



For immediate release

First Subsequent Entry Biologic Approved in Canada

CGPA welcomes competition to Canadian market for biologic medicines

Toronto, April 23, 2009 – The Canadian Generic Pharmaceutical Association (CGPA) today welcomed the first ever approval of a subsequent entry biologic (SEB) in Canada and urged Health Canada to move forward with the completion of its SEB guidance without further delay.

On April 20, 2009, Health Canada approved Sandoz's Omnitrope™, the first version of a previously approved recombinant biologic drug to be approved by Health Canada under the regulatory term Subsequent Entry Biologic. It is a recombinant human growth hormone used for the treatment of children with growth failure due to growth hormone deficiency (GHD) and for the treatment of adults with either adult onset or childhood onset GHD. The product received market authorization in both the European Union and United States in 2006.

“This approval demonstrates that generic companies can develop safe and effective biologic medicines, and clearly demonstrates that a sound scientific and legal environment already exists in Canada to support the approval of subsequent entry biologics,” said CGPA president Jim Keon.

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. Many of these drugs cost more than \$10,000 per patient each year – expenditures that many consumers, businesses, insurers and private and public health care providers find unacceptable and unaffordable.

“Competition from safe and effective subsequent entry biologics will 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.

In Canada, the existing legislative and regulatory framework for pharmaceuticals and biologics serves as the legal basis for approval of subsequent entry biologics. Health Canada is currently working to provide greater clarity to its submission and approval requirements through the development of a guidance document. Consultations on the second draft of this guidance document will conclude at the end of May 2009.

“Canadian generic pharmaceutical companies have already successfully developed and registered generic biologics in other jurisdictions, clearly demonstrating their scientific, medical and technological capabilities,” said Keon. “We urge Health Canada to move forward with the completion of its SEB guidance document without further delays in order to bring additional clarity of the requirements for sponsors of these products and ensure patient access to these cost-saving medicines as soon as possible.”

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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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