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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.

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[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.

discussed in the next section. Three others were genericized since the implementation of the TDSPA.

The study found that the OPDP and Quebec prices for generic drugs that were introduced before October 2006 dropped 21% after the TDSPA price caps were implemented.[9] The OPDP and Quebec prices for the drugs that lost patent protection after the TDSPA was implemented also dropped, reflecting the lower price caps required under the two provinces' legislation.

The prices paid by others - private plans in Ontario and public and private plans in other provinces except Quebec - for the generic drugs available prior to implementation of the TDSPA neither increased nor decreased significantly. Their prices continued to reflect the former OPDP price cap of 63% of the brand product price. However, the prices paid for generic copies of the drugs that lost patent protection after the TDSPA was implemented were not limited to the former OPDP price cap. Rather, these drugs were introduced at prices ranging between 70 and 75% of the interchangeable brand product price even when multiple suppliers were active in the market.[10]

2.2 Recent Drug Plan Developments

The period following the release of the Generics Study has also seen important developments in public and private drug plan generic drugs policies.In November 2007, Manitoba announced new submission criteria for multi-source products. The criteria includes a requirement to provide an analysis of the price-benefit that the submitted product offers over other products within the same interchangeable grouping, and a declaration that, at the time of the submission, the price included in the submission is not higher than, and is at least equal to, the price of the submitted product in any other Provincial/Territorial jurisdiction [or if the price is higher, a price comparison and explanation as to the reason that the offered price is higher]. The new criteria represent the first instance where a provincial government has acted on the findings of the 2007 Study.[11]

In December, 2007, the B.C. Ministry of Health issued its first tender for a generic drug, olanzapine, with the winning bidder to be determined primarily on the basis of confidential rebates off of the product list price.[12] At the time, two manufacturers were

[9] The decline in Quebec public and private prices took place in February 2008, when the province's requirement to receive the lowest available price provided to other provinces was implemented.

[10] These findings are consistent with analysis done by Brogan Inc., an independent consulting company and analysis and views provided by other industry participants. See Brogan Inc., "Assessing the Impact of the TDSPA Pricing on the Environment in Ontario and Across Canada", presented at The Canadian Institute's Drug Pricing & Reimbursement Conference, June 24, 2008.

[11] See, Manitoba Drug Standards and Therapeutic Committee, Manitoba Health "Submission Requirements," available at: http://www.gov.mb.ca/health/mdstc/subreq.html#interchangeable.

[12] See, Jonathan Fowlie (2008) "Tendering touted as B.C.'s drug solution. Competition will save Pharmacare from ever-rising costs: health minister," in, Vancouver Sun, Saturday, February 02, 2008, available at: http://www.canada.com/vancouversun/news/westcoastnews/story.html?id=36ca7117-6c47-4416-b8b9-35cadc225fa8.

licensed by Health Canada to supply olanzapine: Eli Lilly, the brand product supplier; and Novopharm, a generic company.[13] The winning bidder, Eli Lilly, received exclusive listing on the public plan formulary[14] for 14 months.[15] In addition, the BC Pharmacy Task Force Report, released in May 21, 2008, calls for a fundamental shift in the province's generic drug policies.[16]

Alberta has also announced its intention to re-examine the province's generic drug policies. The province is working on a strategy to lower the cost of prescription drugs including generics.[17]

Ontario is taking steps to directly obtain competitive generic drug prices. In July 2008, OPDP initiated a "competitive agreements" tendering process for preferential listing of suppliers for four drugs. Together, these drugs had annual sales to the ODB plan of more than $80 million.[18] The government dropped the process for one of the drugs, ranitidine, when the brand manufacturer reduced its Ontario formulary prices by 75%.[19] The province will award the agreements for the other three drugs based

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[13] A second generic manufacturer, Pharmascience has since been issued a Notice of Compliance for olanzapine on April 2, 2008. See, "Notice of Compliance, Prescription Products for Human Use," issued by Health Canada for January 1 to July 11, 2008 at: http://205.193.93.51/NocWeb/viewnoce.jsp?noc=kmmd also, new product announcement by Pharmascience at: http://www.pharmascience.com/pms_en/news/5_1.asp.

[14] BC PharmaCare will only reimburse the Eli Lilly products, except in individual cases of documented intolerance to them. See, BCPharmaCare Newsletter, "Update on Olanzapine Tablet Coverage", June 27, 2008 Edition 08-007, at**:** http://www.health.gov.bc.ca/pharme/newsletter/08-007news.pdf

[15] See, Request for Proposals, Olanzapine Product Listing, Ministry of Health Request for Proposals Number: PSD-1205 Issue Date: December 5, 2007.

[16] See "Report of the Pharmaceutical Task Force to the Honourable George Abbott Minister of Health, Province of British Columbia, April. 2008." The report finds that significant savings on generic drugs that can be achieved for PharmaCare. It further states that if the government fails to reach agreements with manufacturers or the pharmacies within six months, it should move unilaterally through legislation or other means. This, and the other recommendations made in the Task Force Report, have been accepted by the B.C. Minister of Health. See, B.C. Ministry of Health (2008), "Government accepts Drug Plan Recommendations, News Release, 2008Health0047-000615, May 21, 2008, available at: http://www.lifesciencesbc.ca/News/BC_Industry_News/bcnews05210801.asp.

[17] Michelle Lang (2007) "Alberta revisits drug funding," in, Calgary Herald, September 4, 2007, Available at: http://www.canada.com/calgaryherald/story.html?id=adec39bb-d6c0-4553-931f-acc8e6cc704a&k=78631. Substantive proposals are yet to be announced. For example, in May 2007, the Alberta and BC governments signed an agreement to, "*explore* the joint procurement of pharmaceuticals, medical equipment and other medical devices" (emphasis added). See, "B.C.-Alberta Agreements Since the Alberta-British Columbia Protocol of Co-operation," May, 2007, where there is listed, "MOU on Joint Procurement for Medical Devices and Pharmaceuticals," Available at: http://www.gov.bc.ca/igrs/attachments/Alberta_BC%20Memorandums.pdf.

[18] The four drugs are enalapril (tablets only), gabapentin, metformin and ranitidine (tablets). Among the key considerations in the selection of these drugs is the availability of multiple generic alternatives, that significant volumes of the drugs are reimbursed under ODB plans, and observations from other jurisdictions suggest that substantial savings are possible. Details in the July 4, 2008 *Ontario Public Drug Programs Competitive Agreements Briefing to Stakeholders*, available at: http://www.health.gov.on.ca/english/providers/program/drugs/opdp_eo/notices/stakeholder_briefing.pdf.

