



Contents

Executive Summary

- 1. Introduction
- 2. Canadian Generic Drug Manufacturing
 - 2.1. Manufacturing Description
 - 2.2. Generic Drug Supply Considerations
 - 2.3. Barriers to Enter the Supply of a Generic Product
 - 2.4. Competitive Dimensions
 - 2.5. State of Competition
- 3. Independent Pharmacy Distributors
 - 3.1. The Canadian IPD Sector
 - 3.2. Role of IPDs in the Generic Drug Competitive Framework
- 4. Retail and Hospital Pharmacies
 - 4. A. The Canadian Retail Pharmacy Sector
 - 4.A.1. Overview
 - 4.A.2. Role of Retail Pharmacies in the Competitive Framework For

Generic Drugs

- 4.B. Hospital Pharmacies
 - 4.B.1. Overview
 - 4.B.2. Role of Hospitals in the Competitive Framework for Generic Drugs
- 5. The Generic Drug Reimbursement Framework
 - 5.A. Public Drug Plans
 - 5.A.1. Scope and Nature of Public Plans
 - 5.A.2. Public Plan Generic Drug Related Policies
 - 5.A.3. Public Plan Generic Drug Policies Competitive Effects
 - 5.B. Third Party Drug Plans
 - 5.B.1. Overview
 - 5.B.2. The Canadian Private Drug Plans Sector
 - 5.B.3. The Role of Private Drug Plans in the Generic Drug Competitive

Framework

- 6. Summary of Key Findings
- Appendix 1. Federal Regulatory Framework for Pharmaceutical Products
- Appendix 2. Data Description
- Appendix 3. List of Acronyms



List of Tables

- Table 1. Ranking Of Generic Manufacturers By Sales
- Table 2. Status Of The First Generic Entrant
- Table 3. Status Of The Authorized Generic After Independent Generic Entry
- Table 4. Share Of Pharmaceuticals (\$) By Distribution Channel (DC)
- Table 5. Pharmacy Sales By Therapeutic Class, 2006
- Table 6. Retail Pharmacy Count By Category
- Table 7. Canadian Frontstore and Dispensary Revenue by Pharmacy Category
- Table 8. Historic Pharmacy Return On ODB Branded Versus Generic Drugs Sales
- Table 9. Current Pharmacy Return On ODB Branded and Generic Drug Sales
- Table 10. Top Ten Therapeutic Classes By Hospital Purchases, Canada, 2006
- Table 11. Ranking Of Hospital Sales By Generic Manufacturer, 2006
- Table 12. Inter-Provincial Pharmacy/Hospital Price Ratio Analysis, 2006
- Table 13. Average Unit Pharmacy Invoice Prices Of Generics Relative To Canada Average, 2006
- Table 14. Current Formulary Listing Price Of Generics Drugs As A Percentage Of The Brand Price
- Table 15. Public Plans versus Private Plans Unit Price Ratio, 2006
- Table 16. Sources of Provincial Formulary Prices

List of Charts

Chart 1. Generic Entry



Executive Summary

The Competition Bureau promotes and protects competitive markets across the entire economy. The Bureau is not only responsible for enforcing the civil and criminal provisions of the *Competition Act*, it is also responsible for advocating for greater reliance on market forces to deliver the benefits of competition to Canadians.

Canada's health system is an area where competition is often viewed as playing a limited role. The reality is that competitive markets are responsible for delivering many of the products and services on which our health system relies. Given their importance to the welfare of Canadians and because this is a large market - at approximately 10% of GDP, health related markets have been a key enforcement and advocacy priority for the Bureau for several years.

The Bureau's health-related advocacy activity has focused on pharmaceuticals. This reflects the role of pharmaceuticals in treating patients and their importance as a source of health care costs – at \$17.8 billion in 2006, they are the second largest source of health care costs. The Bureau has specifically focused its attention on prescribed generic pharmaceuticals. Generics play an important role in keeping health costs down by providing competition for brand drugs when they lose patent protection.

Several studies have found prescription generics to be relatively more expensive in Canada than in other countries. The studies prompted the Bureau to conduct the generic drug sector study to examine the generic drug market and identify areas where changes in the market framework may secure greater benefits through competition.

In conducting the study, the Bureau relied on publicly available information, data purchased from data providers, and information voluntarily provided by sector participants. In July 2007, a preliminary draft of the study was circulated to key interest groups for fact-checking and to provide them with an opportunity to offer additional information.

Key findings in the study include the following:

- Generic drugs are supplied through a unique and complex framework. Physicians prescribe medication to be taken by patients. In filling the prescription, pharmacies can supply any brand-name or generic drug product listed on formularies (or drug plan product lists) as interchangeable for the prescribed medication. Drugs are paid for by drug insurance plans or out-of-pocket by consumers. Government and private drug plans provide coverage for approximately 98% of all Canadians. Pharmacies are normally paid the invoice price.
- Generic manufacturing has become more competitive over the past 15 years. It appears that strong competition exists in the supply of many generic drugs in



Canada. The end of patent protection for a drug can now lead to supply within a short period of many interchangeable generic products.

- In most provinces, an important way in which manufacturers compete to have their product stocked by pharmacies is by offering them rebates off invoice prices. Rebates provide incentive for pharmacies to select a particular manufacturer's product. It has not been possible to obtain detailed evidence regarding the size of these rebates. Public sources and information provided by parties interviewed for this study indicate that these are on average 40 per cent of the price the pharmacy is invoiced. Rebates are currently prohibited in two provinces, Ontario and Quebec. However, legislation adopted in Ontario in 2006, and under consideration in Quebec, allows generic drug manufacturers to provide professional allowances to pharmacies.
- Competition by generic manufacturers to offer lower prices through rebates is not reflected in prices paid by either public or private plans, or out of pocket. Rather, until recently, prices paid for generic drugs across the country tended to reflect the maximum generic drug prices allowed under Ontario's drug plan. This changed in 2006 when Ontario reduced the maximum it would pay for generic drugs to 50% of the brand-name product price. These lower prices are not paid by private drug plans in Ontario, or drug plans in other provinces, although this pricing discipline is due to be adopted in Quebec in 2008.
- Plans incorporate various policies, such as maximum generic prices and so-called "most favoured nation" clauses, to reduce their generic drug costs. However, these policies provide limited incentive for manufacturers to compete by offering competitive generic prices to the plans.

A regulatory and market framework where incentives to supply drug plans more closely reflect the underlying market dynamics could provide significant benefits to drug plans, and in turn to insurers, employers and Canadians.

The Competition Bureau will continue its work in the generic drug sector by examining possible options for obtaining the benefits from competition and the impediments to their adoption. Measures for accomplishing this goal may include, for example:

- providing manufacturers with incentives to compete to be listed on plan formularies;
- using competitive tendering processes to determine the products that can be dispensed by pharmacies;
- monitoring of the net price paid by pharmacies for generic drugs to ensure the price paid by plans reflects competitive prices; and,
- an increased role for private plans in obtaining lower prices for their customers.



DOCKET

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

