Kirkland, January 24th 2007

Douglas Clark
Director
Patent Policy Directorate
Industry Canada
(613) 952-2118
e-mail: **clark.douglas@ic.gc.ca**

Brigitte Zirger
Director
Therapeutic Products Directorate
Health Canada
(613) 957-6451
e-mail: **bpsip_info_bpspi@hc-sc.gc.ca**

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

Mr. Clark, Ms. Zirger,

On behalf of Pfizer Canada, I am writing in response to the request for comment on November 24, 2006 concerning the Government's accelerated statutory review of *Canada's Access to Medicines Regime* (CAMR). As the leading pharmaceutical and animal health company in Canada, Pfizer is working tirelessly to discover and develop innovative life-saving and life-enhancing medicines for all Canadians. We are committed to extending the frontiers of treatment and prevention, because we believe every age should be a healthy age.

As a member of Canada's Research-Based Pharmaceutical Companies (Rx&D), Pfizer has contributed to, and is supportive of, the written commentary prepared by Rx&D on behalf of its member companies in response to the above (see Attachment 1).

Pfizer also fully supports 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 aimed for in the Doha 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.

We have also attached for your reference, a more detailed summary of some of Pfizer's humanitarian and philanthropic initiatives which are relevant to this file, and which we believe help to illustrate Pfizer's commitment to finding effective solutions that address this global health issue (see Attachment 2).

**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 for any products. While we appreciate that the Government of Canada is mandated to review the legislation in 2007, we would urge that Canada 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.

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 many least developed and developing countries are unaware of it, we 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 we believe 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.

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.

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[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.

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 Intellectual Property 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.

On behalf of Pfizer Canada, I thank you for the opportunity to provide commentary on this review that will undoubtedly set an international precedent for humanitarian aid legislation. Please do not hesitate to contact me or my Pfizer Canada colleagues if you have any questions regarding our position, or if we can provide you with more detailed information regarding our broader global humanitarian efforts in the developing world.

Sincerely,

Jennifer A. Buttars
Director – Federal Relations & Policy

Tel: (514) 426-7039
Fax: (514) 426-6835
Email: jennifer.buttars@pfizer.com

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Cc : Mr. Steven Hogue – Manager, Federal Relations, Pfizer Canada Inc.
Mr. Darren Noseworthy – Senior Legal Counsel, Pfizer Canada Inc.

*Attachment 1* Canada's Research-Based Pharmaceutical Companies' (Rx&D) Submission, January 24, 2007 – Response to the Government of Canada's Consultation Paper, November 24, 2006 on *Canada's Access to Medicines Regime*

*Attachment 2* Overview of Selected Pfizer Humanitarian and Philanthropic Initiatives – January 24, 2007

**Overview of Selected Pfizer Humanitarian and Philanthropic Initiatives**

- Pfizer is engaged in significant philanthropic activities that provide access to life-saving medicines, resources and skills to help improve patient care for people throughout the world living with HIV/AIDS. In 2005, Pfizer's philanthropic programs (including HIV/AIDS initiatives) donated USD $1.62 billion in monetary donations and product. This is the second year the company has exceeded USD $1 billion in donations. This includes USD $99 million in financial contributions and USD $1.52 billion in product donations.

- Since 1995, Pfizer Canada has made in-kind donations valued at $27,131,000. Almost 100% of these in-kind donations were to Health Partners International Canada (HPIC) (www.hpicanada.ca)

- Through the Diflucan Partnership Program, Diflucan is made available free of charge to governments and non-governmental organizations for HIV patients who are often lacking even the most basic healthcare. Partners include Axios International, Interchurch Medical Assistance and the International Dispensary Association. Over 1,100 facilities in 46 countries have been involved in the program to date, treating over 200,000 patients for life-threatening fungal infections. The Diflucan Partnership Program provides training of healthcare workers on diagnosis and management of fungal infections – nearly 20,000 healthcare providers to date.

- Through the building of the Infectious Diseases Institute (IDI) on the Makerere University campus in Kampala, Uganda, Pfizer is supporting efforts to develop new approaches to address the disease. Partners include the Academic Alliance Foundation, Pangaea Global AIDS Foundation, the Infectious Diseases Society of America, Makerere University, Mulago Hospital and the AIDS Support Organization (TASO). The institute serves as a regional center for HIV training and care. Care is currently being provided to approximately 19,000 patients through the IDI; the facility was officially signed over to Makerere University on June 30, 2005.

- Since 2002, the Pfizer Foundation awarded USD $7 million to 35 organizations through its International HIV/AIDS Grants program. The grants focus on HIV/AIDS training of healthcare professionals and capacity building for home based care. Grants have gone to Latin American, Caribbean, African and Asian countries.

- The Global Health Fellows Program sends Pfizer employees on up to six month assignments to work with nongovernmental organizations addressing HIV/AIDS, tuberculosis, malaria and other devastating diseases in developing countries. Since 2003, more than 100 Fellows have worked with 23 non-governmental organizations in 29 countries to deliver healthcare and health system support to those in need around the world.

- The Pfizer Foundation has been supporting The AIDS Support Organization (TASO) in Uganda for the last four years to expand their capacity in Kampala and Mbarara to provide HIV/AIDS services including counseling, nutrition support and mentorship to people living with HIV/AIDS.