[19] See, "Notice From Executive Officer: Notice of Cancellation of Call for Application for Ranitidine Hydrochloride," September 19, 2008, Helen Stevenson, Executive Officer, Ontario Public Drug Programs available at: http://www.health.gov.on.ca/english/providers/program/drugs/opdp_eo/notices/exec_office_2000919.pdf.

principally on the level of confidential rebates off of the Ontario formulary price of the relevant product. Security of supply is also a major decision criterion.[20] The first contracts are scheduled to begin in the last quarter of 2008 and end December 31, 2010, with tenders for other drugs possibly to follow.

In the private sector, Medavie Blue Cross entered into a competitive pricing arrangement in December 2007 with Abbot Laboratories for clarithromycin, an antibiotic used for the treatment of bacterial infections. Under the arrangement, Medavie received off-list rebates from the brand product supplier following its loss of patent protection. The rebates brought the net price of clarithromycin below the price of generics. Following the agreement, the generic versions were removed from coverage under Medavie plans in Atlantic Canada.[21] However, objections by the pharmacy sector led to the arrangement being withdrawn by Abbott. Medavie has indicated that it will continue to pursue such options to reduce drug costs for its clients.[22]

Not only do these developments show an increasing use of competitive processes by plans to reduce generic drug prices, they also provide evidence of a change in the competitive dynamic between generic and brand drug manufacturers. In the past, brand manufacturers did not compete with generic manufacturers on the basis of price. But now they appear to be more willing to discount prices to maintain market share for their drugs after they have lost patent protection.

This emerging dynamic creates both opportunities and challenges for private and public drug plans. On one hand, increased price competition by brand manufacturers may help public and private plans overcome obstacles to obtaining competitive generic drug prices by introducing an additional competitor in the marketplace. However, a potential long-term concern is that brand manufacturer price discounting may lead to a reduction in generic drug competition for some drugs. [23]

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[20] The competitive agreements process is described in the July 4, 2008 *Briefing to Stakeholders, supra,* note 18. Winning bids are to be chosen on the basis of: a weighting of volume discounts offered (50%); the ability to provide security of supply (40%); and experience, particularly in the Ontario market (10%). The offering of a lower net price through the bundling of drugs is not permitted.

[21] Medavie Blue Cross, Benefit Update, December 2007, "Product Listing Changes in Atlantic Canada for Generic Versions of the Antibiotic Biaxin." Available at: http://www.medavie.bluecross.ca/cs/BlobServer?blobcol=urldata&blobtable=MungoBlobs&blobheadervalue2=abinary%3B+charset%3DUTF-8&blobheadername2=MDT-Type&blobkey=id&blobwhere=1187208874215&blobheader=application%2Fpdf.

[22] Medavie Blue Cross Special Communiqué, March 20, 2008. "Abbott Laboratories ends preferred Biaxin BID arrangement with Medavie Blue Cross" available at: http://www.medavie.bluecross.ca/cs/BlobServer?blobcol=urldata&blobtable=MungoBlobs&blobheadervalue2=abinary%3B+charset%3DUTF-8&blobheadername2=MDT-Type&blobkey=id&blobwhere=1187211028309&blobheader=application%2Fpdf.

[23] As it takes time and significant costs to introduce a generic drug to the market, a potential generic competitor may be reluctant to sink the drug development costs if at entry it may be faced with price competition from the branded product. This is the case particularly for smaller drugs where the market can support only a small number of competitors.

CHAPTER 3: MAXIMIZING THE BENEFITS OF GENERIC DRUG COMPETITION FOR PUBLIC PLANS

Public drug plans account for about 48% of all prescription drug expenditures in Canada. While federal drug plans are a significant part of this total, about 3% of total expenditures, the prices they pay for generic drugs tend to be determined by conditions prevailing at the provincial level.[24] Each province maintains its own public drug benefit plans covering many of its residents. Provinces also pay for drugs dispensed in hospitals. As noted in the Generics Study, hospitals already make extensive use of competitive tendering and supply processes to obtain generic drugs at low prices.[25]

Provincial plans share certain characteristics in terms of scope and coverage. They commonly cover seniors and other high drug cost groups as well as low-income persons and families.[26]Although these aspects of provincial plans may be similar, the interests, goals and obstacles of various provinces with respect to generic drug policies can vary considerably. For example, sustaining in-province generic drug manufacturing is an important issue in Ontario and Quebec where domestic manufacturing is based. Provincial objectives may also differ with respect to such matters as the role of public plans in obtaining benefits for private sector payers, the use of patient deductibles and co-payments, and the roles of pharmacies and their relationship with the provincial governments. The size of the population covered and associated bargaining power further distinguish provincial plans.[27]

Although there has been a high level of cooperation in some drug plan areas, the development of generic drug pricing and reimbursement policies remains under the individual provinces' control. [28] Inter-provincial work has been conducted on generic drug pricing and purchasing under the National Pharmaceutical Strategy (NPS), but this has not resulted in joint action.[29] Rather, individual provinces are developing their own drug policies to address generic drug pricing and rebates.

Obtaining the benefits from competitive generic drug prices for public plans does not require that a national, rather than a province by province approach, be used. One motivation that has been expressed for establishing a national generic drug pricing and purchasing framework would be to provide public plans the buying power that would

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[24] The main Federal Drug Plans are described in the Generics Study, *supra,* note 3, section 5.A.1.

[25] See the Generics Study, *supra,* note 3, section 4.B.

[26] The scope and coverage of public plans is discussed in the Generics Study, *supra,* note 3, Chapter 5.

[27] As discussed further in section 3.1.1, size and bargaining power can be an important issue for consideration in developing policies that will induce manufacturers to offer low competitive prices to public plans.

[28] An example of an area where there has been a high level of cooperation is the establishment of the Common Drug Review process. See, Canadian Agency for Drugs and Technology in Health "Common Drug Review," at: http://cadth.ca/index.php/en/cdr.

