



For immediate release

CGPA Welcomes President Obama's Support for Generic Biologics: Urges Canadian Government to Implement Approval Pathway

Toronto, March 2, 2009 – The Canadian Generic Pharmaceutical Association (CGPA) today urged the Government of Canada to follow United States President Barack Obama's budget proposal and implement an approval pathway for generic biologic drugs.

"President Obama recognizes the importance of providing patients suffering from cancer, diabetes and other diseases access to affordable alternatives by implementing an approval pathway for generic biologics," said Jim Keon, CGPA President. "We call on the Government of Canada to make that same commitment to Canadian patients."

President Obama's budget, which was released last week, called for the removal of barriers to allow for the approval of generic biologics, which are drugs made from living organisms, not chemicals. Brand-name biologics can cost hundreds of thousands of dollars per patient each year. In Canada, a number of these biologics will be coming off-patent over the next five years, and the patents for others have already expired.

"Competition from safe and effective generic biologics would save consumers, provincial drug plans and private insurers millions of dollars each year and provide many more patients with access to lifesaving treatments," Keon said.

Health Canada has held extensive consultations on a Canadian approval pathway for generic biologics, but to date there is no firm target for implementing this important cost-saving measure. An approval pathway has been available for generic biologics in the European Union since 2004.

CGPA member companies have already successfully developed and registered generic biologics in other jurisdictions, clearly demonstrating the scientific, medical and technological capabilities of Canada's generic pharmaceutical industry.

One example of a generic biologic that would benefit Canadian patients is epoetin alpha, a man-made version of human erythropoietin (EPO). Epoetin is used to treat severe anemia in people whose bodies cannot produce enough natural EPO. Epoetin may also be used to prevent or treat anemia caused by other conditions, such as AIDS, cancer, or surgery. The brand-name version of this product, Eprex, has been on the market in Canada since 1990 and had sales of approximately \$142-million in Canada in 2008.

Another example is filgrastim, which is used to treat neutropenia, a condition that can be caused by chemotherapy, bone marrow transplants, and advanced HIV infections. Sold under the brand-name Neupogen, the product had Canadian sales of over \$88-million in 2008.

Both epoetin alpha and filgrastim are two of the generic biologics already approved by the European Medicines Association (EMA) for patient use in the European Union, and the generic pharmaceutical industry expects these will be among the first generic biologics available to patients in both Canada and the United States once federal approval pathways are implemented.

About the Canadian Generic Pharmaceutical Association

The Canadian Generic Pharmaceutical Association (CGPA) represents Canada's generic drug industry – a dynamic group of companies that specialize in the production of high quality, affordable generic drugs and fine chemicals and in conducting the clinical trials required for government approval of generic drugs. The industry plays an important role in controlling health-care costs in Canada. Generic drugs are dispensed to fill 52 per cent of all prescriptions but account for only 23 per cent of the more than \$20-billion Canadians spend annually on prescription medicines.

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For more information, please contact:

Jeff Connell

Director of Public Affairs

Canadian Generic Pharmaceutical Association (CGPA)

Tel: (416) 223-2333

Email: jeff@canadiangenerics.ca

Website: www.canadiangenerics.ca