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Mr. Douglas Clark
Director, Patent Policy Directorate
Industry Canada
235 Queen Street
Ottawa, ON K1A 0H5
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Ms. Brigitte Zirger
Director, Therapeutic Products Directorate
Health Canada
1600 Scott Street
Ottawa, ON K1A 0K9
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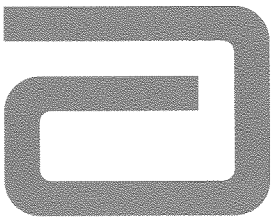
Re: Review of *Canada's Access to Medicines Regime*

Dear Mr. Clark and Mrs. Zirger:

This letter is in response to the request for comment issued on November 24, 2006 concerning *Canada's Access to Medicines Regime* (CAMR). Abbott Laboratories is a large multi-national health care company with a long-standing presence in the field of HIV-AIDS.

In August 2003, the World Trade Organization (WTO) reached a decision (the Doha Decision) on implementing the Declaration relating to the Trade-Related Aspects of Intellectual Property Rights Agreement and Public Health (the Doha Declaration). Canada was the first country to take steps to provide local legislation that would implement the Doha Decision in order to facilitate the exportation of certain medicines by Canadian generic pharmaceutical manufacturers to developing and least developed countries. Under the Doha Decision, member countries may allow patented products to be manufactured under license by someone other than the patent holder for humanitarian purposes in response to a major public health crisis or emergency situation by a country that has insufficient pharmaceutical manufacturing capacity.

We support the laudable goals of the Doha Decision, and it is commendable that Canada was the first country in the world to take steps to enact the decision. The principles in the Doha Decision and further taken by Canada are of particular interest to the citizens and governments in many least developed and developing countries. Many citizens in these countries, unlike the citizens of Canada, are in desperate need of high quality, affordable medications to treat diseases.



Getting More Information to Potential Users

Following Canada's example, other countries including Norway, the Netherlands and the European Union have enacted similar legislation. However, it is important to highlight that no country has implemented the legislation, as no importing country has notified the WTO of a need to import products under this mechanism. While we appreciate that the Government of Canada is mandated to review the legislation in 2007, **we urge caution about changing legislation that has yet to be tested anywhere in the world.**
We understand that most of the countries requiring medicines are not sufficiently aware of this policy and that access to medicines is available. Although, the Canadian legislation has only been in effect since May 2005, CAMR provides for the establishment of an advisory committee to assist on the recommendations with respect to medicines that will be subject to the regime. To date this committee has not been named.

Furthermore, with respect to access to medicines, while patented medicines are part of the solution, it should be noted that patents protect approximately 5% of the products on the WHO's List of Essential Drugs, upon which the Canadian schedule of eligible drugs is based. Greater access to non-patented medicines is also therefore essential to improve health care outcomes in developing or least developed countries.

Helping Africa is not just about providing medicines

Although CAMR is focussed on access to patented medicines, companies such as Abbott are making significant contributions to developing and strengthening the health care infrastructure in developing countries. Although not under the purview of CAMR, there needs to be an equal or greater emphasis on efforts to assist developing nations by building health care clinics, training health care personnel and strengthening supply chain management. These are all as important as access to medicines. 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."

Abbott's contributions to the developing world

Since 2001, Abbott has invested more than $100 million through its *Global AIDS Care* programs and the *Abbott Fund* to support and strengthen the infrastructure in these developing nations. This has been accomplished by promoting HIV testing, HIV treatment and support services in 69 developing countries (including all of Africa). Abbott provides a rapid HIV test (at no profit) to testing programs in developing countries, with more than 70 million rapid tests distributed to date and a further 5 million rapid HIV tests donated to enable pregnant women to know their HIV status.

In addition, we have helped more than 500,000 children and families in a partnership between the *Abbott Fund* and the Baylor College of Medicine. The first and only pediatric clinic for children affected by HIV-AIDS was opened in November 2006 in Lilongwe, Malawi. This new clinic, representing a US$1.5 million investment by the *Abbott Fund*, will offer hope to some of the estimated 83,000 children living with HIV-AIDS in Malawi. Another long term public-private partnership is with the government of Tanzania to assist them to improve their health care systems and infrastructure, expand access to voluntary counseling and HIV testing services and improve access to HIV treatment. In 2005, with support from Abbott and the *Abbott Fund*, a new three-story outpatient treatment center was built at Muhimbili National Hospital in Dar Es Salaam. Abbott has invested over $45 million in Tanzania in the past 5 years.

In August 2006, after gaining input from representatives of the international HIV community, Abbott introduced a new sustainable pricing structure that reduces the price of lopinavir/ritonavir tablets to $2,200 per patient, per year in 45 low-income and low-middle-income countries, as defined by the World Bank. This mid-tier pricing plan broadens Abbott's preferential pricing to 114 countries from the 69 African countries and least developed countries.

Preventing the Diversion of Medicines

One of our industry's primary concerns is to prevent the diversion of medicines in the pharmaceutical supply chain. Abbott continues to have concerns that one of the most important features of CAMR, that is; its anti-diversion language, remains intact and is not diluted in any way. The past history of diversions is well documented; therefore it is essential that any opportunities for unscrupulous individuals to tamper with or divert therapeutic products intended for humanitarian purposes be minimized.

The counterfeiting of medicines also continues to be a serious international health problem. Accordingly, it is necessary that there be oversight by Health Canada over the products to be exported, including the requirement for regulatory approval, as well as the ability to inspect products destined for export. The labelling requirements of CAMR, as well as the requirement for companies exporting from Canada to identify all parties in the distribution chain, further aid against counterfeit products entering the distribution chain in importing countries.

In light of these significant issues, it is essential to ensure that the anti-diversion provisions of the CAMR remain in place. As underlined in the Report:

Corruption in any one of the critical decision points in the pharmaceutical system can be harmful to a country's ability to improve the health of its population by limiting access to high-quality medicines and reducing the gains associated with their proper usage. While corruption affects the entire population, it is typically the poor who are most susceptible when officials hoard drugs, or waste resources on the wrong kind of medicines. Good governance is therefore a sine qua non for ensuring better access to essential medicines.

Protecting IP Rights is Part of the Solution

Finally, we would note that respect for intellectual property (IP) rights is not only beneficial for innovators, but is also in the interest of the developing world nations intended to benefit from CAMR. Without reasonable and effective IP protection, the medicines and vaccines of the future will be delayed, or may not be developed, to the detriment of those patients who are most vulnerable to disease conditions.

Since undermining IP rights creates a powerful disincentive to future innovation, the CAMR review must carefully consider whether any additional measures aimed at enhancing access to medicines at the expense of IP rights will have serious unintended consequences for essential research and development activities in Canada and other nations.

We appreciate the opportunity to provide commentary on this review.

Sincerely,

Marcelo Vizio, General Manager,
Abbott Laboratories