[29] The most recent progress report of the NPS was delivered in 2006. See, Federal/Provincial/Territorial Ministerial Task Force on the National Pharmaceuticals Strategy (2006) "National Pharmaceuticals Strategy: Progress Report," June, available at: http://www.hc-sc.gc.ca/hcs-sss/pubs/pharma/2006-nps-snpp/index-eng.php.

allow them to obtain generic drugs at competitive prices. However, the Generics Study showed that large size is not needed to obtain competitive prices, which are already being provided to individual pharmacies and pharmacy groups. The challenge is to develop provincial drug plan approaches that provide the benefits from these competitive prices to provincial governments, patients and taxpayers.

As indicated in the Generics Study and Chapter 2, progress has been made toward obtaining these benefits in some provinces. However, the remaining potential savings are large particularly for the provinces and territories that have not benefited from price decreases under the Ontario TDSPA. As noted above, they are facing the prospect that generic versions for drugs losing patent protection will be priced at 70% or more of the brand product price.

To obtain the maximum benefits of generic drug competition the Bureau believes that provincial plans should consider putting four key elements in place:

1. Mechanisms to obtain competitive generic drug prices.
2. Reimbursement of generic drugs separate from the reimbursement of pharmacist services.
3. Incentives for generic drugs, where they are lower-priced, to be dispensed in replacement for their interchangeable brand products.
4. Coordination of individual provinces' actions to avoid unintended anti-competitive effects.

3.1 Obtaining Competitive Generic Drug Prices

The Generics Study found that public plan generic drug policies have traditionally provided limited incentive for manufacturers or pharmacies to offer them low competitive prices.[30] Rather, manufacturers competed by setting high list prices to pharmacies and offering off-list rebates and allowances. The true competitive price of generics, reflecting rebates, was generally not billed to provincial plans that instead reimbursed the high list price.

To obtain the benefits of generic drug competition, it is essential that public plans incorporate incentives or mechanisms to reveal true competitive prices. A variety of approaches and related options can be used to accomplish this goal, depending on the goals, interests, objectives, capabilities and obstacles of the individual province. These approaches include:

i Competitive Tendering;
ii Competitive Price Monitoring;
iii Sequential Formulary Listing.

[30] For discussion, see the Generics Study, *supra* note 3, section 5.A.3.

Other approaches that might be considered include the development of pharmacy preferred provider networks, use of mail order pharmacies where appropriate, or the structuring of plan member co-payments and deductibles to promote competitive generic drug pricing. However, since these latter approaches may be better suited for private drug plans, they are discussed further in the next chapter.[31]

3.1.1 Competitive Tendering

Section 2.2 describes how increasing consideration is being given to competitive tendering as a means to obtain competitive generic drug prices for provincial plans. This interest is largely based on the cost savings that competitive tendering of generics has provided for New Zealand.[32] Competitive tendering normally involves the restriction of generic products that will be reimbursed by a public plan based upon bids provided by potential suppliers. It is used extensively by Canadian community and hospital pharmacy sectors to obtain competitively priced generic drugs, but, to date, has had limited use at the provincial plan level.[33] Competitive tendering has the potential to provide large cost savings to public plans in Canada. It directly shifts the focus of manufacturer competition from pharmacies to the plans and provides a strong incentive for manufacturers to offer low competitive prices by offering them exclusive or preferential market access in return.

In conducting sector contacts for this report, a number of potential issues with and obstacles to the use of competitive tendering by public plans in Canada were raised. Each of these issues is dealt with in turn below.

Ensuring secure supply

A frequently expressed concern regarding competitive tendering is that it could lead to shortages when winning bidders are unable to meet demand. However, a range of approaches can be used to address this issue. Bidders can be made subject to strict requirements to demonstrate the ability to meet demand to qualify to bid. More than one successful bidder may be selected, as in the Ontario competitive agreements process described in Chapter 2, to ensure a back up source of supply. In addition, contracts may include provisions requiring that successful bidders, in the event of shortages, be subject to appropriate penalties.[34]

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[31] For example, the use of preferred provider networks requires that plan members be provided incentive to purchase drugs at certain pharmacies. While this may be feasible for more mobile working age populations that may be covered by private plans, it may be difficult to implement for less mobile populations tending to be covered by public plans. Similarly, options that are feasible for provincial plans may be difficult to implement in a private sector setting. For example, widespread use of competitive tendering for formulary listing for private plans could lead to pharmacies having to stock multiple generic variants of the same drug to supply the patients covered under different plans.

[32] See for example, S. Morgan, G. Hanley, M. McMahon and M. Barer (2007) "Influencing Drug Prices through Formulary-Based Policies: Lessons from New Zealand," in, *Healthcare Policy*, 3(1) 2007: 1-20 and Jonathan Fowlie (2008), *supra*, note 12.

[33] Exceptions are Saskatchewan, which uses competitive tendering for a limited number of generic drugs and the competitive tendering processes discussed in Section 2.2.

[34] For example, in the event of failure to meet demand, the winning supplier may be required to reimburse any additional costs to the plan from having to meet its requirements through an alternative source.

Avoiding Negative Patient Reactions

Another concern that was expressed by some parties contacted for this report is that, in some cases, the effectiveness of drugs for some patients may be sensitive to the specific formula used in the drug products they are taking.[35] While generic drugs must meet Health Canada bio-equivalence standards, they may have different component ingredients in addition to the relevant molecule and may vary in the timing of the delivery of the active ingredient into the bloodstream.

This issue can be avoided by excluding from competitive tendering drugs for which potential negative reactions are a concern. Alternatively, provinces might want to structure competitive tendering processes so that there is more than one qualifying generic product. Another option would be to provide authorization processes, as is currently done for drugs coming off of patent protection, allowing coverage to continue for patients on a specific interchangeable product where negative reactions are a concern.[36]

Dealing with Existing Inventories

A potential concern with competitive tendering is that it can impose significant costs on distributors and create oversupply and waste by eliminating the market for products already in the distribution pipeline. However, parties contacted for this report indicated that this issue can be avoided using an appropriate transition period between the awarding and implementation of contracts to allow stocks within the distribution system to be used up.[37]

Protecting Generic Manufacturer Competition

The view that competitive tendering could lead to an erosion of the Canadian generic manufacturing base and a high level of concentration and lack of competition among Canadian generic manufacturers was expressed by a number of parties contacted for this report. The basis for this concern is that competitive tendering by public plans could lead to a small number of provincial contracts accounting for a large share of the market for generic drugs. With a limited number of large contracts to compete for, when compared with the current framework with multiple pharmacy buyers, the concern is that the Canadian market will not be able to sustain enough competitors to ensure effective competition.

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[35] An area where it was suggested that this concern could arise is treatment of patients for mental health issues.

