



Bristol-Myers Squibb Canada

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Mr. Douglas Clark
Director, Patent Policy Directorate
Industry Canada
235 Queen Street
Ottawa, ON K1A 0H5
Canada

Ms. Brigitte Zirger
Director, Therapeutic Products Directorate
Health Canada
1600 Scott Street
Ottawa, ON K1A 0K9
Canada

Dear Mr. Clark and Mrs. Zirger:

On behalf of Bristol-Myers Squibb Canada (BMS), I am writing in response to the request for comment concerning *Canada's Access to Medicines Regime (CAMR)*. While BMS fully supports the submission by our industry association, Rx&D, we would like to make several additional points.

BMS supports the laudable goals of the Doha Decision, and we are proud that Canada was the first country in the world to take steps to enact the decision.

It is worth noting that other jurisdictions have enacted legislation similar to Canada's, including Norway, the Netherlands and the European Union. While we appreciate that the Government of Canada is mandated to review the legislation in 2007, we would urge you to be cautious about changing legislation that has not been tested in Canada or abroad.

In fact, the Canadian legislation has only been in effect since May 2005. Even now, the entire system contemplated by the legislation has not yet been implemented. CAMR provides for the establishment of an advisory committee to assist on recommendations with respect to medicines that will be subject to the regime, but to date this committee has not been formed. Prior to contemplating significant changes to CAMR, it is important to implement its provisions.

CAMR – A piece of a complex puzzle

CAMR is focussed exclusively on access to patented medicines. Unfortunately, medicines are only part of the solution to a complex puzzle. Indeed, some would argue they are the last piece of

the puzzle, with other forms of humanitarian aid being pre-requisites to the successful delivery of medicines.

Unfortunately, these equally critical forms of humanitarian aid, required in developing and least-developed countries, are not under the purview of CAMR, yet they nonetheless will play a major role in getting medicines to the people who need them most.

BMS believes that medicines cannot be properly administered without proper infrastructure, including, clinics, trained personnel, community engagement, and testing capabilities. This is especially true in the hardest hit regions of Africa.

As Dr. Margaret Chan, the Director General of the World Health Organization (WHO), noted in her acceptance speech on November 9th, 2006: “[Health] systems are the tap root for better health. All the donated drugs in the world won’t do any good without an infrastructure for their delivery.”

Indeed, Sub-Saharan Africa is home to 64 per cent of all people living with HIV and one third of global AIDS deaths come from this region. UNAIDS sites South Africa, Botswana, Lesotho and Swaziland as areas of great concern, all areas where BMS is actively engaged in the fight against AIDS.

Medicines alone will not solve the problem of HIV/AIDS in Africa. A successful CAMR requires a holistic approach, one that considers the challenges posed by resource limited settings.

This is the approach BMS has taken.

BMS and Treatment Infrastructure

BMS is a world leader among all private sector companies when it comes to engagement, treatment and prevention of HIV in Sub-Saharan Africa.

Secure the Future (www.securethefuture.com) is a BMS run and funded program designed to combine medical treatment and care with research, social support, community education and training for doctors and other health care professionals. Its focus is to go where the needs are greatest and where it can have the most significant impact.

BMS and the BMS Foundation launched *Secure the Future* in 1999 and have committed \$150 million to date in key initiatives including; Children’s HIV/AIDS Clinical Centres of Excellence; Community-Based Treatment Support Programs and a Pediatric AIDS Corps.

Children’s HIV/AIDS Clinical Centres of Excellence have been built and are operating in Botswana, Lesotho and Swaziland with new centres planned for Burkina Faso and Uganda. These state-of-the-art centres offer outpatient clinics, procedure rooms, pharmacies, labs, conference centres, nutritional, psychological and social counselling along with HIV/AIDS specialty care.

Community-Based Treatment Support programs are based on the principal that community mobilization against HIV/AIDS reduces the stigma and addresses the severe lack of knowledge about prevention and transmission. These programs encourage people to get tested; those who test

negative are given counselling and information about prevention. Those who test positive are flowed into care and treatment programs. BMS has established these programs in Botswana, Mali, South Africa, Swaziland and Lesotho.

The Pediatric AIDS Corps is a partnership between BMS and the Baylor College of Medicine to send up to 250 doctors to Africa to treat 80,000 children and to train local health care professionals.

BMS and Access to Medicines

In addition to working to improve infrastructure and understanding in the region, BMS launched its Global Access Initiative in 2001 to enable and enhance access to our leading HIV medicines. For Sub-Saharan Africa the program is critical because it is based on the pillars of no profit pricing, generous patent policies and facilitating generic companies.

BMS has a no profit pricing policy for its HIV medicines in Sub-Saharan Africa. Additionally, in 2005 we further reduced the price of pediatric formulations from no-profit to significantly below cost. Finally, we have implemented a differential pricing policy to enable us to work with governments and support their activities in the poorest parts of the continent.

With respect to patent policy, BMS has not enforced its patents for HIV products in Sub-Saharan Africa. Toward that end, we have a number of immunity from suit agreements for key drugs with Aspen PharaCare, Afrika BioPharma Investments, Adcock-Ingram, Aurobindo Pharma and Thembalani. We are currently working on additional agreements.

BMS has also taken the next step on the path to greater access by engaging with generic manufacturers to enable them to produce critical HIV/AIDS drugs. We recently signed an agreement for full technology transfer on our newest antiretroviral drug to two generic companies, Aspen and Emcure.

Finally, BMS is a founding member of the Accelerating Access Initiative (AAI), which involves seven research-based pharmaceutical companies and five United Nations partners, including UNAIDS, WHO, the World Bank, UNICEF and the United Nations Population Fund (UNFPA).

The AAI is designed to work with partners to establish practical, long term solutions to improve access to HIV healthcare in the poorest countries of the world.

For its efforts, BMS recently received the first Pan African Health Award for Excellence and Innovation, given by the Pan African Health Congress.

Next Steps

While we are pleased with the progress made to date, we are focused on learning as much as we can in order to multiply our successes in the future.

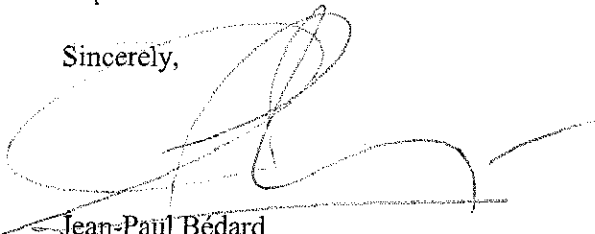
We are engaged in an aggressive program to document the lessons learned from *Secure the Future* in order to ensure we build on our accomplishments, by sharing our experiences with

governments, non-governmental organizations, other private sector companies and academics engaged in the fight against HIV.

With respect to CAMR, we believe that it can play a key role in furthering the response to the challenges in Africa however, it is critical that the Canadian Government recognize it is not a panacea.

Indeed, in order for the legislation to be properly reviewed it should first be fully implemented, tried and tested. Moreover, it should be tested in an environment where all its provisions are in place and solutions to infrastructure related barriers to treatment are being addressed and/or implemented.

Sincerely,

A handwritten signature in black ink, appearing to be 'Jean-Paul Bédard', written over a horizontal line. The signature is stylized and somewhat cursive.

Jean-Paul Bédard
Vice-President, Corporate Affairs