

**Presentation by
Jim Keon, CGPA President**

to the

Standing Committee on Health

**Review of the 10-Year Plan to
Strengthen Health Care**

GENERIC DRUGS.



SAME QUALITY. LOWER PRICE.

Canadian Generic Pharmaceutical Association

May 13, 2008

CHECK AGAINST DELIVERY

Canadian Generic Pharmaceutical Association

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About CGPA

Thank-you. CGPA is the national association that represents Canada's generic pharmaceutical industry.

Generic drugs are low-cost versions of brand-name drugs, and are produced by several manufacturers once the patents expire on the brand-name versions.

There are no differences as far as the quality, purity, effectiveness, and safety of generic and brand-name drugs. All drugs sold in Canada must be reviewed and approved by Health Canada. Each product – brand or generic – must meet the strict regulations and standards established by the *Food and Drugs Act*.

Canadian generic pharmaceutical companies are proud of our contribution to affordable health-care in Canada. In Canada, the use of lower-cost generic prescription medicines saves governments, employers and consumers almost \$3-billion every year.

National Pharmaceuticals Strategy

In September 2004, CGPA congratulated First Ministers on their National Pharmaceuticals Strategy.

CGPA is disappointed, however, that this initiative does not appear to be moving forward and we urge all governments – federal and provincial – to continue to take action on the NPS priorities.

I would like to highlight the current status of two NPS priorities this morning – generic drug pricing and faster access to non-patented medicines.

1. Generic prices

Many members of this Committee will be familiar with the Competition Bureau's Generic Drug Sector Study, which was published in October 2007.

In Canada, generic drugs fill fully 49 percent of all prescriptions yet account for only 21 percent of the \$19 billion Canadians spend annually on prescription medicines. Despite this, there has been some evidence that the retail prices paid for generic drugs in Canada are higher than the prices paid in other jurisdictions. This was of great concern to the generic pharmaceutical industry and other stakeholders, and the Competition Bureau report represents the first comprehensive analysis into the reasons why.

The study confirms that the generic pharmaceutical sector is highly competitive. When a product comes off patent, there are generally multiple generic entrants competing for a share of the market. In some cases, seven or more different companies will develop a generic version of a single product.

The problem is that while the industry itself is highly competitive, there are other elements of the provincial market frameworks for generic drugs that may prevent the full savings generated by this competition from reaching end payers.

I am pleased to advise this Committee that some provinces have already reviewed and made enhancements to their market framework for generic drug products. CGPA was pleased to work with the provinces of Ontario and Quebec to achieve savings of 20-25 per cent, and is actively working with other provinces to reduce their prescription drug costs.

With these changes, there is little doubt that retail prices for generic drugs in Canada will be in line with other jurisdictions in the OECD, and this will be reflected in future international surveys. Generic drugs save the health-care system billions of dollars each year, and are now better value than ever.

2. Faster access to non-patented medicines

With respect to the NPS priority of faster access to non-patented medicines, several provinces, including British Columbia, Saskatchewan, Ontario, Quebec, Newfoundland & Labrador, and Prince Edward Island, have taken measures to speed up the listing of generic medicines on their drug benefit formularies to increase savings.

Other provinces, such as New Brunswick and Nova Scotia, already have efficient systems for listing generic medicines on their drug plan formularies.

The federal government has not done its part to help achieve the First Ministers' directive. In fact, new delays have been introduced in the three-and-half years since the strategy was created, further slowing access to cost-saving generic medicines.

In October 2006, regulatory changes were made to the Patented Medicines (Notice of Compliance) Regulations to limit the practice of "evergreening" of drug patents by brand-name companies. These tactics unfairly kept generic competition off the market and forced Canadians to pay for monopoly prices much longer than they should have.

Unfortunately, the October 2006 changes also introduced a new data exclusivity regime, which give brand-name drug companies an 8-year ban on generic competition.

This is three years beyond our international trade obligations under NAFTA and TRIPS, and puts our member companies at a significant disadvantage compared to their US competitors who are subject to just 5 years of data exclusivity. These extended monopolies also add more than \$100-million to Canada's prescription drug bill each year.

CGPA and its member companies have launched a legal challenge to the extended period of data exclusivity, and the Federal Court agreed to proceed with the case in November. We are confident that our case will be successful.

There is now yet another new development that is threatening timely access to generic medicines.

The Government of Canada recently published proposed amendments to these Regulations that would override a Supreme Court of Canada ruling and reopen the evergreening loopholes that allow brand-name companies to abuse the patent system and unfairly delay generic competition.

The government has allowed only 15 days for public comment, which ended yesterday. CGPA is asking for the Committee's support in opposing the proposed amendments, and urging the government to withdraw the proposals immediately.

Conclusion

CGPA thanks members of the committee for the opportunity to appear before you today. I would be pleased to answer any questions members may have on these or other priorities outlined in the National Pharmaceuticals Strategy this morning. Thank you.