[36] As outlined in the Generics Study, *supra*, note 3, all provinces already allow physicians to specify that patients are not to be switched to generic products from brand products losing protection for medical reasons.

[37] The Ontario competitive agreements process described in section 2.2 provides for a transition period of 4 months.

Whether this could happen would depend on a variety of factors such as:

- the extent to which competitive tendering is used by public plans across Canada;
- the impact that this may have on competition to supply private payers;[38] and
- barriers to entering supply of particular generic drugs.

With these factors still to be determined, it is too early to determine what effect, if any, competitive tendering may have on the structure and competitiveness of generic manufacturing in Canada.

But if the need to protect the competitiveness of the marketplace becomes a real possibility, various measures could be taken to address it. For example, rather than supplying entire provinces, contracts may be awarded for areas or regions within them. Tendering processes may allow for two or more suppliers to be qualified. The timing and awarding of contracts may be coordinated across provinces to protect long-term competition.

Developing the necessary tendering capabilities

The use of competitive tendering requires that public plans obtain the necessary capabilities and capacities to run tendering processes. While there may be some up front costs required for this, the benefits from competitive tendering can be expected to far outweigh them. Indeed, as indicated by the Generics Study, hospitals widely use competitive tendering for generic drugs even though this is for much smaller quantities than are required by public plans for most drugs. [39]

Shifting the focus of generic competition

A more difficult obstacle to the effective use of competitive tendering may be structuring competitive processes that will effectively shift the focus of manufacturer competition from pharmacies to drug plans.

When a generic manufacturer provides a low price under a competitive tendering process it is unlikely to be able to provide as high a level of pharmacy rebates or allowances as it could when plans reimburse pharmacies at a higher price. Pharmacies still must stock the manufacturer's drug product in order to meet the needs of patients covered by the plan for which the manufacturer is the exclusive supplier. However, they also have the potential to discourage the offering of low prices by reducing or eliminating purchases of the manufacturer's other products.[40] The possibility of such reactions by pharmacies may

[38] The awarding of a public contract could provide the winning bidder with a competitive advantage in competition to supply generic drugs for private payers by providing pharmacies the option of stocking only one generic product. The potential significance of this effect on competition to supply private payers remains to be determined.

[39] The Generics Study found that retail pharmacy invoice prices were on average 39% higher than hospital invoice prices. S*upra,* note 3, page 35.

[40] It may be noted that such disciplinary actions, in some circumstances, could contravene the *Competition Act.* This may be the case, for example, if pharmacies collectively take disciplinary action.

make manufacturers reluctant to offer low prices even under competitive tendering processes.

To ensure that this does not create an obstacle to low priced tendering by manufacturers, it will be essential to develop competitive tendering programs that provide manufacturers with commercial opportunities outweighing any perceived threat to their other business. A strong and ongoing commitment to a well-designed competitive tendering process will be necessary.[41]

Dealing with MFN clauses

The use of most-favoured nation (MFN) clauses can create a further obstacle to the effective use of competitive tendering particularly for smaller provinces.[42] The result can be to not only increase prices in these provinces, but to sustain higher prices in all provinces.

MFN clauses require that a province be given the lowest price that is provided to another province or private payers. This means that when a manufacturer reduces its price to win a competitive contract in one province it must also reduce its price in the provinces with MFN clauses. In the former case, offering the low competitive price provides the advantage of exclusive or preferential listing on the plan formulary. In the latter case, the lower price does not provide any such advantage and may only result in lower returns on sales with no corresponding increase in market share. The disincentive that MFN clauses can create for manufacturers to participate in competitive tendering processes is particularly significant to consider when the provinces with MFN clauses are large relative to the province competitively tendering.

The most effective means to prevent provincial MFN clauses from having anti-competitive effects would be for provinces to abandon their use. Alternatively, these clauses may be structured or enforced to minimize their potential anti-competitive effects. Avoiding application of MFN clauses to off-list rebates and allowances, as are being used to award contracts in the competitive tendering process outlined in section 2.2, would still allow provinces to use such tendering processes as a means to obtain low competitive prices.

3.1.2 Competitive Price Monitoring

The option of competitive price monitoring involves pharmacies being reimbursed for generic drugs based on their cost of sourcing the drugs from suppliers net of any rebates or allowances. Unlike competitive tendering, this approach does not alter the traditional relationship between pharmacies and manufacturers. Rather, it requires

[41] For smaller provinces, given that their demand for drugs is relatively small, cooperation on competitive tendering may initially be required to provide large enough commercial opportunities to induce manufacturers to participate.

[42] Currently, MFN clauses are used by Quebec and Newfoundland and Labrador.

that effective mechanisms be developed to monitor the amounts paid for generic drugs by pharmacies.

Mechanisms for revealing generic drug costs can involve either monitoring the actual drug acquisition costs of pharmacies, or net price reporting by manufacturers.

Actual Acquisition Cost Reimbursement

Under actual acquisition cost reimbursement (AAC), competitive generic prices are revealed through pharmacy reporting of their net drug acquisition costs including off-invoice rebates, allowances or other benefits provided by generic manufacturers. All generic products are listed on the public formulary with pharmacies free to select a product to dispense. Pharmacies are allowed to claim their actual acquisition cost for drugs dispensed under public plans plus any mark-ups or other rebates they are allowed to retain. [43]

Effectively applying AAC pricing involves substantial implementation challenges, including sophisticated pharmacy auditing capabilities and effective remedies for inaccurate reporting.[44] A further concern is ensuring that incentive is maintained for pharmacies to seek out low priced generic drugs. This may require that pharmacies be permitted to retain a portion of the savings they achieve by obtaining discounts or rebates off list prices.

Manufacturer Price Monitoring

Under manufacturer price monitoring, generic manufacturers' prices to pharmacies net of rebates are disclosed or estimated so that they may be used as a basis for reimbursing or monitoring pharmacies. For example, in Ontario, manufacturers are required to report periodically to the province their pharmacy invoice prices and allowances, from which the province can calculate the net price to pharmacies.[45] The UK uses a survey-based form of net price monitoring under which average generic prices to different types of pharmacies are calculated.[46]

As with AAC policies, manufacturer price monitoring raises issues of effective auditing. However, focusing on the manufacturing level mitigates these concerns. While there are

[43] For example, as defined in Alberta, the AAC price is "the net invoice cost after deducting from the invoice cost the value of price reductions paid or credited to the pharmacy by the manufacturer, wholesaler or other party. A price reduction includes any free goods, rebates, discounts, premiums, special promotions and incentives. A price reduction does not include early payment discount, volume rebates or discounts to a maximum of 2%." See Canadian Pharmacists Association, "Provincial Drug Benefit Programs" 34th edition – December 2007.

