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# Canadian Generic Drug Sector Study

October 2007

on the enforcement and administration of the  
Competition Act  
Consumer Packaging and Labelling Act  
Precious Metals Marking Act  
Textile Labelling Act

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## 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.

## Chapter 1: Introduction

The development and supply of pharmaceuticals is an important part of health care delivery in Canada. Pharmaceuticals are the second largest and fastest growing source of health care costs in Canada. In 2006, they accounted for an estimated 17% of all health care spending in the country.<sup>1</sup> Total retail and hospital expenditures on pharmaceuticals (at invoice cost) in 2006 were \$17.8 billion.<sup>2</sup>

Generic pharmaceuticals (“generics”) play an important part in helping to control prescription drug costs in Canada. Generics are determined by Health Canada to be “bio-equivalent” to patented pharmaceuticals. Their role is to provide competition for brand-name products when their patent protection ends.

Generics account for a large and growing portion of pharmaceuticals dispensed in Canada. Their share of prescriptions dispensed through retail pharmacies in 2005 was 43%. In 2005, total generic drug spending was \$3.2 billion, with an annual growth rate of 13.6%. From 2004 to 2005, retail purchases of generic drugs grew at 12.1%, twice the growth of brand-name drugs. Generic drugs captured a smaller share of hospital spending at 11.6% in 2005, but were 36.4% higher than in 2004, four times the growth rate for brand-name drugs.<sup>3</sup>

The benefits of generics are indicated by their share of pharmaceuticals costs relative to their share of prescriptions. While accounting for 43% of drug prescriptions in 2005, they accounted for only 18% of drug expenditures.<sup>4</sup> As discussed later in the report, generic retail drug prices are frequently significantly lower than the corresponding bio-equivalent brand-name product prices.

Despite these savings, there is widespread concern in Canada that generics are not providing the benefits they could. A series of studies have found Canadian pharmacy invoice prices for generic drugs, which generally reflect the amount reimbursed by public and private drug plans, to be on average substantially higher than in other countries. For example, the June 2006 report on generic prices by the Patented Medicines Price Review Board (PMPRB) concluded that Canadian retail pharmacy invoice prices for generic drugs are substantially higher than in 10 of the 11 comparator countries considered.<sup>5</sup> The

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<sup>1</sup> In comparison, hospitals accounted for 29.8% of the forecasted \$148 billion spent on health care in Canada in 2006. See Canadian Institute for Health Information (CIHI), “Drug Expenditure in Canada, 1985-2006”, available at: [secure.cihi.ca/cihiweb/products/hcic2006\\_e.pdf](http://secure.cihi.ca/cihiweb/products/hcic2006_e.pdf).

<sup>2</sup> Retail pharmacy expenditures were \$15.74 billion and hospital pharmacy expenditures on drugs were \$2.08 billion. See IMS “News Release for 2006 Canadian Pharmaceuticals Review” available at: [www.imshealthcanada.com/vgn/images/portal/cit\\_40000873/7/25/80533297IMS%20Release%20Final%20English.pdf](http://www.imshealthcanada.com/vgn/images/portal/cit_40000873/7/25/80533297IMS%20Release%20Final%20English.pdf).

<sup>3</sup> Source: IMS Health available at:

[www.imshealth.com/web/content/0,3148,77303623\\_63872702\\_77770096\\_77808854,00.html](http://www.imshealth.com/web/content/0,3148,77303623_63872702_77770096_77808854,00.html).

<sup>4</sup> *Ibid.*

<sup>5</sup> PMPRB, June 2006, “Canadian and Foreign Price Trends”. Other studies finding Canadian generic drugs prices to be high in comparison to other countries include: i) Palmer D’Angelo Consulting Inc, August 2002, “Generic Drug Prices: A Canada US Comparison” PDCI Report Series, available at: [www.pdci.on.ca/pdf/Generic%20Pricing%20Study%20Final%20Report.pdf](http://www.pdci.on.ca/pdf/Generic%20Pricing%20Study%20Final%20Report.pdf); ii) PMPRB, November 2002,



PMPRB estimated that Canadian non-patented prescription drug spending could have been reduced by as much as 32.5%, or \$1.47 billion in 2005, if Canadian retail pharmacy prices were the same as the corresponding international median prices.<sup>6</sup> Acting on these concerns, provincial and federal governments in Canada have taken, or are considering, a number of actions to reduce their generic drug costs.

Generic drugs are an important area of interest under the National Pharmaceutical Strategy (NPS). The NPS is part of the 10 Year Plan to Strengthen Health Care agreed to by First Ministers on September 16, 2004.<sup>7</sup> Under the NPS, in October 2005, the PMPRB was given responsibility to monitor and report on non-patented prescription drugs.<sup>8</sup> Among the nine elements of the NPS are the acceleration of access to non-patented drugs and the achievement of international parity on generic drug pricing.<sup>9</sup>

Provincial governments are also acting individually to reduce their generic drug costs. In June 2006, the Ontario government amended legislation to require that generic drugs reimbursed under provincial drug plans normally be priced at no more than 50% of their brand-name reference product.<sup>10</sup> Previously, maximum prices for the first generic in Ontario were set at 70% of the branded equivalent, with subsequent generics having a maximum price of 90% of the first generic. In February 2007, Quebec adopted a new policy limiting the price of the first generic drug to 60% of the price of the brand-name drug and subsequent generics to 54% of the brand-name drug.<sup>11</sup>

While there is widespread concern regarding the supply and pricing of generic drugs in Canada, there is substantial uncertainty about the underlying causes for the findings of high Canadian prices. Potential explanations include the following:

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"A Study Of The Prices Of The Top Selling Multiple Source Medicines In Canada", available at: [www.pmprb-cepmb.gc.ca/CMFiles/study-e22SHF-8292005-2710.pdf](http://www.pmprb-cepmb.gc.ca/CMFiles/study-e22SHF-8292005-2710.pdf); iii) Brett Skinner, August 2004, "Generic Drugopoly: Why Non-Patented Prescription Drugs Cost More In Canada Than In The United States And Europe", available at: [www.fraserinstitute.ca/admin/books/files/GenericDrugopoly.pdf](http://www.fraserinstitute.ca/admin/books/files/GenericDrugopoly.pdf); iv) Brett Skinner, February 2005, "Canada's Drug Price Paradox: The Unexpected Losses Caused By Government Interference In Pharmaceutical Markets", available at: [www.fraserinstitute.ca/admin/books/chapterfiles/Jun05ffparadox.pdf](http://www.fraserinstitute.ca/admin/books/chapterfiles/Jun05ffparadox.pdf); and v) PMPRB, October 2006, "Trends in Canadian Sales and Market Structure". Both PMPRB reports are available at: [www.pmprb-cepmb.gc.ca/english/view.asp?x=805](http://www.pmprb-cepmb.gc.ca/english/view.asp?x=805).

<sup>6</sup> Federal/Provincial/Territorial Ministerial Task Force, June 2006, "National Pharmaceuticals Strategy Progress Report", available at: [www.hc-sc.gc.ca/hcs-sss/alt\\_formats/hpb-dgps/pdf/pubs/2006-nps-snpp/2006-nps-snpp\\_e.pdf](http://www.hc-sc.gc.ca/hcs-sss/alt_formats/hpb-dgps/pdf/pubs/2006-nps-snpp/2006-nps-snpp_e.pdf).

<sup>7</sup> Available at: [www.hc-sc.gc.ca/hcs-sss/delivery-prestati/fptcollab/2004-fimm-rpm/index\\_e.html](http://www.hc-sc.gc.ca/hcs-sss/delivery-prestati/fptcollab/2004-fimm-rpm/index_e.html).

Participants in the NPS include the federal government and all provinces with the exception of Quebec.

<sup>8</sup> Non-patented drugs include brand-name drugs that lost patent protection as well as generic drugs. The June 2006 PMPRB report referred to above was the first of these quarterly reports.

<sup>9</sup> NPS Progress Report, June 2006, *supra*, note 7.

