



**GENERIC DRUGS
SAME QUALITY
LOWER PRICE**



CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

FEDERAL GENERIC DRUG APPROVAL TIMES

THE ISSUE

Generic drug approval submissions often wait many months before they are reviewed by Health Canada's Therapeutic Products Directorate (TPD) due to a lack of resources. These delays hold up the entry of generic drugs to the Canadian market, and result in millions of dollars in lost savings every year for provincial governments, private insurers, and those Canadians who pay out of pocket for their prescriptions.

BACKGROUND

All generic pharmaceutical products must undergo an exhaustive evaluation process through Health Canada's Therapeutic Products Directorate (TPD) before they can be licensed for sale in Canada. The acceptance standards applied to this evaluation process are amongst the highest in the world, and the expertise of TPD is internationally recognized and respected.

The Government of Canada has undertaken smart regulation initiatives aimed at improving regulatory performance in a number of areas in recent years, with a strong focus on projects emphasizing

the importance of safeguarding the health and safety of Canadians, and securing the conditions for an innovative economy. Efficiencies to the regulation of generic pharmaceutical products is in line with these priorities.

While some measures have been taken in an attempt to improve the average approval time for generic pharmaceutical products, Health Canada continues to fall far short of its own performance targets. TPD officials have expressed concern about the heavy backlog of submissions awaiting review. The directorate has a shortage of qualified scientific professionals to manage its current workload for generic drug approvals, and lacks the long-term resources required to improve its regulatory performance for the approval of generic pharmaceutical products.

The Auditor General's November 2006 report examined both the process by which Health Canada decides what resources to allocate to each of its branches and the information used as the basis for resource allocation. The Auditor General found the budget for core

funding for Health Canada's drug products program decreased by 32 percent over a period of three years. The report also suggested that, "the complexity of programs and the growing demands on programs could significantly affect Health Canada's ability to meet its regulatory responsibilities." In response, Health Canada has undertaken a review of funding allocated to regulatory programs, which it plans to complete by March 31, 2008.

CGPA POSITION

The Therapeutic Products Directorate at Health Canada must have the long-term, stable resources to expedite the review process and ensure timely approvals of new generic drugs waiting to enter the market. Longer approval times and unnecessary delays in getting lower-priced generic drugs to the market results in millions of dollars in lost savings to the health-care system.