[44] As indicated in the Generics Study, section 5.A.2, AAC has been a policy of some provinces but has had limited effect due to the need to establish these requirements.

[45] Pharmacies are required to direct rebates in excess of the net prices to activities specified in regulations. The reporting framework is presented in detail at: http://www.health.gov.on.ca/english/public/legislation/drugs/reporting_framework.html.

[46] In the UK, the estimated prices are used to calculate pharmacy rebate claw-backs retained by the public plans.

thousands of pharmacies in the country, there are less than 20 manufacturers whose transactions would have to be monitored. Also, as in the case of AAC policies, important concerns in applying manufacturer price monitoring are preserving the incentive for pharmacies to seek out low priced generics and ensuring that undue monitoring costs are not borne by taxpayers.

Whether AAC or manufacturer price monitoring is used, a concern with cost-based pricing is ensuring that it cannot be circumvented by charging high prices to pharmacies for drugs dispensed under the relevant provincial plans and low prices for drugs dispensed to private payers or in other provinces. Therefore, effectively applying the approach may require the ability to monitor all generic drugs sales to pharmacies within the province, both private and public, as well as prices charged to pharmacies in other provinces. Avoiding the latter concern may eventually require inter-provincial cooperation on, or national monitoring of, generic drug prices.

3.1.3 Sequential Formulary Listing

Under sequential formulary listing approaches, manufacturers are required to provide lower prices or other benefits to plan providers in order to be listed on their formularies. A limited form of this practice has long been a part of Ontario public drug plan policies, which require that the second generic and subsequent generics added to the formulary have lower prices than the first. As noted in section 2.2, a sequential formulary listing approach has been implemented in Manitoba with generic companies being required to provide value-added to the province in order to be listed on the provincial formulary.

Sequential formulary listing requirements have the potential to lead to public plan prices that more closely reflect competitive pharmacy prices. However, because they do not provide exclusive or preferential listing advantages, they create incentive only to provide the minimum price or other benefits required in order to be added to the formulary. Therefore, their effectiveness in obtaining competitive drug prices depends on the number of potential generic suppliers and the structure of price decreases or other benefits required in order to be listed on the formulary.

3.2 Separate Remuneration of Pharmacy Services

A view expressed to the Bureau in conducting this Report is that rebates have been used to offset under-funding of dispensing services under provincial regulations and to support the provision of other pharmacy services to patients. Determining the effects of generic drug rebates requires that they be examined within the business and economic framework for pharmacies in Canada. Considered within this framework, rebates may have a variety of other effects such as increasing pharmacy profits, increased advertising, the building or maintenance of additional pharmacies, extended hours of operation, and investment in store look, feel and non-drug related product selection to attract patients in order to obtain more rebates.

Separate remuneration of pharmacist services based on their supply by pharmacies, as compared to allowing generic drug rebates, would allow public money to be directed more effectively to desired uses. This involves clearly identifying these uses and establishing appropriate remuneration levels.

The costs of dispensing services have recently begun to be systematically examined in Canada. The *Activity Based Costing Study*, released in January 2007, examined average dispensing fees for 47 pharmacies in British Columbia.[47] Another study, *Costs of Ontario Community Pharmacy Services*, completed in June 2008, calculates total pharmacy costs per prescription for 505 pharmacies in Ontario, 16.3% of all pharmacies in the province.[48] This study organizes pharmacies both geographically, into rural, small town, suburban and urban locations, and by pharmacy business model, chain stores and independents versus grocery and mass merchant stores. In both studies estimated costs are based upon self-reported data and information provided by pharmacies. In October, 2008, a study into the economics of community pharmacy in Newfoundland and Labrador was conducted by Wade Locke Economic Consulting for the Pharmacists' Association of Newfoundland and Labrador.[49] The study utilized an activity-based-costing approach that drew upon surveys administered to 91 pharmacies in Newfoundland and Labrador, which represent about 51% of the total number of pharmacies.

The use of such studies for setting maximum fees requires careful consideration. The studies consider the current cost structure of dispensaries and pharmacies within the existing competitive framework that has included high generic drug rebates and/or allowances. However, this framework can lead pharmacies to engage in activities having the effect of inflating their costs, such as operating during low volume periods or maintaining or building low volume or inefficient pharmacies in order to obtain rebates and allowances. Setting dispensing fees based on these current market conditions may serve to support high pharmacy costs at taxpayer expense.

Simple estimates of average pharmacy costs do not adjust for the different business models within which dispensaries operate and how these can affect the level of dispensing fees needed to sustain pharmacies. This is most clearly the case with pharmacies located in food and mass merchandising outlets. The *Costs of Ontario Community Pharmacy Services* report found that these pharmacies have the highest costs among the pharmacy groups considered, thereby raising the average cost for all

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[47] The study, done by AT Kearney, was jointly sponsored by the Canadian Association of Chain Drug Stores, BC Pharmacy Association and BC Ministry of Health and is available at: http://www.cacds.com/bccostingstudy/.

[48] Costs include all pharmacy related costs including, overhead, rent, drugs, personnel, inventory and other costs. These are simply divided by the number of prescriptions dispensed at the pharmacy and not including any over the counter drug sales. Report available at: http://www.opatoday.com/CODstudy.asp.

[49] Wade Locke Economic Consulting, "An Activity-Based-Costing Estimate for the Average Cost of Pharmacy Services in Newfoundland and Labrador and an Evaluation of the Real Cost of the Proposed Legislative Change to the Formulary Requiring a Manufacturer's Guarantee of Best Prices for Generic Drugs". See http://www.panl.net/Documents/2008/News%20Release%20Dr.%20Locke's%20Study%2008OCT28.pdf.

pharmacies. Despite their seemingly high costs, these pharmacies are able to maintain the lowest average dispensing fees – $7.85.[50] That they still provide net benefits to their owners is indicated by the apparent success of this business model, which has been the fastest growing segment of the Canadian pharmacy sector over the past seven years.[51]

Regardless of the levels at which a province may establish maximum pharmacist service fees, a key consideration should also be to avoid unnecessary regulatory, legislative and professional restrictions on inter-pharmacy competition. This competition can provide substantial cost savings to payers. Professional restrictions on inter-pharmacy competition are extensively examined in *Self-Regulated Professions: Balancing Competition and Regulation* released by the Competition Bureau in 2007.[52] The study found extensive restrictions to exist on pharmacy price and other advertising and recommends that they be removed unless they can be shown to have offsetting benefits to patients. To obtain the full benefits from inter-pharmacy competition, it will also be important to ensure that there are no unnecessary restrictions to alternative delivery models for pharmaceuticals and pharmacist services such as mail order pharmacy and automated dispensing.