<sup>10</sup> The *Transparent Drug System for Patients Act 2006*, S.O. 2006, c. 14, passed third and final reading in the Legislative Assembly of Ontario on June 19, 2006 and received royal assent on June 20, 2006. Certain provisions of the Act came into force upon royal assent and the balance came into force on October 1, 2006.

<sup>11</sup> Price regulation in Ontario and Quebec is examined in more detail in Chapter 3.

- The use of inappropriate statistical methodologies<sup>12</sup>
- Higher domestic concentration of the generic manufacturing industry
- Provincial and federal government regulatory practices
- Provincial pharmaceutical reimbursement practices.

Assessing these and other possible reasons for the performance of the Canadian generic drug sector requires an understanding of the underlying competitive framework. This framework involves a complex interplay of:

- Provincial and federal legislation and regulation
- Domestic and foreign generic drug manufacturers and suppliers
- Distributors
- Pharmacy benefit managers
- Rural, banner, mass merchandise and other pharmacies
- Provincial, federal and private insurance plans.

While studies have been done concerning separate elements of this framework, the interplay between the various elements has not been systematically examined.

### **Bureau Purpose and Interest in Conducting the Generic Drug Sector Study**

The Competition Bureau, under the direction of the Commissioner of Competition, is responsible for the administration and enforcement of the *Competition Act*, a federal statute that applies to all sectors of the Canadian economy. The Commissioner is also responsible for the administration and enforcement of the *Consumer Packaging and Labelling Act*, the *Textile Labelling Act* and the *Precious Metals Marking Act*. The purpose of the *Competition Act*, as set out in section 1.1, is to maintain and encourage competition in Canada in order to promote the efficiency of the Canadian economy and provide consumers with competitive prices and product choices.

The Act defines a number of practices that are prohibited as criminal offences or are subject to review by the Competition Tribunal under the civil provisions of the Act. The Act does not provide the Bureau with any authority to decide the law or to compel business to adopt any particular type of conduct. Further information is available on the Bureau website, at [www.competitionbureau.gc.ca](http://www.competitionbureau.gc.ca).

The Bureau promotes competition in two ways.

- It is a law enforcement agency. It investigates allegations of anti-competitive conduct and pursues criminal and civil remedies to stop anti-competitive behaviour.

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<sup>12</sup> D'Cruz J., Hejazi W. and G. Fleischman, 2005, "Comparisons of Retail Prices of Generic Prescription Drugs in Canada vs. United States: A Comprehensive Study", available on the CGPA website at: [www.canadiangenerics.ca/en/issues/Comparison\\_of\\_Retail\\_Prices\\_of\\_Generic\\_Drugs\\_in\\_Canada\\_vs\\_US\\_DCruz\\_et\\_al\\_Nov\\_2005.pdf](http://www.canadiangenerics.ca/en/issues/Comparison_of_Retail_Prices_of_Generic_Drugs_in_Canada_vs_US_DCruz_et_al_Nov_2005.pdf).

- It also acts as an advocate for competition. To that end, it frequently makes submissions to legislative bodies or regulators on how to implement reforms that encourage competition.

In its advocacy role, the Bureau strives to ensure that competitive factors are taken into consideration in the formulation of policies. It advocates that regulators and policy makers rely on market forces to achieve the benefits of competition, namely lower prices, better quality and improved product choice for Canadians. Given the important benefits of competition, regulation should only interfere with market forces where necessary, and then, only to the minimum extent needed to achieve other policy objectives.

The Bureau's interest in conducting the current study comes from its advocacy role. The intent of the study is to outline and describe the competitive framework for prescribed generic drugs in Canada, with a focus on market structure and regulatory features.

The purpose of this study is not to examine Canadian generic drug prices relative to other countries. Rather, it is to provide an understanding of the underlying competitive framework in order to identify potential areas for further promoting the benefits of competition. These areas will provide the basis for further Bureau analysis and advocacy work on generic drugs.

In conducting this study, 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.

### **Organization of the Report**

The competitive framework for generic drugs involves a complex set of interactions between manufacturers, distributors, drug dispensers (pharmacies and hospitals) and payers or reimbursers (public and private drug plans and patients). This report outlines key features and roles of industry participants at each level related to generic drug competition.

Chapter 2 examines generic drug manufacturing in Canada. Chapter 3 discusses the role of independent pharmacy wholesalers and distributors (IPDs). Chapter 4 addresses the practices of dispensers of generic drugs. Section A considers retail pharmacies, section B deals with hospital pharmacies. Chapter 5 examines key features of the reimbursement framework for generic drugs. Public drug plans, the largest source of retail prescription drug funding in Canada, are considered in Section A. The role of private insurers is examined in Section B. Chapter 6 provides a summary of key findings.



## Chapter 2: Canadian Generic Drug Manufacturing

Section 2.1 of this Chapter describes the Canadian generic drug manufacturing sector. Section 2.2 outlines the considerations manufacturers take into account in determining whether to supply a particular generic drug. Section 2.3 discusses the barriers to entry into the supply of a generic drug. Section 2.4 examines the dimensions for competition among generic manufacturers. Finally, section 2.5 considers the state of manufacturing competition in Canada.

### 2.1 Manufacturing Description

There are over 15 suppliers of generic drugs in the country with 13 companies having manufacturing facilities in Canada. The largest Canadian manufacturer, Apotex, is domestically owned and controlled.<sup>13</sup> Of the next nine largest suppliers, seven have a parent company or group that is foreign-based.

The larger manufacturers tend to offer a large portfolio of drugs across multiple therapeutic classes and in a variety of forms, while others are less diversified or more specialized. For example, Taro Pharmaceuticals, an Israeli pharmaceutical company entered the Canadian market in 1984 and specializes in topical products. Hospira, a 2005 entrant, specializes in products used in hospitals including critical care products and specialty injectable pharmaceuticals. Sandoz acquired Sabex in 2004, and it specializes in injectable and ophthalmic generic pharmaceutical products.

Table 1 shows the ranking of generic manufacturers based on the value of their sales to hospitals and retail pharmacies in Canada.

Table 1. Ranking of Generic Manufacturers by Sales

2006 Rank	Manufacturer	Year 2006 \$(000s)	Year 2006 (%)	Year 2006 Cumulative (%)
1	Apotex	1,100.8	34.16	34.16
2	Novopharm	483.0	14.99	49.15
3	Genpharm <sup>14</sup>	365.3	11.34	60.48
4	Ratiopharm	359.5	11.16	71.64
5	Pharmascience	280.5	8.70	80.34
6	Sandoz Canada	190.1	5.90	86.24

<sup>13</sup> For the purpose of this analysis, we use the term "manufacturer", even though a company did not manufacture but just distributes the product in Canada. According the *Food and Drug Regulations, C.R.C., c. 870*, a "manufacturer" of a drug is not necessarily the company that makes the product, but the company to which the product is registered at the time of approval.

<sup>14</sup> Recently bought by Mylan Laboratories Inc. as part of its acquisition of Merck KGaA's generic business, Genpharm's parent company.

7	Cobalt Pharma	77.4	2.40	88.65
8	Mayne Pharma Canada <sup>15</sup>	54.8	1.70	90.35
9	Taro Pharmaceuticals <sup>16</sup>	37.3	1.16	91.50
10	Ranbaxy Pharmaceuticals Canada	34.2	1.06	92.56
11	Laboratoires Riva	28.2	0.88	93.44
12	Nu-Pharm	14.8	0.46	93.90
13	Hospira	14.3	0.44	94.34
14	Dominion Pharmacal	12.5	0.39	94.73
15	ProDoc	11.6	0.36	95.09
	Others	158.2	4.91	100.00
	All Manufacturers	3,222.5	100.0	

Source: IMS Health.

Generic manufacturers provide their products through three main supply routes: Independent pharmacy distributors (IPDs), pharmacy chain self distributors, and direct to pharmacy shipments. IPDs, discussed in the next chapter, are the principal supply route followed by self distribution. Some direct sales continue to occur but are a declining means for providing supply.

