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Benefiting from Generic Drug Competition in Canada: The Way Forward

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EXECUTIVE SUMMARY

Canadian taxpayers, consumers and businesses could save up to $800 million a year if changes are made to the way private plans and provinces pay for generic drugs. The potential savings could climb to over $1 billion per year in coming years, as several blockbuster brand name drugs lose patent protection. Obtaining these savings, however, requires changes to allow the price Canadians pay for generic drugs to be based on the competitive price of the drug.

The potential drug cost savings are particularly large for private payers – businesses, employees and individuals – who account for 52% of generic drug expenditures. Obtaining generic drugs at competitive prices could save them up to $600 million per year with the potential for hundreds of millions of dollars in additional savings as more major drugs lose patent protection. For private drug plans, these costs could be redirected to reduce drug plan costs or expand employee coverage. The report describes a number of possible strategies that private payers could promote to achieve these savings. They include:

- developing preferred pharmacy networks;
- promoting greater use of mail-order pharmacies; and
- providing patients with incentives to seek lower prices.

Governments can assist private payers by ensuring that there are no unnecessary regulatory or professional barriers to the development of innovative approaches by the private sector. Individual plan members and Canadians paying out-of-pocket can also play a role by becoming more savvy buyers and shopping for lower pharmacy prices.

Public plans account for the remaining 48% of drug expenditures. The Competition Bureau is pleased to note that some provinces have begun to take action to improve the ways they reimburse patients and pharmacies for generic drugs. However, further drug cost savings up to $200 million annually, are available. These savings could be redirected in many ways, including towards paying for other parts of the health care system.

To obtain the full benefits from generic drug competition, public plans should:

- introduce measures for reimbursing pharmacies for the true cost of their drugs;
- reimburse pharmacy services such as dispensing and patient counselling separately from drug costs;
- remove unnecessary restrictions to pharmacy competition; and
- coordinate generic pricing and reimbursement policies to ensure that they promote and sustain effective generic drug competition.

The recommendations for private payer and provincial drug plans are a follow-up to the Canadian Generic Drug Sector Study released by the Competition Bureau in October 2007, in response to widespread concern that generic drug prices in Canada were high in comparison to those in other countries. The 2007 Study concluded that, although there is

strong competition for many generic drugs, the design of drug plans has not resulted in the benefits of this competition being passed along to Canadians in the form of lower prices.

The Competition Bureau is an independent agency that contributes to the prosperity of Canadians by protecting and promoting competitive markets and enabling informed consumer choice. This report is conducted under the Bureau's role as an advocate of the benefits of competition. In preparing the report, the Bureau relied on publicly available information as well as information provided voluntarily through extensive interviews and contacts with industry participants from the private and public sectors.

CHAPTER 1: INTRODUCTION

Pharmaceuticals are the second largest source of health care costs in Canada. In 2007, prescription pharmaceuticals accounted for over $19 billion in health care spending.[1] Generic pharmaceuticals ("generics") play an important part in helping to control these costs. Generics are determined by Health Canada to be "bio-equivalent" to patented pharmaceuticals. Their role is to provide competition for brand-name drugs when their patent protection ends.

There has been widespread concern that generic drugs have not provided the benefits to the Canadian health care system that they should. In 2006-2007, the Competition Bureau (the "Bureau") initiated a study into the competitive framework for generic drugs in the country to examine this issue.[2] In October 2007, the Bureau released the Canadian Generic Drug Sector Study (the "Generics Study").[3]

The Study found that many generic drugs are subject to a high level of competition in Canada with the end of patent protection often leading to the entry of multiple generic competitors within a short period. However, the design of drug plans in Canada has focussed this competition on pharmacies with generic manufacturers providing them off-list price rebates and allowances to have them stock their interchangeable products. The prices charged by pharmacies to the public did not take into account these rebates and allowances. As a result, competitive generics prices have not been passed on to public plans, private payers, including plan sponsors, such as employers, unions and professional associations, and persons paying out of pocket.[4] The rebates paid to the pharmacies have accounted for a large portion of payers' generic drug costs, 40% or more of generic drug expenditures.

When it released the Generics Study, the Bureau announced that it would conduct a second phase of work in the sector in which it would examine ways for Canadians to obtain the full benefits of generic drug competition. This report provides the results of this examination. In preparing the report, the Bureau relied on publicly available information as well as information provided voluntarily through extensive interviews and contacts with industry participants from the private and public sectors. The Bureau would like to thank all parties that have provided information for the study.

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[1] IMS Health Canada, 12 months ending March 2008. Source: Canadian Generic Pharmaceutical Association "The Real Story Behind Big Pharma's R&D Spending in Canada", *News Release*, July 2008, available at: http://www.canadiangenerics.ca/en/news/if_realstory_2008.asp.

[2] This concern was based on a number of studies, such as "Non-Patented Prescription Drug Prices Reporting. Canadian and Foreign Price Trends" conducted by the Patented Medicines Prices Review Board in June, 2006, finding Canadian generic drug prices to be high in relation to comparator countries. Available at: http://www.pmprb-cepmb.gc.ca/CMFiles/Canadian-Foreign_Price_Trends_-released_July_04_0638LHG-742006-1490.pdf.

[3] Competition Bureau "Canadian Generic Drug Sector Study," available at: http://www.competitionbureau.gc.ca/epic/site/cb-bc.nsf/en/02495e.html.

