

THE CANADIAN CHAMBER OF COMMERCE LA CHAMBRE DE COMMERCE DU CANADA

January 24, 2007

Mr. Douglas Clark, Director, Patent Policy Directorate Industry Canada 235 Queen Street Ottawa, ON K1A 0A5

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

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The International Chamber of Commerce (ICC)

The Business and Industry Advisory Committee (BIAC) to the OFCD

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Dear Mr. Clark and Ms. Zirger,

I am writing to you in response to the request for comment on the November 24, 2006 Canada's Access to Medicines Regime (CAMR) consultation paper.

The Canadian Chamber of Commerce is Canada's largest and most representative business association. We speak for 170,000 businesses of all sizes and sectors through our 350 local chambers of commerce and boards of trade located in every province and territory, including the pharmaceutical industry.

Canada was the first country to take steps to provide local legislation that would implement the WTO Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) Doha Decision to facilitate the exportation if certain medicines by Canadian generic pharmaceutical manufacturers to developing countries. Under the Doha Decision, member countries would allow patented medicines to be manufactured under license by someone other than the patent holder for humanitarian purposes destined for use in a nation that has insufficient pharmaceutical manufacturing capacity.

While the legislation regarding CAMR has been in effect since 2005, in no country has such legislation actually been tested and used. Caution should be used when contemplating changes to legislation that has not been tested to date. It would be useful for the government to ensure those who need this humanitarian aid are aware of the access to medicines. It is vital that the essential elements of CAMR remain intact to ensure that the pharmaceutical supply chain is not diluted and that that medicines designated for use in developing nations do not improperly find their way back onto Canadian markets.

The counterfeiting of medicines continues to be a very serious problem worldwide. Health Canada must ensure diligence over the products that are to be exported to developing nations, including the requirement for regulatory approval and 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 aids against counterfeited products entering the distribution chain in the importing countries. To this end, it is essential that the anti-diverting provisions of CAMR remain in place in the existing legislation and strengthened to ensure products do not make their way back onto domestic markets.

The Canadian Chamber believes that intellectual property rights protection is vital to ensuring that Canada remains a competitive and innovative nation. Recently, the government has taken positive steps to ensure that Canadian innovators have a longer period of data protection for their products. Without continued and effective intellectual property (IP) protection in the pharmaceutical industry, necessary medicines and vaccines could be delayed onto market, to the detriment of vulnerable patients. This review of the CAMR must ensure that measures that are designed to enhance access to medicines do not do so at the expense of IP rights of Canadian pharmaceutical manufacturers.

Sincerely,

Chris Gray, Policy Analyst