## 2.2. Generic Drug Supply Considerations

Manufacturers consider several factors when determining whether or not to develop and introduce an independent generic (IG) product. Key considerations include the following:

- Demand size and competition: The projected aggregate demand size of the reference brand product as well as the related therapeutic class, play important roles. First, the generic manufacturers take into consideration how many manufacturers are expected to introduce competing generic versions (independently or under licensing agreements) of the targeted molecule. Second, branded companies may in some cases provide added competition to the generic manufacturer by introducing: (i) a competing drug within the same therapeutic class, or (ii) brand extensions to replace older formulations whose patents are about to expire. Brand extensions may reduce the potential demand size available to the generic industry once the original drug loses patent protection, with a proportion of patients being prescribed the new version.<sup>17</sup>

<sup>15</sup> Recently bought by Hospira Inc. as part of its acquisition of Mayne Pharma Limited, Mayne Pharma Canada's parent company.

<sup>16</sup> Recently bought by Sun Pharmaceutical Industries Limited, an Indian pharmaceuticals company.

<sup>17</sup> While *NOC Regulations* prevent a firm from using the process to delay a generic version of the original formulation when the brand-name drug loses patent protection, it does not prevent a brand-name firm from marketing "new and improved" formulations.

- **Development and approval costs:** An important part of the entry decision is the evaluation of the total costs of introducing a generic drug to the market. These costs relate to drug development, the need to conduct bio-equivalence and/or clinical studies and federal and provincial approvals.
- **Timing:** The length of time it would take to develop the product and obtain approval from Health Canada is a crucial consideration. This is especially so if it results in the late release of a generic product after the relevant brand-name product loses patent protection.<sup>18</sup>
- **Specialization and product portfolio:** For example, a manufacturer involved in some related work, or specializing in drugs within a certain therapeutic class or in certain dosage forms (creams, ointments, injectables), would benefit from economies of scale or scope in production. On the other hand, manufacturers may wish to supply a drug to make their product portfolio more attractive to customers.
- **Legal challenge costs:** Challenging brand patents, as discussed below, can be a costly and time-consuming process. A generic manufacturer already involved in legal challenges may decide not to enter into another challenge.

Once all factors and risks are considered, the manufacturer is then in a position to calculate its projected sales versus costs. If the expected return on investment is favourable, then the decision to develop the product may go forward. There is no unique entry threshold for molecules coming off patent. It varies among manufacturers and depends on the characteristics of the molecule, the manufacturer and the barriers to entry.

### **2.3 Barriers to Entering the Supply of a Generic Product**

Generics may be classified into IGs, developed and supplied without authorization by the brand drug manufacturer, and authorized generics (AGs) that are supplied under licenses granted by the relevant brand drug company.<sup>19</sup> In bringing an IG to the market, a manufacturer encounters various barriers to entry. Key barriers to entry relate to sunk costs associated with drug development, regulatory approval and provincial formulary listings.<sup>20</sup>

#### *Drug Development*

The development of IGs normally involves three key steps:

- Securing the active pharmaceutical ingredient (API): Described by some as the "key to the industry", an API can be obtained through two sources: (a) international suppliers from India, China and other countries operating in Canada; or (b) internal sourcing through integrated arms of the manufacturer.

<sup>18</sup> The approval process is described in more detail in the next section.

<sup>19</sup> Licensing may also take place between two generics manufacturers.

<sup>20</sup> Sunk costs are costs that are non-recoverable once spent.



ii. Pre-Formulation: At this stage, generic manufacturers engage their chemists to develop drug formulations based on an analysis of the product itself as well as its monograph (listing both the active and non-active ingredients).

iii. Formulation: This stage involves continuing research and development (R&D) and the actual preparation of test batches of generic versions, first in the laboratory (initial small batches) and then in the manufacturing facilities (pilot batches).

The development costs of an IG may not be specific to the sale of the product in any particular country. Generic products developed and manufactured in one country can be supplied to other countries, provided they meet the other countries' specific regulatory requirements for approval.

Those contacted for this study indicated that development costs for a generic product can vary greatly from one to the next. Even in simple cases, costs may be around \$1.5 million. However, they can be several times higher for more complicated products, such as biologics.

### *Regulatory Approval*

In order to market an IG in Canada, a manufacturer must obtain approval from Health Canada under the *Patented Medicines (Notice of Compliance) Regulations (NOC Regulations)*. The *NOC Regulations*, as explained in detail in Appendix 1, address two issues, first, whether the IG is bio-equivalent to the Canadian brand reference product, and, second, whether the IG infringes any valid patents.

### Bio-equivalency

To market an IG, the manufacturer must file an Abbreviated New Drug Submission (ANDS) with the Therapeutic Products Directorate (TPD) of Health Canada, containing data that demonstrate the drug's bio-equivalence with a Canadian reference brand product.

The ANDS must contain sufficient information for Health Canada to assess the bio-equivalence of the generic to the brand-name product, as well as evidence of tests conducted on potency, purity and stability of the new drug.<sup>21</sup>

Standard bio-equivalence studies measure the rate and extent of absorption - or bio-availability - of a generic drug. This is then compared to the same characteristics of the reference drug product. The bio-availability of the generic drug must fall within an acceptable range of the bio-availability of the reference product. According to those

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<sup>21</sup> The generic firm may undertake its own clinical trials instead of conducting bio-equivalence studies. In practice, however, showing bio-equivalence is much less expensive and generic firms almost always choose this path. See *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26.

contacted for this study, typical costs for conducting bio-equivalency studies are in the range of \$1-1.5 million per product.

In the case of generic drugs, clinical trials are generally required for:

- More complex formulations
- When a brand-name product is claimed to be 'process-dependent';
- When a blood-sample study is inappropriate.

For example, topical products do not enter the blood stream so they are tested through clinical trials.

Clinical trials are research programs conducted to evaluate a new medical treatment, drug or device. These studies involve patients in the testing of treatments and therapies. Clinical trials, measure a drug's safety, effectiveness, dosage requirements and side effects. They are normally much more costly and time-consuming than bio-equivalence studies.

In doing its assessment of the bio-equivalence of a generic product (or an ANDS), Health Canada relies on data provided by the brand-name firm at the time it applied for a Notice of Compliance (NOC) for its product. These data are subject to a minimum period of protection from the date the reference product received its approval from Health Canada to be marketed. This period of protection, originally five years, was lengthened to eight years under amendments to the *NOC Regulations* in 2006. Where it extends beyond the life of the patent, the extended period of data protection may create an additional delay in bringing the generic drug to the market. The new regulations also allow six added months of data protection for drugs that have been the subject of clinical trials in children.

Once the ANDS is filed and, when applicable, the period of data protection ends, Health Canada typically takes between 12 and 18 months to complete its review.<sup>22</sup>

#### Patent Infringement

After filing an ANDS with the Minister, generic manufacturers are required under the *NOC Regulations* to serve a Notice of Allegation (NOA) on the patentee that the generic product will not infringe any patent rights. The patentee may then apply to the court for an order prohibiting the Minister of Health from issuing an NOC on the basis that one of its patents is being infringed. In such cases, the Minister cannot issue an NOC until 24 months have passed or the application has been dismissed. Therefore, the patentee can prevent a generic product from entering the market for up to 24 months, simply by alleging that its patents have been infringed.

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<sup>22</sup> In the case of topical products, the NOC application cannot be submitted until after the clinical trial results are available. Once the NOC application has been submitted, approval of topical prescription products takes from six to eight months.

Prior to 2006, generics were required to address all patents added by the patentee to the Patent Register with respect to the reference drug product. In 2006, the *NOC Regulations* were amended to restrict the ability of a drug innovator to prevent a generic from getting an NOC by adding patents to the patent register after the generic manufacturer files an ANDS.<sup>23</sup> The generic now only has to address patents that were listed on the register in respect of the reference drug prior to the filing date of the ANDS.<sup>24</sup>

If a patentee obtains a stay preventing the Minister from issuing an NOC, but the patents relied upon are later found to be invalid or not infringed, the generic firm that was kept off the market may seek damages for its losses. Under s. 8 of the *NOC Regulations*, the court may “make any order for relief by way of damages that the circumstances require”.<sup>25</sup>

In addition to the *NOC Regulations*, in some cases, the patentee may rely on a patent lawsuit to prevent entry of a generic drug or to recover damages. In such cases, a generic might succeed under the *NOC Regulations*, market the drug and then be sued by the brand-name manufacturer for patent infringement. In this case, if the brand-name manufacturer is successful, the generic would likely be required to pay damages to the patentee. Conversely, a generic manufacturer may challenge the validity of a patent under the *Patent Act* if it is preventing the company from receiving a NOC.

