BIOTECanada

January 24, 2007

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

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

Re: Review of *Canada's Access to Medicines Regime*

Dear Mr. Clark and Ms. Zirger:

BIOTECanada is pleased to respond to the Government of Canada's consultation on its review of Canada's Access to Medicines Regime (CAMR). BIOTECanada is the national association representing the broad spectrum of biotech constituents including emerging and established companies in the health, agricultural, and industrial sectors, as well as academic and research institutions and other related organizations. Our members are dedicated to the sustainable commercial development of biotechnology in Canada.

BIOTECanada members support the basic principles of the CAMR which was enacted in 2005 in support of the August 2003 WTO Decision on the Implementation of Paragraph 6 of the Doha Declaration on Trade-Related Aspects of Intellectual Property Rights Agreement and Public Health; allowing patented medicines to be manufactured under licence by a manufacturer other than the patent holder for humanitarian purposes in response to a pubic health crisis in lesser developed countries. Because Canada's biotechnology companies recognize the desperate need of citizens in these developing countries, they have gone to extraordinary lengths, through licensing agreements, patent non-enforcement and special pricing arrangements, to ensure that patented medicines are available at reasonable prices in these countries.

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The Government of Canada is to be commended for being the first country to take steps to enact domestic legislation to implement the Doha Decision. Other jurisdictions such as, Norway, China, India and the European Union have adopted similar legislation. To date, not one developing country has requested access to therapeutic products under these laws.

The CAMR is a relatively young piece of legislation and as stated above has yet to be fully implemented in any of the jurisdictions where similar laws have been enacted. Even in Canada, important sections of the law such as the establishment of an advisory committee on medicines subject to the law have not been implemented. The law itself was enacted in 2005 and while the Government of Canada is mandated to review the law in 2007, BIOTECanada urges the government to proceed with caution given it is too early to reach conclusions as to whether change is in fact necessary. In addition our members ask the government to consider a number of important issues with respect to biologic products during this review.

The Importance of Intellectual Property for Biotechnology

A strong intellectual property system is critical to the development of Canada's biotechnology industry. The ability of Canada's emerging biotechnology companies to develop world-leading therapeutics and for Canada to realize a return on its investment in biotechnology research is dependent on a stable intellectual property regime. The Government of Canada has recently brought its intellectual property system more in line with international standards by enacting 8 years of data protection for new biological therapies and vaccines.

Biotechnology companies must have confidence that legislation such as CAMR will not jeopardize their intellectual property positions if they are to continue to develop and introduce new therapies in Canada. For instance, the requirement that manufacturers seeking an export license under CAMR pursue a voluntary license with the patent holder prior to asking the government to issue a compulsory license is a key element in ensuring that the program does not erode the rights of Canadian patent holders. Both the patent holder and the potential export manufacturer have a responsibility to negotiate license terms in good faith, prior to a compulsory license issuing, in order to meet the objectives of the CAMR.

Process Transparency

CAMR mandates the publication of Schedule 1 listing the biologic and pharmaceutical products eligible for license under the law and the regulatory procedure necessary for adding new products to the schedule. Schedule 1 is an important element of transparency necessary for efficient implementation of CAMR. The Schedule 1 process

ensures that all parties have a clear knowledge of which products are most in need by developing countries and are eligible for an export license under the program.

Health Canada Review

BIOTECanada believes that it is critical that any products designated to be exported from Canada under the CAMR undergo a thorough Health Canada review. While Health Canada does not currently have a separate regulatory policy for subsequent-entry biological products, this issue is gaining importance both here and abroad, especially for CAMR-listed products such as insulin. Canada has a reputation for high-quality regulatory reviews and the manufacture of safe, effective therapeutic products. The citizens of any country that would receive Canadian-made products under the CAMR deserve this same guarantee of safety and efficacy. This requirement is especially necessary for biological products which have unique manufacturing, immunological and cold chain requirements.

Health Canada must at the same time, ensure that the process for CAMR requests does not impede nor delay the review of new submissions for biological therapies and vaccines destined for the Canadian market. The timely Health Canada review for new products benefits both Canadian patients and Canadian biotechnology companies. BIOTECanada supports the allocation of resources specifically for this initiative, which are separate from those dedicated to other product reviews.

Preventing the Diversion of Medicines

The anti-diversion features of CAMR are some of the most important in reference to biological products and must not be diluted. Due to the fact that many biological therapeutics and vaccines must be shipped and stored under cold chain conditions, the post-export handling of these products must be adequately tracked and documented to ensure the products remain safe and effective. The exporting company and the importing country, or its agent must have the ability to properly store, deliver and administer the products to the patients in need. Diverted product that is improperly handled or counterfeit product could lead to severe health consequences for people who eventually receive it. The anti-diversion features of CAMR provide one more critical measure to ensure that the therapies approved for export under CAMR are reaching the people most in need and providing effective treatment for their conditions.

Given the potential health consequences for diversion or improper handling of biological therapeutics, the consequences for diversion should be strengthened. If product has been found to have been knowingly diverted from its intended destination, the exporting company should not only have its license terminated, but should also be prevented from applying for another license until it has demonstrated to the government that is can meet the anti-diversion requirements of the CAMR.

Additional Solutions to Meet Developing Country Health Needs

As Canadian innovation in biotechnology and health care continues to develop new therapies and vaccines for some of the globe's most deadly diseases, the need to ensure equitable access to advanced biotechnology will grow. While CAMR and similar legislation is one way to assist developing countries in meeting their pressing health issues, other solutions exist. As mentioned above, Canada's biotechnology companies work in many countries of the world to ensure that patented medicines are available at reasonable prices. These efforts take the form of non-enforcement of patent rights, to special pricing arrangements to licences with local manufacturers.

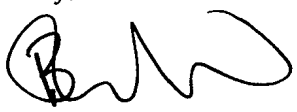
BIOTECanada members also donate medicines and vaccines to Health Partners International of Canada (HPIC), a Canadian charitable organization that has been sending donated medicines, vaccines and medical supplies to people in need in developing countries, since 1995. Tax incentives that would allow companies to donate more product to organizations such as HPIC would also assist the effort in supplying needed health products to the most needy.

Finally, investment in health systems infrastructure and education is one of the most important interventions that can be made by the Canadian government to improve health in the developing world. All the therapeutics and vaccines in the world will not improve health if there is not a system in place to deliver these innovative products, ensure compliance and educate the population about basic health issues.

BIOTECanada appreciates the opportunity to participate in the consultation regarding the review of CAMR and our members support the goals of the legislation. However, we also recognize the potential for damage to Canada's intellectual property protection system that could result from abuse of this system. We urge the government to maintain the system's well-considered checks and balances that were designed to ensure that the law benefits those it was intended to help and does not inhibit the ability of Canada's biotechnology industry to continue to develop the next generation of biotechnology based vaccines and therapeutics.

Our members look forward to working with you on this issue as the review progresses.

Sincerely,



Peter Brenders
President & CEO