IRISH PHARMACEUTICAL HEALTHCARE ASSOCIATION

24th January 2007

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

Ms Brigette Zirger
Director, Therapeutic Products Directorate
Health Canada
1600 Scott Street
Ottawa, ON KIA 0K9
Canada

Dear Mr Clark and Mrs Zirger,

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

I am writing further to the request for comment concerning *Canada's Access to Medicines Regime* (CAMR).

The Irish Pharmaceutical Healthcare Association (IPHA) represents the international research-based prescription medicines and consumer healthcare industries in Ireland. Ireland is the largest net exporter of pharmaceuticals in the world and the pharmaceutical industry based here takes a keen interest in the arrangements in place for the conduct of that trade worldwide.

IPHA supports the goals of the Doha Declaration, the principles contained in the Declaration, which Canada was the first country to implement into local legislation, 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.

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 utilised as no importing country has given notification of a need for product. While we appreciate that the Canadian Government is mandated to review the legislation in 2007 we would recommend caution 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 for a little over 18 months and even now, the entire system contemplated by the legislation has not yet been fully implemented. Given these realities we would suggest that the Canadian Government consider undertaking 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 the CAMR.

Placing CAMR in Proper Context

CAMR is focused exclusively on access to patented medicines. However, there are many other forms of humanitarian aid that are delivered to developing/least developed countries that are not under the purview of

CAMR that deserve equal or greater emphasis in efforts to assist these nations. Clinics, trained personnel, supply chain management and access to clean water are all as important as access to pharmaceuticals. 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 to non-patented medicines is also therefore essential to improve health care outcomes in developing/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 assisistance, relate to anti-diversion. These features of CAMR are essential and must no 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, published by Transparency International, 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 that 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 Global Corruption 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."

Protecting IP Rights is Part of the Solution

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. Undermining IP rights creates a powerful disincentive to future innovation, as a result the CAMR review should 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 welcome the opportunity to provide our views on this review that will undoubtedly set an international precedent for humanitarian aid legislation.

Yours sincerely

Anne Nolan
CHIEF EXECUTIVE