Success in the NOC proceedings by a particular firm does not automatically create free entry for all generic firms. Other generic firms still have to obtain an NOC, and address any patents on the Patent Register. Subsequent generic firms may, however, make the same arguments in litigation as the first successful generic. In some cases, the patentee may stop contesting these NOC cases.

Those interviewed for this study, while not providing related data, indicated that patent challenges under the *NOC Regulations* are commonly encountered and are a normal part of bringing an IG to market. Legal costs for the first generic to challenge were said to be commonly in excess of \$1 million and potentially much higher in complicated cases. However, the costs for subsequent generic manufacturers, for the same reference product, can be as low as a few thousand dollars when NOAs are no longer being challenged.

#### *Provincial Formulary Listing*

Once an NOC is issued, a product can be sold anywhere in Canada. However, in order to be reimbursed under provincial drug programs and obtain significant sales volumes the generic product must be listed on provincial formularies. For an IG, the formulary listing process can take several months from the time an NOC is issued.

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<sup>23</sup> In a subsequent 2006 decision, the Supreme Court of Canada held that a generic manufacturer is only required to address patents on the Patent Register that are relevant to the actual comparator drug. In addition, the generic manufacturer is not required to address patents issued after the NOA was made (since the generic manufacturer could have received no benefit from those patents). See *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, [2006] S.C.J. No. 49.

<sup>24</sup> SOR/93-133, s. 4.

<sup>25</sup> *Ibid.*, s. 8(4).



In sum, from the time a decision is made to produce a generic drug, manufacturers typically require between three to six years to bring the product to market. While costs can vary widely from case to case, they can be in the range of \$3.5 million (including costs for bio-equivalence studies, development and regulatory approval) even for a relatively non-complex product.

These costs may be lower where, for example, patent challenges are not encountered or product development costs can be spread across sales in countries other than Canada. On the other hand, they can be much higher when product development is more complicated, clinical trials are required, or relatively high patent challenge costs are encountered. For example, the costs for the development of bio-generics can be as high as \$25 to \$50 million. Industry sources have indicated that it may take as long as three years after a generic product is introduced to market before it will break even, recouping its sunk developmental and approval costs.

## **2.4 Competitive Dimensions**

Competition between generic manufacturers takes place in a number of dimensions. The key ones are: timing to market, patent challenges, pricing, AGs, and breadth of product line.

### *Timing to Market*

Those contacted for this study cited timing to market as being a key dimension of generic competition. Pharmacies are less likely to switch to a new generic product if they already have one or two versions in stock. Stocking multiple manufacturers of the same molecule is cumbersome and inefficient. For this reason, "timing is of the essence" in the generic drug industry. Product development and approval is carefully planned to maximize the likelihood of having a generic version ready as soon as a brand-name product loses patent protection.

The advantage of being first to market is supported by analysis performed on molecules that lost patent protection and encountered generic entry between January 1998 and December 2006. As shown in Table 2, for about two thirds of the molecules, the first entrant was able to maintain the leader's position at the end of 2006.

Table 2. Status Of The First Generic Entrant

	Number of Molecules	Percentage
First generic entrant stayed first	49	65.3
First generic dropped to 2 <sup>nd</sup> position	14	18.6
First generic dropped to 3 <sup>rd</sup> position	6	8.0
First generic dropped to 4 <sup>th</sup> position or lower	6	8.0
<b>Total</b>	<b>75</b>	<b>100.0</b>

Data source: IMS Health.

### *Patent Challenges*

A competitive dimension related to timing to market is companies' patent challenge strategies. A generic company may file its ANDS to market a generic because the brand-name drug's main patent has expired or is about to expire. By marketing the generic, the generic company is not infringing on any of the other patents that are held by the brand-name company.<sup>26</sup> However, sources contacted for the study indicated that generic companies commonly enter the market prior to the expiry of all listed patents based on the belief that any remaining brand company patents are invalid or would not be infringed.

Companies that are the first to file a challenge may gain an advantage over others by getting their product into the supply chain earlier. However, not all generic manufacturers aggressively pursue legal challenges. According to industry sources, some generic manufacturers challenge only those patents where there is a perceived certainty of a positive outcome, such as where a brand company is no longer challenging NOAs. They may avoid the costs of legal proceedings altogether by timing their entry to the market in line with the brand's patent expiration.

While a generic that first successfully challenges brand patents may have the advantage of being first to market, this can be a costly process. The generic manufacturer has to evaluate whether costs sunk into a patent challenge can be recouped after the product launches.

In cases where the brand manufacturer fights the first generic challenger but gives up further challenges, thereby opening the market to all generics, the first generic challenger may not obtain a major first mover advantage. The generic may be in a situation where it

<sup>26</sup> In addition to patents related to the active ingredient(s), formulation and process patents are listed by brand-name companies on the Patent Register. Typically, the patents on active ingredients expire first, thus giving generic manufacturers the possibility to enter the market by challenging the remaining patents prior to their expiration.

is out of pocket for legal costs and has to compete against other generics, IGs or AGs, which did not incur the same costs.<sup>27</sup>

### *Pricing*

In the case of sales to retail pharmacies, pricing decisions by manufacturers consist of two elements: the establishment of the product's invoice price and the net pharmacy price. The net pharmacy price is the price paid by the pharmacy net of any off invoice rebates and discounts. Invoice prices are the amounts typically reimbursed by public and private drug plans. As developed further in section 5.A., limited competition appears to take place in invoice prices. Until recently, invoice prices have tended to reflect maximum generic prices allowed under Ontario legislation. Price competition among manufacturers has tended to take place at the pharmacy level in the form of lower net pharmacy prices. Once generic versions of brand-name products are placed on provincial formularies and are designated as interchangeable, they essentially become commodity products.<sup>28</sup>

This situation results in pharmacies being the most important and influential customers of generic manufacturers. Traditionally, the most important factor in competing for pharmacies' business, where there are multiple generics available, has been generic manufacturers providing rebates off invoice prices.<sup>29</sup> Rebates on generic drugs are not recorded on invoices, but are provided to pharmacies and hospitals in a separate transaction often as a lump sum for drugs purchased in a given period.

It has not been possible to obtain information about the precise size and nature of rebates from manufacturers to retail pharmacies and hospitals. Average rebates have been estimated to be 40%, although sources indicated they may have been higher.<sup>30</sup> Sources further indicated that rebates have been as high as 80% for individual generic products.

The traditional role of rebates as a competitive dimension is being altered by the *Ontario Transparent Drug System for Patients Act, 2006*, discussed further in Section 4.A.2. The legislation prohibits the granting of rebates to pharmacies. While it allows professional allowances to be provided as a possible alternative to rebates, these are capped at 20% of pharmacies' costs for drugs dispensed under Ontario Drug Benefit (ODB) programs. In addition, the legislation, with certain exceptions, reduces the maximum amount that can be reimbursed for generics, under ODB plans, to 50% of the brand drug price. These

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<sup>27</sup> It has been suggested that this could result in there being limited incentive to challenge patents. While this may be unlikely to be the case for popular drugs, it could affect the supply of generics for drugs with limited use and/or smaller sales. Examining this matter is an empirical issue beyond the scope of this study.

<sup>28</sup> As developed in section 5.A., there may be limited exceptions for medical reasons.

<sup>29</sup> Effective supply chain management is another key consideration. Pharmacies want to be sure that a drug is available to be dispensed to patients when needed.

