



For immediate release

## **Generic Pharmaceutical Industry Supports Increased Patient Safety**

*Health Canada needs tools to monitor prescription drugs after they come to market*

**Toronto, April 8, 2008** – The Canadian Generic Pharmaceutical Association (CGPA) today expressed support for legislative changes to help increase patient safety after new prescription drugs are approved in Canada. The CGPA made the comments after Bill C-51 (*An Act to amend the Food and Drugs Act and to make consequential amendments to other Acts*) was tabled in Parliament earlier today.

“Health Canada needs tools to ensure patient safety after prescription drugs are approved and come to market,” said Jim Keon, President of CGPA. “We look forward to reviewing the proposed legislation in further detail and hope this legislative overhaul will provide those tools.”

Keon said that when new, brand-name drugs come to market, they have been tested in clinical trials on perhaps a few thousand people. But once they are approved by Health Canada and drug companies begin marketing these new drugs to physicians and the public, the number of prescriptions increases quickly. It is at this stage, when many more patients are taking the drugs and for longer periods of time, that previously unknown safety issues can come to light.

Keon also pointed to some high-profile safety problems with new brand-name prescription drugs that were marketed heavily to physicians and patients after they received regulatory approval as further evidence that the legislative amendments to the *Food and Drugs Act* tabled today are an important step forward.

Keon said that Canadians can feel assured when they are taking generic prescription drugs. “When generic prescription medicines are approved in Canada, the brand-name version has already been on the market for an average of 10-14 years, and the safety issues are generally well known.”

“Ensuring ongoing patient safety and monitoring the use and effect of medicines is an essential focus for Canadian generic pharmaceutical companies,” added Keon. “The proposed changes should serve to formalize the robust post-market surveillance steps that generic pharmaceutical companies already take in Canada, and increase consumer confidence regarding the safety of drug products sold in this country.”

Health Canada has stated that the current pre-market approval requirements and standards will not be lessened under the proposed product life-cycle approach to safety. Instead, the ongoing assessment of a product’s risks and benefits in the post-market environment would be an additional requirement. The CGPA supports this Health Canada position, and is strongly opposed to any lessening of the upfront approval requirements and standards for new drugs.

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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 49 per cent of all prescriptions but account for less than 21 per cent of the \$19-billion Canadians spend annually on prescription medicines.

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