3.3 Incentive to Dispense Generics

As outlined in the Generics Study, all provinces have adopted interchangeability legislation or regulations to facilitate the substitution of less expensive generic drugs for brand products. Generic drug rebates have complemented these policies by providing a financial incentive for pharmacies to dispense generic drugs in replacement for brand name drugs for which rebates, typically, are not provided.

To continue to promote economic substitution of generics, it will be important to sustain incentives for such substitution by pharmacies when adopting measures to address generic drug rebates. Current plan practices basing dispensing and other pharmacy fees on pharmacies' drug costs may have to be reviewed to ensure that pharmacies return on dispensing generics remains at least as high as the return for dispensing their interchangeable brand products.

3.4 Inter-provincial Coordination

As provinces take actions to address generic drug issues, it will be necessary that the actions of individual provinces be coordinated to avoid unintended negative

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[50] Calculated using dispensing fees reported by pharmacies located in grocery and mass merchant stores. See Canadian Association for Pharmacy Distribution Management, *The Complete Report on Trends and Insights in Canada*, 2008.

[51] Food and mass merchandise outlets increased their share of all retail pharmacies in Canada from 16.6% to 20.05% from 2001to 2007. See: IMS Health, Pharmaceutical Trends, "Retail Pharmacies by outlet type, Canada, 2001-2007", at: http://www.imshealthcanada.com/vgn/images/portal/cit_40000873/7/59/79016648Trends08_En_07.pdf.

[52] See Chapter 6 of the Competition Bureau report on self-regulated professions. See, Competition Bureau (2007) "Self-Regulated Professions. Balancing competition and regulation," available at: http://www.competitionbureau.gc.ca/epic/site/cb-bc.nsf/en/02523e.html.

consequences for other provinces or for the country as a whole. To maximize the benefits from generic competition, provinces should take into account the effects that their policies can have on others and, more generally, the competitive supply of generic drugs in the country.

MFN clauses, discussed in section 3.1.1, are an example of an individual provincial policy that can have anti-competitive effects on other provinces. While their purpose may be to ensure that the province implementing the policy benefits from low prices provided to others, the net effects of MFN clauses may be to prevent other provinces from successfully pursuing competitive mechanisms to reduce their drug costs and to lead to higher prices for all plans.

A practice adopted independently by provinces that can jointly have negative consequences for the supply of generics is competitive tendering for formulary listing. As discussed in section 3.1.1, extensive use of competitive tendering by provinces, unless it is effectively coordinated, has the potential to concentrate demand into a small number of provincial contracts leading to fewer generic manufacturers and a potential loss of competition in the generics marketplace.

CHAPTER 4: ACTIVATING PRIVATE PLANS

Private drug plans, though not as large as public plans, still account for 35% of prescription drug expenditures in Canada[53] and provide coverage for about 58 % of all Canadians.[54] Most private coverage is sponsored by businesses, unions, association and other groups, although a significant amount, about 5% is paid for by individuals.[55]

While private plans account for a high level of drug expenditure, the Generics Study found that they have had limited impact on generic drug pricing in Canada. Rather, amounts reimbursed for generic drugs under private plans in Canada are normally based on pharmacy invoice prices that do not include rebates or allowances provided to pharmacies. The limited impact of private plans on generic drug pricing, is a major difference between the generic drug competitive framework in Canada and that which is found in the U.S. where private drug plans also play an important role.[56] U.S. plan providers engage in a variety of practices to obtain generic drug rebates or discounts from manufacturers and pharmacies that can provide major savings for plan sponsors.[57]

Obtaining generic drugs at competitive prices has the potential to provide major benefits to Canadian private plan sponsors, businesses, unions, associations, individuals and others. Based upon private plan drug expenditures of 35% of annual prescription drugs costs and a conservative estimate of rebates and allowances of 40%, potential savings in drug costs are in the range of $540 million annually.[58] This number may increase by $300 million or more over the next three years with the impending loss of patent protection for drugs accounting for over $2.8 billion of current Canadian drug costs.

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[53] See, Canadian Institute for Health Information (CIHI), 2008, Drug Expenditure in Canada, 1985-2007, Table A CA-Total, "Expenditure on Drugs by Type, by Source of Finance and as a Share of Public, Private and Total Health Expenditures, Canada, 1985 to 2007" p. 60. available at: http://secure.cihi.ca/cihiweb/products/Drug_Expenditure_in_Canada_1985_2007_e.pdf.

[54] See, Fraser Group/Tristat Resources (2002) "Drug Expense Coverage in the Canadian Population, Protection from Severe Drug Expenses," August, p. 11, available at: http://www.frasergroup.com/downloads/severe_drug_e.pdf

[55] See, the Generics Study, section 5B2, *supra*, note 3.

[56] North American countries are the exception among countries examined in CIHI, supra, note 53, pp. 29-36, in not having their entire populations covered through public insurance and the role that is played by privately financed and unregulated drug plans.

[57] See Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, August, 2005, p. 9 which reports maximum allowable costs to plan sponsors of generic drugs obtained through pharmacy benefit managers of, on average, 62% off the manufacturer's wholesale price. Available at: http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf.

[58] Estimate is based on retail pharmacy purchases of $3.86 billion of generic drugs in 2007, private insurance accounting for 35% of those purchases and rebates being 40%. See, IMS Health Canada, (2006) "Prescription drug purchases by Canadian hospitals and pharmacies reach $16.57 billion in 2005," *News Release*, March 15, 2006, available at http://www.imshealthcanada.com/web/content/0,3148,77303623_63872702_77770096_77808854,00.html and IMS Health Canada, (2008) "Canadian Prescription Drug Sales Experience Slowest Growth in a Decade with 6.3 Percent Increase," *News Release*, March 26, 2008.