<sup>30</sup> Public sources that put the average rebate at 40% include: i) CIBC World Markets, "2003 Investors' Guide To The Canadian Drugstore Industry", May 26, 2003 and ii) Ontario Ministry of Health and Long-term Care, "Challenges Facing Ontario's Drug System And How We Are Responding To Them", available at: [www.health.gov.on.ca/english/media/news\\_releases/archives/nr\\_06/apr/bg\\_041306\\_a.pdf](http://www.health.gov.on.ca/english/media/news_releases/archives/nr_06/apr/bg_041306_a.pdf). The implications of rebates for pharmacies are discussed in section 4.A.2.



generic drug price or professional allowance caps do not apply to drugs dispensed under private drug plans. The legislation makes Ontario the second province in Canada to prohibit rebates. Such rebates have been prohibited for several years in Quebec and have been recently the subject of a number of legal actions.<sup>31</sup>

While the full effects of the Ontario legislation are to be determined, the capping of generic drug professional allowances limits a key dimension of competition among generic drug manufacturers. The altered competitive framework may be particularly problematic for generic drug manufacturers with limited product portfolios. The ability to grant higher rebates or allowances can provide them a means to enter and expand market share in competition against rivals with broader product lines. With rebates and allowances being restricted or prohibited, it can be anticipated that competition in other areas, such as breadth of product line, will assume greater importance.

#### *Authorized Generics*

AGs are “the actual brand-name drug product manufactured by the brand company, but sold as a generic by a licensee or subsidiary of the brand, competing with independent generics.”<sup>32</sup> Because they are identical to the branded drugs and approved by the patent holder, AGs do not encounter the product development and federal regulatory approval barriers to entry that apply to IGs. Although in some provinces listing of AGs on provincial drug formularies can be faster, under the streamlined formulary listing process employed by most provinces there is no advantage for AGs.

Introducing an AG prior to the expiration of a brand-name product’s period of patent protection runs counter to the business interests of a brand-name manufacturer. The lower-price AG will simply erode the market share of its higher priced brand-name counterpart diminishing the brand company’s revenues. However, licensing the supply of an AG after the end of patent protection potentially provides the brand company a means to make some returns on a portion of generic drug sales.

A brand-name manufacturer may decide to license the manufacturing and distribution of the AG to an IG manufacturer. The decision of an IG manufacturer to partner with a brand-name manufacturer for the release of an AG is based on several factors. These may include their ability to source APIs to produce their own generic version and the expected return on supply of the AG versus developing and marketing its own IG. IG

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<sup>31</sup> In 2004, the province took four different legal actions before the Superior court of Quebec against four manufacturers of generic drugs (Apotex, Novopharm, Pharmascience and Ratiopharm) alleging that they had, between 2000 and 2003 given approximately 37% of illegal rebates and discounts. See for example the decision of the Superior Court of Quebec dated July 27, 2004, with respect to *Quebec (Régie de l'Assurance-maladie) c. Pharmascience Inc.*, 2004 CanLII 4667 (QC C.S.). See also respective files of the Superior court of Quebec no 500-17-015571-030, no 500-17-015460-036 and no 500-17-015406-039. In Quebec, Bill 130 adopted in 2005 and the Quebec Drug Policy published in February 2007 have set the stage for future “professional allowances” similar to Ontario’s to be provided. However, they are not yet included in regulations.

<sup>32</sup> Aidan Hollis and Bryan Liang, “Assessing the effects of authorized generics on consumer prices” *Journal of Biolaw and Business*, forthcoming.

manufacturers differ on their AG strategies. While some engage in little if any supply of AGs, others incorporate them as a component of their business strategy. According to industry sources, the number of AGs available in the Canadian market has been trending downwards. In 2006, AGs accounted for only about 7% of the generic sales, compared to about 15% in the early 90s.

An issue about introducing an AG is that it may affect the incentive for a generic manufacturer to develop an IG.<sup>33</sup> This is unlikely to be an issue for drugs having high sales relative to entry costs. However, it has the potential to affect the entry of IGs for drugs having relatively smaller valued sales. This may be particularly significant when the AG is able to obtain a first mover advantage. This matter is considered in Table 3.

Statistical analysis was performed on a set of molecules that lost patent protection between 2001 and 2006 and where the first generic competitor entered within the period. An AG entered 26 (36%) of the 75 drug markets in the sample.<sup>34</sup> No clear pattern was found of AGs entering first. Of the 26 markets in which both an AG and an IG entered, the IG entered first in 12, the AG entered first in 11. They both entered in the same month in three markets. Note that in about half of the cases, the AG entered the market after an IG. However, in only two of the cases where it entered first, was the AG able to maintain the highest share. Table 3 shows the status of the AG in January 2007 and the timing of AG entry.

Table 3. Status Of The Authorized Generic After Independent Generic Entry

	Number of molecules
AG entered before the IG	11
AG entered 1 <sup>st</sup> and retained highest share	2
AG entered at the same time as the IG	3
AG entered after the IG	12
<b>Total</b>	<b>26</b>

Data source: IMS Health.

The sample does not show a clear and consistent pattern of AGs entering before IGs. Moreover, where they do enter first, AGs, while they may obtain high market share for an initial period, retain leadership over time in only a small number of cases.<sup>35</sup>

<sup>33</sup> The issue of authorized generics and their role in providing competition to independent generics is being considered by the US Federal Trade Commission, which is conducting a related market study.

<sup>34</sup> A drug market was defined for the purpose of the study as a unique combination of molecule and dosage form.

<sup>35</sup> These results are partial, based on a limited set of drugs. More information (e.g. a broader sample size, information on terms of contract and market size) is needed to assess fully the impact of AGs on the competitive framework for generic drugs.

### *Breadth of Product Line*

As discussed further in section 4.A, given the commodity nature of generic drugs, other things equal, pharmacies can reduce their costs by dealing with as few manufacturers as possible. This provides more diversified manufacturing firms with a competitive advantage over competitors with smaller product lines as they are able to bundle a portfolio of products across multiple therapeutic classes.<sup>36</sup> As indicated above, one means by which less diversified manufacturers have been able to overcome this disadvantage has been by offering lower net pharmacy prices.

### **2.5 State of Competition**

The current competitive structure of the Canadian generic drug manufacturing sector is significantly different from that of the early 1990's. At that time, Apotex and Novopharm accounted for the majority of sales in the domestic market (72.8%).<sup>37</sup> In 2006, although the two largest firms remained Apotex and Novopharm, with approximately 50% of sales, the top four firms accounted for under 72% of sales.

The dynamics of the generic drug manufacturing sector is also being altered by increasing globalization. In 2000, Teva, a large Israeli generic drug manufacturer, entered the Canadian sector by purchasing Novopharm. This was followed by the expansion into Canada of Ratiopharm, a German generic drug company and one of the leading international generic producers. The third Canadian largest supplier, Genpharm, was recently acquired by a U.S. generic company, Mylan Laboratories from Merck, based in Germany. Indian generic manufacturers have also entered the Canadian sector through the entry of Ranbaxy in 2005, and the acquisition of Taro by Sun Pharmaceuticals in 2007.

An in depth analysis of the competition across the sector could not be done as the information on such matters as the net pharmacy prices and manufacturing costs for individual drugs was unavailable.<sup>38</sup> However, it appears that supply for many generic products is highly competitive. The expiration of brand-name pharmaceutical patents can be met by the introduction of multiple generic products. The number of competitive suppliers is more likely to be large in markets for popular molecules, the so-called "blockbuster drugs." Chart 1 shows the number of generic entrants per molecule and the sales of the brand in the year prior to generic entry. As the chart indicates, molecules with large sales tend to attract a large number of generic competitors.<sup>39</sup>

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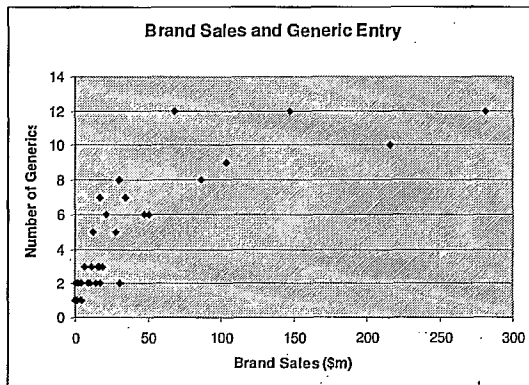
<sup>36</sup> While such bundling is not inherently anti-competitive, bundling can have anti-competitive effects in certain circumstances, for example, where it is used by a dominant firm to exclude competitors from the market resulting in a substantially lessening of competition.

