International **F**ederation of **P**harmaceutical **M**anufacturers & **A**ssociations
Fédération **I**nternationale de l'**I**ndustrie du **M**édicament
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Re: Review of *Canada's Access to Medicines Regime*

Dear Mr. Clark and Ms. Zirger:

On behalf of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), I am writing in response to the request for comment on November 24, 2006 concerning *Canada's Access to Medicines Regime* (CAMR). The International Federation of Pharmaceutical Manufacturers & Associations is a non-profit, non-governmental organisation representing national industry associations and companies from both developed and developing countries with official observer status with United Nations Organizations and other international organizations. Member companies of the IFPMA are research-based pharmaceutical, biotech and vaccine companies.

In August 2003, the World Trade Organization (WTO) reached a decision on a waiver of certain obligations under the WTO Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS), as mandated by the WTO Ministerial Declaration on TRIPS and Public Health issued at the WTO Ministerial Meeting in Doha in 2001 (the Doha Declaration). This Decision provided a mechanism for Member Countries to allow the manufacture and export of patented pharmaceutical products for humanitarian purposes by someone other than the patent holder to countries which have no or insufficient manufacturing capacity in the pharmaceutical sector. Canada was the first country to take steps to provide local legislation that would implement the August 2003 Decision to facilitate the exportation of certain medicines by Canadian generic pharmaceutical manufacturers to developing and least developed countries. The WTO Decision of August 2003 has now been formalized as an amendment to the TRIPS Agreement, passed by consensus of all WTO Member States, including Canada.

We support the laudable goals of the WTO Decision and Amendment, and it is commendable that Canada was the first country in the world to take steps to enact the decision. The principles aimed for in the WTO Decision and further acted on by Canada are of particular interest to the citizens and governments in many least developed and developing countries. Many citizens in these countries are in desperate need of high quality affordable medications to treat diseases, including those that people in Canada have not been threatened by for many years.

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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, in no country has the legislation been actually put to use, as no importing country has notified of a need to products. While I appreciate that the Government of Canada is mandated to review the legislation in 2007, I would urge that we be cautious about changing legislation that has not yet been tested anywhere in the world.

The fact that the legislation is relatively new has a direct effect on the number of decision makers that are aware of the ability of this legislation to help their citizens. We understand that many of the countries that most need help are not even aware that help is available from Canada via this mechanism.

Indeed, the Canadian legislation has only been in operation 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 named.

With the knowledge that the legislation is relatively new, and that the representatives in Canada of many least developed and developing countries are unaware of it, I would urge the government of Canada to undertake a comprehensive educational program to ensure that those who need this humanitarian aid are aware of its existence and are encouraged to use it prior to contemplating significant changes to CAMR.

Placing CAMR in Proper Context

CAMR is focussed exclusively on access to patented medicines. However, there are many other forms of humanitarian aid that are delivered to developing and least developed countries that are not under the purview of CAMR that deserve equal or greater emphasis in efforts to assist developing nations. Clinics, trained personnel, supply chain management, and access to clean water are all as important as access to pharmaceuticals. As Dr. Margaret Chan, the Director General of the World Health Organization (WHO), noted in her acceptance speech on November 9th, 2006: "[H]ealth 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."

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

Preventing the Diversion of Medicines

Some of the most important features of CAMR, such as identifying the developing nation that seeks to benefit from the assistance, relate to anti-diversion. These features of CAMR are essential and must not be diluted, since one of the main challenges in the medicine delivery system is the corruption of the pharmaceutical supply chain.

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The Global Corruption Report 2006[1] (the Report) cites several sources of corruption in the pharmaceutical supply chain. From procurement, to distribution, to counterfeit medicines, each provides an opportunity for unscrupulous individuals to tamper with or divert therapeutic products intended for humanitarian purposes. The Report states that procurement transactions are often poorly documented and processed, which makes them a far easier target for supply chain corruption than in other sectors.

The counterfeiting of medicines 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 parties in the distribution chain, also aid against counterfeit products entering into the distribution chain in the 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, I 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.

I thank you for the opportunity to provide commentary on this review that will undoubtedly set an international precedent for humanitarian aid legislation.

Yours sincerely,

/Harvey E. Bale, Jr.

Dr. Harvey E. Bale, Jr.
Director General, IFPMA

[1] The Global Corruption Report is published by Transparency International annually, and provides examples of abuse of entrusted power for private gain in different industry sectors and in different countries.