The remainder of this chapter outlines relevant features and aspects of the U.S. private sector market for generic drugs and discusses the potential adoption of strategies by private plan providers in Canada to obtain competitive generic drug prices.

4.1 Generic Drugs Under U.S. Drug Plans

The treatment of generic drugs in the U.S. private insurance market is outlined in detail in the 2005 US Federal Trade Commission market study *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies.*[59] Management of drug benefit plans for plan sponsors is done by Pharmacy Benefit Managers (PBMs). PBMs in the U.S., as in Canada, provide a variety of services pertaining to claim and drug formulary management such as:

- maintaining and updating drug formularies;
- adjudicating claims;
- processing and settling claims;
- maintaining relations with pharmacy networks; and,
- analyzing and assessing claims.

Unlike their Canadian counterparts, U.S. PBMs also engage in a variety of activities designed to obtain low competitive drug prices that, in turn, provide them with a source of competitive advantage in competing to provide PBM services to drug plan providers. These activities may pertain not only to generic drugs, but to patented drugs as well. Key activities used by PBMs to obtain competitive drug prices include the following.

Preferred Pharmacy Networks

U.S. PBMs establish geographic networks of retail pharmacies so that patients can obtain their drugs without traveling long distances. [60] Retail pharmacies compete to belong to networks, typically by offering discounts off of drug wholesale prices to the PBMs, in order to increase their numbers of prescriptions. Discounts tend to be higher for networks that are more exclusive.

Generic drug products stocked by pharmacies within a PBM network are not determined by the PBM. Rather, the PBM negotiates generics reimbursement prices with member pharmacies. Differences between the reimbursement price and the pharmacy cost of obtaining the drugs are retained by the pharmacy. This allows pharmacies to continue to

[59] See Federal Trade Commission, *supra*, note 57, Chapter I.

[60] It should be noted that PBMs also provide such services to public plans in the US. In 2003, Congress added a new benefit to Medicare that provides senior citizens and other Medicare beneficiaries with a voluntary prescription drug benefit beginning in 2006. Congress intended that competition among private sector insurers would ensure that Medicare enrollees have a choice of prescription drug plans and be assured of low prices for drugs. Congress anticipated that PBMs would help administer the benefits. See, Federal Trade Commission, *supra*, note 57, pp. 19-20.

stock only one generic product even if it is a member of multiple PBM or plan networks, and to benefit from being effective at competitively sourcing generic drugs.

Mail Order Pharmacies

Most U.S. PBMs also offer mail order pharmacies to complement their pharmacy networks. The pharmacies may be owned by the PBM or PBMs may contract with third party mail order pharmacies. Mail order pharmacies provide an alternative means for dispensing prescription drugs other than through community pharmacies. Although mail order is confined primarily to persons with chronic conditions, it accounts for over 17% of prescription drug sales in the US. In comparison, mail order dispensing in Canada is limited.[61] The operation of mail order pharmacies provides a competitive alternative to pharmacies that PBMs may use for the dispensing of drugs to repeat order customers.

Competitive Payments on Patented Drugs

U.S. PBMs may also use formulary or other practices to obtain savings on patented drugs where there are competing patented drugs within the same therapeutic class. Manufacturers may give PBMs formulary or market share payments, commonly referred to as rebates, to encourage use of their products by plan sponsors. The amount of the rebate is typically determined by the ability of the PBM to increase market share of a manufacturer's drug.

Significant rebates typically are not offered on unique, pioneer brand drugs that enter the market. As competition within a therapeutic class expands, so too may the size of rebates that PBMs are able to obtain.

Patient Incentives

Private drug plans in the US also typically include patient incentives or restrictions to keep plan costs down. For example, where co-payments apply, plan members may be able to avoid or reduce them by obtaining drugs through mail order or from pharmacies within a preferred provider network.[62]

Together, these measures in combination with other activities engaged in by U.S. PBMs provide them with the flexibility to meet individual plan sponsors' goals and needs in terms of drug pricing and dispensing fees, retail network, extent of the formulary and other dimensions.[63]

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[61] CIBC World Markets, 2003 Investors' Guide To The Canadian Drugstore Industry, May 26, 2003, p. 20, available at http://www.envoycapital.com/includes/docs/drugstore_industry.pdf.

[62] The Federal Trade Commission, *supra*, note 57, p. 19 reports that US United Autoworkers Union uses mail order to supply members repeat medications. .

[63] Typical attributes and dimensions for negotiation are outlined in Federal Trade Commission, *supra*, note 57, Chapter I, section 3.

4.2 Obtaining Competitive Prices for Canadian Private Plans

In an increasingly competitive global marketplace, Canadian businesses need to find new ways to cut costs and meet employee needs more effectively. Many parties contacted for this report expressed concerns regarding increased co-payments and deductibles, and reduced coverage under private plans. Economizing on generic drug costs by obtaining competitive prices can provide a means to protect or extend current coverage levels and to reduce plan costs.

While there are obstacles to overcome, the costs of maintaining the status quo continue to increase as more major drugs lose their patent protection. Savings on direct generic drug costs are not the only potential benefits to take into consideration. In addition, alternative models may allow plans to be developed that are better tailored to the specific needs and interests of plan sponsors with respect to the supply of pharmacist services and other plan dimensions.

Obtaining competitive generic drug prices for private payers will require the implementation of new and innovative approaches to drug plan management and delivery in Canada. To allow the development of alternative delivery methods, plan sponsors and beneficiaries will be required to accept and demand changes to the manner in which drug plans have traditionally been delivered. Otherwise, employers, unions and other plan sponsors will continue to pay high generic drug prices. Provincial governments can help private plan sponsors to obtain the benefits from generic drug competition by ensuring that there are no unnecessary legislative, regulatory, professional or other barriers preventing these sponsors from promoting new drug plan approaches.[64]

Manufacturers and pharmacies may be reluctant to accept and participate in alternative delivery models. Overcoming this reluctance will require a strong commitment to change and the development and exercise of the countervailing bargaining power and incentives needed to support the deployment of alternative delivery models. The development and exercise of such bargaining power would have to be undertaken in a manner that does not contravene the *Competition Act*. In pursuing alternative plan designs, parties should also be aware of protections against potential anti-competitive practices by others that are provided under the *Competition Act*.

[64] For example, the use of MFN clauses by provinces within their boundaries, requiring them to receive the lowest price paid to any party in the province, can serve as a barrier to the offering low generic drug prices to private payers. Unnecessary barriers to alternative dispensing models should also be removed.