<sup>37</sup> Source: Canadian Generic Pharmaceuticals Association (CGPA).

<sup>38</sup> Further, such an analysis would require detailed information regarding which products should be included in the relevant markets and related barriers to entry. For example, the mere finding that a non-patented product has one or a small number of suppliers, is not adequate to conclude that is not subject to competition.

<sup>39</sup> A set of 32 molecules for which the first generic entered between January 2002 and July 2006 was analyzed. Brand sales in the year prior to the first generic entrant are considered.

Chart 1. Generic Entry



Data source: IMS Health.

The effects of the competition among manufacturers have traditionally not been reflected in invoice prices for generic drugs. Rather, with price competition focused on pharmacies, its effects are reflected in net pharmacy prices. As indicated above, these prices have been estimated to be on average at least 40% below the invoice prices used by the PMPRB and other pricing studies.

This suggests that other elements of the Canadian generic sector competitive framework must be taken into consideration to explain the differences between invoice prices in Canada and other countries. As noted above, work done by the PMPRB indicates that although Canada ranks in the middle of six countries studied in terms of the average number of generic suppliers for each non-patented product, the country has substantially higher invoice prices for generic drugs than 10 of 11 countries covered in its 2006 generic prices study.<sup>40</sup>

<sup>40</sup> PMPRB, October 2006 and June 2006, *supra*, note 6.



## **Chapter 3: Independent Pharmacy Distributors**

Independent pharmacy distributors (IPDs) are third party companies which acquire generic and brand drugs, as well as other products to distribute to retail pharmacies and hospitals. IPDs play an increasingly important role in the supply and management of prescription pharmaceuticals. Well over 50% of all prescribed pharmaceuticals are distributed to pharmacies through IPDs with this share increasing.

This section outlines the Canadian IPD sector and discusses its role in generic drug competition in Canada.

### **3.1 The Canadian IPD Sector**

As independent intermediaries between the manufacturers and suppliers of drug store products, and pharmacies, IPDs stock and supply a wide range of prescribed pharmaceutical products as well as typical retail pharmacy products. These include over the counter (OTC) medicines, health and beauty aids, and confectionery items.

They may provide a variety of services including the following:

- Daily delivery or sometimes twice a day delivery, depending on the location of the pharmacy
- Consolidation of purchases, reception and payments of products by the pharmacy, including the management of expired products and their return to the manufacturers
- Serving as a back-up source of supply for other wholesalers' customers or for a self-distributing chain, when the chain's warehouse runs out of stock or closes for weekends
- Inventory management with continuous replenishment through a linked information system
- Electronic access to a product catalogue, product orders, billing and information research
- Controlled storage and temperature control of a variety of pharmaceutical products
- Refrigeration systems for specialty products
- Inventory of high-value-low-turnover products.

Because of these services, distributors' costs include major expenses for warehousing, transportation, human resources and information systems. They may also help finance customers' inventory by providing them with lines of credit.

McKesson Canada is the largest pharmacy distributor in the country. It carries more than 35,000 products, in 16 distribution centers. It provides logistics and distribution to over 800 manufacturers delivering their products to 6,800 retail pharmacies, and 1,350 hospitals, long-term care centres, clinics and institutions all over Canada.

AmerisourceBergen Canada is the second largest distributor in the country. It has 12 distribution centers and services independent retail pharmacies, national and regional chains, and hospitals. Kohl & Frisch Limited has 5 distribution centers across Canada.

Other distributors, such as Unipharm Wholesale Drugs Ltd, UPE Group of Companies and McMahon Distributeur Pharmaceutique Inc., tend to be more regionally focused.<sup>41</sup>

### 3.2 Role of IPDs in the Generic Drug Competitive Framework

IPDs are one of three means by which generic drug manufacturers can distribute their products. The others are through drugstore group self-distribution, and direct distribution by manufacturers.

Under self-distribution, distribution centres are maintained by pharmacy chain, banner and franchise groups, for supply to pharmacies within the group. Self-distribution involves similar roles and activities to those of IPDs, but within a group of pharmacies.

Major self-distributors include, Shoppers Drug Mart, Groupe Jean Coutu (PJC), Familiprix Inc., Lawton's Drugstore, and London Drugs.

In direct distribution, as the name implies, manufacturers ship directly to drugstores.

IPDs are becoming an increasingly important means for distributing pharmaceuticals in Canada. In 2006, they accounted for 57% of pharmaceuticals distributed in Canada, other than to Wal-Mart. This is 6% more than in 2002. Self-distribution also increased over this period from 30 to 34%. In contrast, direct distribution fell by more than half, to 9% from 19%.

Table 4. Share of Pharmaceuticals (\$) by Distribution Channel (DC)

	Distributor (%)	Chain DC (%)	Direct (%)	Total (%)
2002	51	30	19	100
2003	54	30	16	100
2004	56	32	12	100
2005	57	33	10	100
2006	57	34	9	100

Source: Canadian Association for Pharmacy Distribution Management (CAPDM) Industry Trends Report, December 2006.

According to those contacted for the study, the increased use of IPDs is due principally to their ability to provide their customers with one-stop shopping. While they play an important intermediary role in the sector, IPDs' impact on the competitive framework and pricing of generic drugs appears to be limited. According to interviews, IPDs do not enter into or maintain restrictive supply agreements or contracts with drug manufacturers. They purchase pharmaceuticals from all manufacturers as required to meet their pharmacy customers' needs. Once a relationship is established, purchases from manufacturers to distributors may be automated to deliver inventory on time. The

<sup>41</sup> Sources: interviews with sector participants, company web sites and other public sources.

warehouse information system can be connected to that of the manufacturer. When a product is needed, it can be ordered electronically.

While ancillary terms may vary, such as discounts for prompt payment, the price paid by wholesalers for pharmaceuticals is based on the provincial formulary or manufacturers' list price. In the case of generic drugs, the price to distributors is discounted by the distribution fee (or mark-up) allowing the drugs to be distributed to pharmacies at their invoice price. According to sources, these fees are typically in the range of 5% of the value of the generic drugs distributed. This is not the case with branded products, where distribution fees are typically paid by the pharmacy and are in addition to the drug invoice price.

## Chapter 4: Pharmacies and Hospitals

Pharmacies and hospitals provide the main interface between generic drug suppliers, patients and reimbursers. They are the main focal point for competition among generic manufacturers.

This chapter provides an overview of relevant features of the Canadian pharmacy and hospital sectors, and develops their role in the competitive framework for generic drugs.

### 4.A The Canadian Retail Pharmacy Sector

#### 4.A.1 Overview

There are more than 7,900 retail pharmacies in Canada.<sup>42</sup> In 2006, they purchased \$15.74 billion worth of prescription pharmaceuticals and filled over 422,000,000 prescriptions.<sup>43</sup> The ten therapeutic classes of drugs most frequently dispensed by retail pharmacies in 2006 are indicated in the following table.

Table 5. Pharmacy Sales By Therapeutic Class, 2006

Rank 2006	Therapeutic Class	Purchases 2006 (\$000,000s)
1	Cardiovasculars	2,409
2	Antihyperlipidemic agents	1,653
3	Psychotherapeutics	1,623
4	Antispasmodic/antisecretory	1,275
5	Analgesics	746
6	Bronchial therapy	718
7	Anti-arthritis	649
8	Hormones	634
9	Neurological disorders, miscellaneous	617
10	Diabetes therapy	567

Source: IMS Health.

Retail pharmacies in Canada are organized into a range of business structures. Key categories include the following:

<sup>42</sup> Source CAPDM *Industry Trend Report: Focus on Retail Pharmacy*, December 2006.

<sup>43</sup> See IMS News Release for "2006 Canadian Pharmaceuticals Review" available at: [www.imshealthcanada.com/vgn/images/portal/cit\\_40000873/7/25/80533297IMS%20Release%20Final%20English.pdf](http://www.imshealthcanada.com/vgn/images/portal/cit_40000873/7/25/80533297IMS%20Release%20Final%20English.pdf).