[4] An exception is hospitals that purchase drugs directly for dispensing within their own pharmacies.

This report comes at an important time in the evolution of the Canadian generic drug sector. The importance of generic drugs for managing Canadian health care costs is increasing rapidly. Between 2006 and 2007, generic drug expenditures increased over 20% to $4.1 billion. Drugs scheduled to come off patent over the next three years have annual Canadian sales of more than $2.8 billion.

At the same time, the generics sector is adapting to major reforms introduced under the Ontario government's *Transparent Drug System for Patients Act* (the "TDSPA") adopted in June 2006.[5] The Generics Study pointed out how these reforms ended the traditional pricing framework for generic drugs across Canada based upon maximum prices allowed under Ontario Drug Benefit (ODB) plans. But the full impact of this legislation on generic drug prices across Canada was still to be determined. In addition, both the public and private sectors have shown increasing interest and activity in measures to lower the prices of generic drugs.

1.1 Bureau Purpose and Interest in the Generic Drug Sector

The Competition Bureau is an independent agency that contributes to the prosperity of Canadians by protecting and promoting competitive markets and enabling informed consumer choice. Headed by the Commissioner of Competition, the Bureau is responsible for the administration and enforcement of the *Competition Act*, the *Consumer Packaging and Labelling Act*, the *Textile Labelling Act* and the *Precious Metals Marking Act*.

This report was prepared under the Bureau's role as an advocate of the benefits of competition. In this role, the Bureau strives to ensure that competitive factors are taken into consideration by federal and provincial government decision-makers. It advocates that regulators and policy makers regulate only where necessary and that they rely on market forces as much as possible to achieve the benefits from competition, namely lower prices, better quality and new and innovative products and services.

1.2 Organization of the Report

The report is organized as follows. Chapter 2 outlines and analyses the implications of developments taking place in the Canadian generic drug sector since the release of the Generics Study in 2007.

Chapters 3, 4 and 5 discuss actions that may be taken by public drug plans, private drug plans and patients to obtain the benefits of generic drug competition. Chapter 6 provides a summary.

[5] *Transparent Drug System for Patients Act,* available at: http://www.ontla.on.ca/web/bills/bills_detail.do?locale=en&BillID=412&isCurrent=false&ParlSessionID=.

CHAPTER 2: GENERIC DRUG SECTOR UPDATE

The Canadian generic drug sector is undergoing an unprecedented period of change. The sector continues to adapt to the major generic drug policy changes implemented in Ontario under the TDSPA. Other provinces are also taking steps to obtain the benefits of generic drug competition, and the private sector is developing a stronger interest in the issue. This Chapter discusses these developments and their implications for the evolution of the Canadian generic drug sector.

2.1 The Evolving Canadian Generic Drug Pricing Framework

The implementation of Ontario's TDSPA marked an important milestone in the development of the Canadian generic drug sector. Prior to the Act, introductory prices for generic drugs across the country for public plans, private insurers and persons paying out of pocket tended to reflect the maximum prices allowed for generic drugs under ODB plans. For most generics, this amounted to about 63% of the interchangeable brand reference product formulary price.[6] The TDSPA reduced the maximum price reimbursed by Ontario Public Drug Programs (OPDP) for most generic drugs to 50% of the interchangeable brand product price.[7]

The Generics Study reported that the TDSPA led to the establishment of a two-tier pricing system for generic drugs. Private payers in Ontario and public and private payers in other provinces did not obtain the reduced OPDP prices. The exception was Quebec, which requires that generic manufacturers provide the province the lowest price available in other provinces. When the Generics Study was released, the full impact of the TDSPA on generic drug pricing across the country remained to be determined.

To examine this matter, the Bureau obtained public and private drug plan data for the 10 top selling generic chemicals in Canada for the period from July, 2006 to June, 2008, accounting for 36% of Canadian generic drug sales.[8] Two of the drugs in the sample are part of the first wave of generic "competitive agreements" in Ontario,

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[6] A maximum price of 70% of the brand reference product formulary price was allowed where one generic was introduced, with the maximum price falling to 90% of the first generic price where multiple generic products were available. The changes made in Ontario are described in *The Generic Drug Sector Study*, *supra,* note 3, section 4.A.2.

[7] A price is negotiated where only one generic product is available. The TDSPA also prohibits the granting of rebates to pharmacies by generics manufacturers. Rather, manufacturers may provide allowances to pharmacies in support of specified services or activities including: certain continuing education programs; clinic and education days; disease management and prevention initiatives; and the building or maintenance of private counseling areas. Allowances for generic drugs dispensed under ODB plans are capped at 20% of the reimbursement price. There is no limit on the level of allowances that can be provided in relation to drugs dispensed under private plans or to persons paying out of pocket. See *Transparent Drug System for Patients Act, supra,* note 5.

[8] The drugs are ranked by sales over the first quarter of 2008. The sample includes: Citalopram Hydrobromide, Diltiazem HCL, Gabapentin, Metformin HCL, Olanzapine, Omeprazole Magnesium, Paroxetine HCL, Ramipril, Simvastatin and Venlafaxine HCL. Brogan Inc. Private Drug Plan Database and Delta PA application as well as data provided by various industry sources were used for the analysis.