5. A ROLE FOR PATIENTS

Individual drug plan members and persons paying out of pocket for medications may also play an important role in helping to obtain the benefits of competitive generic drug prices. Although the vast majority of Canadians are covered under either public or private drug plans, out of pocket payments account for a substantial amount, about 17%, of all drug expenditures.[65] The payments consist principally of deductibles and co-payments required under public and private plans and also include payments for prescription drugs that are not covered by plans or by persons not having drug insurance.

Data and information obtained by the Competition Bureau for this report show that prices of generic drugs and pharmacist services can vary widely across pharmacy outlets. Therefore, patients paying out of pocket for all or part of their generic drug prescription costs may be able to make significant savings by shopping for better deals providing the best combination of price and service. Even though they may not directly benefit, patients who do not pay out of pocket should also purchase carefully to avoiding imposing unnecessary costs on taxpayers, and plan sponsors. The more that consumers compare prices and services when shopping for drugs, the more incentive the pharmacies will have to make lower prices and better services available to patients.

As discussed in section 3.2, advertising of pharmacy prices and services to consumers is subject to extensive, pharmacy board, regulatory and legislative constraints. To allow patients to obtain the potential benefits from competition, these constraints should be kept to the minimum needed to avoid any clearly defined and proven consumer health and safety issues.

[65] The most recent estimate of the percentage of Canadians not having any coverage was 2% mostly in Atlantic Canada. See, Fraser Group/Tristat Resources (2002), p. 11, *supra*, note 54. Since that time, Nova Scotia and Newfoundland have established universal coverage of high drug costs for their residents. The estimate of out of pocket payments is from (CIHI) (2008), Table A CA-Total, "Expenditure on Drugs by Type, by Source of Finance and as a Share of Public, Private Total Health Expenditures, Canada, 1985 to 2007"p. 60, *supra*, note 53.

CHAPTER 6: SUMMARY

The Generics Study released by the Competition Bureau in October 2007 found that generic drugs are provided under a complex competitive framework involving various market participants. Under the framework, many generic drugs are subject to strong competition, with end of patent protection leading to the entry of multiple competitors within a short period of time. This competition has tended to take the form of off invoice rebates provided by manufacturers as incentive for pharmacies to stock their particular interchangeable product. In the past, these rebates normally were not passed on to end payers through lower drug prices.

The traditional design of public drug plans in Canada was found to be a key factor leading to these results. The plans were found to provide limited incentive for pharmacies and manufacturers to compete for the plans' needs through offering lower prices. In the case of private plans, while the PBMs and private insurers in the United States play an important role in obtaining discounted generic drug prices for plan members, there is little such activity in Canada. As a result, private parties are paying generic prices that are as high as or higher than prices being reimbursed by public plans.

The generic drug environment in Canada is rapidly changing. In the past, most generic drugs were introduced at a price about 63% of the interchangeable brand product price. This traditional process for the pricing of generic drugs to payers in Canada no longer applies. Now, while OPDP and Quebec payers are benefiting from reduced price caps, other payers may be paying higher prices for newly genericized drugs that are currently introduced at 70% or more of the interchangeable brand product price.

At the same time, public and private drug plan providers are taking actions to obtain the benefits from generics competition by using a variety of approaches that include: the use of competitive tendering by Saskatchewan, Ontario, British Columbia and Medavie Blue Cross on the private side, and sequential formulary listing in Manitoba.

Measures to obtain competitive generic drug prices have the potential to provide large and increasing drug cost savings to public drug plans. The potential savings are particularly important for provinces like B.C., Alberta, Saskatchewan, Manitoba, New Brunswick, Nova Scotia, PEI and Newfoundland and Labrador, and the territories.

Obtaining the maximum benefits of competitive generic drugs prices does not require the development of a national approach to generic drug pricing and purchasing. Rather, to obtain the maximum benefits from generic competition public plans should consider putting four key elements in place. First, mechanisms are needed allowing reimbursement of generic drugs based on their competitive prices. A number of different approaches may be used to attain this objective, depending on the specific goals and capabilities of individual provinces, as well as the obstacles to their implementation. Competitive tendering for eligibility to be reimbursed by plans has the potential to enable the provinces to obtain competitive prices directly. Alternatively, drug price monitoring,

either at the pharmacy or manufacturer level, may be used. Another possible approach is to require successive generic manufacturers to provide reduced prices or rebates in order to become eligible for reimbursement.

Second, reimbursement of pharmacy services should be provided separately from reimbursement of drug costs. Direct remuneration of pharmacist services based on their supply by pharmacies, as compared to allowing generic drug rebates, would direct public money to more effective uses. To minimize the costs of pharmacist services, provinces should remove any unnecessary professional and other restrictions on competition among pharmacies.

Third, the granting of generic drug rebates and allowances has provided financial incentive to pharmacies to dispense generic drugs in replacement for more expensive interchangeable brand products. It is important to maintain incentive for pharmacies to dispense low cost generic drugs and promote a high level of generic substitution.

Finally, provincial policies need to be coordinated to ensure that individual provincial policies do not unintentionally prevent others (provinces or private payers) from obtaining the benefits of competitive generic drug prices. Moreover, provincial policies, collectively, must not restrict the long-term competitiveness of generic drug manufacturing in Canada.

Private drug plans in Canada have played a limited role in obtaining competitive generic drugs prices for private payers. Whereas strategies for getting competitive generic drug prices, such as preferred provider networks, mail order pharmacy and patient incentives, are widely used by private payers in the U.S. to obtain low generic drug prices, they have had limited application in Canada.

The potential benefits to adopting strategies for getting competitive generic drug prices for private plans in Canada are high and increasing rapidly. The structure of the Canadian pharmacy sector and existing business practices raise obstacles to the adoption of these practices in Canada. Overcoming them will require that plan sponsors and beneficiaries understand the benefits of employing alternative drug plan approaches and that plan providers develop innovative ways to put in place the necessary conditions for change. Governments can assist private plan sponsors and beneficiaries, unions, businesses and individuals and others, to obtain the benefits from generics competition by ensuring that there are no unnecessary, regulatory, legislative, professional or other restrictions to alternative drug plan approaches.

Individual plan members and persons paying out of pocket can also play a key role in helping to obtain the benefits from competition by being effective shoppers. The more that consumers compare prices and services when shopping for drugs, the more incentive the pharmacies will have to make lower prices and better services available to patients.