## *Independents*

An independent pharmacy is not affiliated with any corporately run banner, franchise or chain program. The name of the store is unique to that store, and the owner controls, among other things, ordering, marketing strategies and store image.

## *Pharmacy Groups*

### i Banner

Banner pharmacies are independently owned pharmacies that are affiliated with a central office. They pay fees for the right to use a recognized name (such as I.D.A., Guardian, Uniprix, Price Watchers, Pharmasave) and to participate in centralized buying, marketing, professional programs and other services. While banner stores usually assume a required “look and feel,” the stores themselves are independently owned and the owners retain a high level of autonomy in areas such as local marketing and professional services.

### ii Franchise

Franchise arrangements vary widely for retail pharmacies in Canada. The two largest franchises are Shoppers Drug Mart and Jean Coutu. The franchisees (or “associates” in the case of Shoppers Drug Mart) do not necessarily own the physical store or the fixtures, and master leases are usually held by the franchisor. However, they enjoy some autonomy in local marketing, buying and in-store services, as well as access to programs developed by the head office.

### iii Chain

Chain pharmacies, such as Pharma Plus and Lawtons, employ pharmacy managers who are salaried employees. Head office directs all marketing, merchandising, buying, and professional programs as well as other matters.

### iv Foodstore & Mass Merchandiser (“Food/Mass”)

Food and mass merchandiser pharmacies are departments within supermarket or mass merchandise outlets, such as Loblaws and Wal Mart. They employ salaried pharmacy managers (except in Quebec, where regulations require pharmacists to own the dispensary). The managers follow the direction of the head office for all marketing, merchandising, buying, professional activities, and other matters.<sup>44</sup>

As indicated in the table below, retail pharmacy groups, including chain, banner and franchise pharmacies, collectively accounted for over 4,600 pharmacies in Canada in 2006, or about 58% of all retail pharmacies in the country. Food and mass merchandisers

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<sup>44</sup> These definitions are taken from McKesson Canada Trends and Insights Report, 2006, pp. 12–13.



accounted for 1,592 stores and independents for 1,686 stores, or about 20 and 21%, respectively.<sup>45</sup>

The allocation of Canadian retail pharmacies to the above categories has undergone substantial change over the past several years. Table 6 indicates that there has been a significant trend away from independent pharmacies to other pharmacy categories. Over the 2001 to 2006 period, while the total number of pharmacies increased by more than 900 outlets, the number of independent pharmacies actually fell from 1,837 to 1,686.

While independents remain a major category, their share of all retail pharmacies fell from 31 to 21%. The total number of stores in both other categories increased, with proportionately larger growth in food and mass merchandise outlets. These increased their share of all retail pharmacies from 14% to 20%. While the total number of chain, banner and franchise outlets increased, their share of all retail outlets decreased slightly from 60% to 58%.

Table 6. Retail Pharmacy Count By Category

Pharmacy Category <sup>46</sup>	2001	2002	2003	2004	2005	2006
Food/Mass Merchandisers	979	1,248	1,315	1,503	1,557	1,592
Independents	1,837	1,717	1,614	1,639	1,663	1,686
Chain/Banner/Franchise	4,171	4,298	4,440	4,443	4,558	4,627
Total	6,987	7,263	7,369	7,585	7,778	7,905

Source: CAPDM, Industry Trends Report, December 2006.

The two largest retail pharmacy groups in Canada are the Katz Group (Rexall), with over 1,100 outlets, and Shoppers Drug Mart (Pharmaprix in Quebec) with over 820 outlets. Collectively, they account for close to 25% of all retail outlets in Canada. Other major retailers include Loblaws, Pharmasave and Jean Coutu with, respectively, 470, 364 and 320 outlets. Collectively, these five pharmacy groups account for about 39% of all retail pharmacy outlets in Canada.<sup>47</sup>

The significance of individual pharmacy groups may vary significantly from province to province. Although Jean Coutu has the fourth highest number of outlets in Canada, these are concentrated in Quebec where the company's share of retail outlets is in the range of 18%. The next largest group in the province, Familiprix, has over 260 stores, representing about 16% of all pharmacy outlets.<sup>48</sup>

<sup>45</sup> Note that numbers do not add up to 100 due to rounding.

<sup>46</sup> Independents or banner store pharmacy owners that have 5 or more stores are considered to be pharmacy chains.

<sup>47</sup> Source: CAPDM "2006 Pharmacy Who's Who" and the Rexall Group at [www.Rexall.ca](http://www.Rexall.ca). Note that these numbers do not include pharmacies using independent pharmacy banner programs operated by McKesson Canada. Pharmacies subscribing to these programs number in excess of 650 across Canada.

<sup>48</sup> Total provincial retail pharmacy numbers are as provided by IMS Health for May 2006.

Regardless of their category, retail pharmacies in Canada typically have two main sources of revenue:

- Pharmacy operations, consisting of the dispensing of brand and generic prescription pharmaceuticals;
- Front store operations, consisting of the sale of OTC medication, health and beauty aids, general and seasonal merchandise.<sup>49</sup>

While the importance of these sources of revenue can vary significantly according to pharmacy category, the following table indicates that prescription drug sales are the principal source of revenue for all pharmacy categories. For all categories, prescription sales account for well over 50% of all revenues.

Table 7. Canadian Front-store and Dispensary Revenue by Pharmacy Category

	Independent	Franchise	Banner	Chain	Food	Dept/Mass
Average Rx volume	45,600	81,000	57,500	39,100	38,300	55,400
Usual and customary fee(\$)	9.73	9.90	9.61	8.98	8.01	7.51
Rx share of sales (%)	79	59	74	71	71	72
Total Sales (\$ million)	2.1	6.71	2.56	2.74	3.01	3.25

Source: 2006 Trends and Insights Online Report, The Pharmacy Group.<sup>50</sup>

#### 4.A.2 Role of Retail Pharmacies in the Competitive Framework For Generic Drugs

Retail pharmacies play a pivotal role in the competitive framework for, and pricing of, generic drugs in Canada. Though they do not prescribe pharmaceuticals, after a drug has been prescribed, pharmacists normally have broad scope, under provincial and professional laws, policies and regulations, to substitute among interchangeable generic and brand drugs products when filling prescriptions.<sup>51</sup> As well, to minimize their costs, pharmacies have an interest in stocking only one, or a small number of interchangeable products.

Because of this, competition among generic manufacturers and suppliers to supply generic drugs to patients in the community has tended to focus on pharmacies. As indicated in the manufacturing chapter, this competition takes place in a variety of ways. An important dimension has been to grant rebates to retail pharmacies off pharmacy invoice prices.

<sup>49</sup> CIBC Report, *supra*, note 38, p. 30.

<sup>50</sup> Available at: [www.pharmacygateway.ca](http://www.pharmacygateway.ca), p. 31. Numbers are for pharmacies and do not necessarily cover all sales in the relevant stores.

<sup>51</sup> Within the last year, some prescribing authority has been granted to pharmacists in various provinces, with more jurisdictions contemplating some form of prescribing role for the pharmacists. Provincial interchangeability laws, policies and regulations and other relevant aspect of provincial legislation and pharmaceutical plans are developed in section 5.A.

Previous analysis of the Canadian pharmaceutical sector and testimony provided in recent hearings on amendments to Ontario's generic drug related legislation and regulations indicate that these rebates provide important returns to pharmacies.<sup>52</sup>

Rebates have also provided a financial incentive for retail pharmacies to substitute generic products for branded products. As indicated in the manufacturing chapter and discussed further in section 5.A, off invoice rebates and discounts and other such benefits, have normally not been reflected in prices reimbursed by public and private insurers. Rather, those contacted for this study indicated that reimbursed prices for newly introduced generic drugs reflect the former maximum limits under Ontario provincial drug benefit legislation.

