevalence of less than 1 percent, our two HIV/AIDS medicines are available at significantly reduced prices.
- **Microbicide Development:** In 2005, Merck granted a royalty-free license to the International Partnership for Microbicides to develop, manufacture and distribute a new antiretroviral compound for use as a microbicide to protect women from HIV in resource-poor countries.
- **Once-Daily Single Tablet:** In 2006, Merck, along with Bristol-Myers Squibb Company and Gilead Sciences, Inc. announced the submission of a Marketing Authorisation Application for ATRIPLA™ (efavirenz 600 mg/ emtricitabine 200 mg/ tenofovir disoproxil fumarate 300 mg) in the European Union to the European Medicines Agency. ATRIPLA is a once-daily single tablet combination regimen for the treatment of HIV-1 infection in adults for use either as stand-alone therapy or in combination with other antiretroviral agents.
- **China-MSD HIV/AIDS Partnership**
A public-private partnership with China's Ministry of Health to provide HIV/AIDS prevention, patient care, treatment and support. Announced in May 2005, the project will focus on a range of interventions including: education, counseling, testing, harm reduction and health services, including treatment and care for people living with HIV/AIDS.
- **Romania-Merck Partnership**
Merck has worked with the Romanian government since 1997 to increase access to treatment and care for thousands of its children and adults living with HIV/AIDS. In support of the government's national AIDS strategy, Merck has contributed \$1.5 million toward projects to improve HIV/AIDS infrastructure, helping to raise the standard of care for patients.
- **Merck Partnership with USAID and Jamaica AIDS Support**
In June 2004, Merck and the United States Agency for International Development (USAID) announced a unique partnership with the non-governmental organization Jamaica AIDS Support (JAS) to help fight stigma and discrimination against people living with HIV/AIDS in Jamaica.
- **Merck-ANADER Partnership Program**
Merck is working with the National Agency for Support to Rural Development in Cote d'Ivoire (ANADER) to support the country's response to HIV/AIDS. The partnership began with an HIV prevention and workplace care program, including access to ARV treatment for ANADER's 2,500 employees. Since then, ANADER has extended its services to 3.8 million people living in rural areas.
- **IBANI-SE HIV/AIDS Initiative**
Driven by expanding industrial development, Bonny Island in the Niger Delta region of Nigeria has become a hive of social activity and mobility, and is a focal point for the regional HIV epidemic in West Africa. Merck is providing technical guidance and is helping to facilitate a community-led, comprehensive HIV/AIDS and malaria program on Bonny Island.

Promoting and participating in partnerships

Improving access is about more than simply making our medicines available. The most important factors for long-term sustainability are strengthening health care infrastructure, ensuring adequate financing for health and helping to build local health care capacity through training and support. Public-private partnerships have a critical role to play in this process. Following are examples of some of the many programs and partnerships Merck supports around the world to help address the challenges of HIV/AIDS.

- **The African Comprehensive HIV/AIDS Partnerships (ACHAP)**

A partnership among the Government of Botswana, Merck and The Merck Company Foundation and the Bill & Melinda Gates Foundation to support and enhance Botswana's national response to HIV/AIDS through a comprehensive approach to prevention, care, treatment and support.

To learn more about Merck's commitment to HIV/AIDS, visit www.merck.com/cr or www.msd.com/pro/hiv/home.html