The following table shows the incentive provided to dispense generic drugs through off invoice rebates and discounts, and their impact on the profitability of pharmacies. The table is based on a representative branded drug prescription cost of \$40 reimbursed under the Ontario Drug Benefit (ODB) guidelines prior to the *Transparent Drug System for Patients Act*. The maximum generic drug invoice price, based on the former Ontario maximum generic drug price legislation is \$25.20.<sup>53</sup> The table uses an allowable mark-up of 10% of the cost of pharmaceuticals.<sup>54</sup> Rebates are set at 40%. In recent Ontario provincial generic drug related hearings, this was the lower range of rebates paid on average to independent Ontario pharmacies. Dispensing fees are set at \$6.54.<sup>55</sup>

Based on these numbers, the sale of a generic drug provides a net return to the pharmacy of \$19.18 versus \$10.54 for the brand product.<sup>56</sup>

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<sup>52</sup> See, for example, the comments to the Standing Committee on Social Policy on *Transparent Drug System For Patients Act, 2006*, by Pharmsave Ontario and the Coalition of Ontario Pharmacy, May 29, 2006.

<sup>53</sup> As discussed further in the public reimbursement discussion below, under Ontario legislation the maximum price for generic drugs reimbursed by the provinces was 70% of the brand equivalent price for the first generic product on the market, and 90% of the first generic product's price for subsequent generics. The numbers used for this example are based on the maximum cost of a second and subsequent generic products on the market.

<sup>54</sup> The numbers used in the table reflect allowable mark-ups and dispensing fees in Ontario prior to the creation of the *Transparent Drug System For Patients Act, 2006*. Allowable mark-ups may vary significantly in other provinces. Prior to June 2006, Ontario allowed a maximum mark-up of 10% but this has since been reduced to 8%.

<sup>55</sup> Dispensing fees can also vary substantially from province to province. For a listing of public drug plans allowable dispensing fees and mark-ups see CIHI, *supra*, note 1, Appendix.

<sup>56</sup> The spread between the return to sales of the generic drug versus the brand drug may be greater where allowable mark-ups are not contingent on third party distribution as these costs are normally absorbed by generic manufacturers but not suppliers of brand products.

Table 8. Historic Pharmacy Return On ODB Branded Versus Generic Drugs Sales

	Branded (\$)	Generic (\$)
Invoice Price	40.00	25.20
Allowable Markup(10%)	4.00	2.52
Dispensing Fee	6.54	6.54
Total (=Retail Price)	50.54	34.26
Rebates (40% of invoice)		10.08
Return (mark-up+dispensing fee+rebate)	10.54	19.14

In Ontario, pharmacy returns from the sale of generic drugs under ODB plans are being substantially affected by the changes made to Ontario generic drug legislation and regulations in 2006. The maximum cost for generic products reimbursed under ODB plans has been reduced to 50% of the interchangeable brand product, where more than one generic is available.

Manufacturers are now prohibited from granting rebates on generic drugs but they can provide professional service allowances in eight approved categories. For drugs dispensed under ODB plans, these allowances may equal up to 20% of product costs. For other drugs and other plans, there is no limit on the amount of professional allowances they can provide. In addition to these changes, the maximum allowable mark-up for ODB drugs dispensed to ODB patients has been reduced to 8% from 10% and maximum dispensing fees have been increased to \$7.00 from \$6.54.

The implications of these changes on pharmacies' return on ODB sales are reflected in the following table.

Table 9. Current Pharmacy Return On ODB Branded and Generic Drug Sales

	Branded (\$)	Generic (\$)
Invoice Price	40.00	20.00
Allowable Mark-Up (8%)	3.20	1.60
Dispensing Fee	7.00	7.00
Total(= Retail price)	50.20	28.60
Professional Allowances (20%)		4.00
Return(mark-up+dispensing fee+allowance)	10.20	12.60

Under the new Ontario legislation and policies, if maximum professional allowances are provided, pharmacies retain a financial incentive to dispense generic drugs for provincial plan beneficiaries. However the return to pharmacies in the form of rebates or allowances is reduced by just over 75%, from \$10.08 to \$4.00. The total return, including mark-ups and dispensing fees, is reduced 34.2% to \$12.60 from \$19.14.

Based on 40% rebates prior to the Transparent Drug System For Patients Act, 2006, the net price received by the generic drug manufacturer on ODB sales is higher under the

revised reimbursement framework. This framework, in effect, establishes a net pharmacy price floor at 40% of the brand drug price. By comparison, at 40% rebates under the previous ODB maximum price for multiple source generics, the net pharmacy price received by manufacturers was 37.9% of the brand price.

While the full impact of the new Ontario legislation and regulations on pharmacies and manufacturers is yet to be determined, as developed further in Chapter 5, the lower ODB prices have not been extended to non-ODB drug sales for which there is no maximum allowance. In addition, private sales are not subject to maximum dispensing fees or mark-ups.

It is anticipated that Quebec will receive the benefit of lower Ontario provincial drug plan prices because of their policy that they receive the lowest formulary prices offered in other provinces.<sup>57</sup> However, the potential impact of this change on pharmacies is mitigated by Quebec's pre-existing prohibition of rebates. Further, the province is also considering implementing a professional allowances scheme parallel to Ontario's.<sup>58</sup>

## **4.B Hospital Pharmacies**

### **4.B.1 Overview**

While retail pharmacies are the principal dispensers of drugs in Canada, hospital pharmacies also play a significant role. In 2006, they purchased \$2.08 billion of drugs, compared to \$15.74 billion purchased by retail pharmacies.

Hospital pharmacists oversee the dispensing and storage of all medicines given to patients in the hospital (in-patients). Generally, pharmacists in hospitals face greater clinical complexity in medication management while community pharmacists face more complex business and customer relations issues.

Under the Canada Health Act (CHA), all necessary drug therapy administered in a Canadian hospital setting is insured and publicly funded.<sup>59</sup> Out-patient medications are outside the Act's authority.

Provincial and territorial governments are responsible for providing hospital care in their jurisdictions. This includes planning, financing and evaluation of services, such as drug administration and management. Drugs purchased for hospital patients are covered by hospital budgets.

Hospitals maintain their own drug formularies listing all drugs available for prescription by a physician. Formularies tend to be similar from one hospital to another within the

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<sup>57</sup> The related Quebec policies are discussed in section 5.A.

<sup>58</sup> Ministerial proposal no 24 of the Quebec February 2007 Drug Policy would allow professional allowances similar to those permitted in Ontario.

<sup>59</sup> R.S.C. 1985, c. C-6.



same province. However, significant differences may be found from one province to another, especially on expensive therapies such as cancer drugs. Hospital drug formularies tend to be more specialized than provincial or private plan formularies. This is due to the inclusion of medications that might be given only in a hospital setting, such as intravenous (IV) drugs and other therapies that must be provided on an in-patient basis.

Most hospitals have Pharmacy and Therapeutics (P&T) committees that determine the drug selection for their formulary. Although these committees are multi-disciplinarian, formulary decision-making tends to be physician-driven. Physicians prescribe drugs for patients and the hospital pharmacist ensures that they are available on the formulary. As in retail pharmacies, in cases where there are multiple sources for one drug (brand-name and generics), generic drugs will normally be substituted for the brand drug unless the prescribing physician has indicated "no substitution".

In a retail pharmacy, drugs are dispensed for a specific number of treatment days for acute symptoms, or for a 30-day to 90-day supply for chronic symptoms. The standard of care for a hospital pharmacy is to dispense drugs on a unit-dose - a single dose of the medication. In unit-dose dispensing, medication is dispensed in a package that is ready to administer to the patient.<sup>60</sup>

The main therapeutic classes of drugs used in hospital settings differs greatly from retail pharmacies. Table 10 shows the top 10 therapeutic classes of drugs dispensed in hospitals by purchase cost in 2006. Cancer drugs are, by a wide margin, the largest class of drugs purchased by hospitals although they were not among the 10 largest classes purchased by retail pharmacies. Cardiovascular drugs, the largest class of drugs purchased by retail pharmacies, were the 9th largest class purchased by hospitals. In total, of the 10 largest classes of drugs purchased by hospitals, only 3 ranked among the 10 largest retail pharmacy categories.

Table 10. Top Ten Therapeutic Classes By Hospital Purchases, Canada, 2006

Rank 2006	Therapeutic Class	Hospital purchases \$(000,000s)
1	Oncology	557.3
2	Anti-Infectives, systemic	191.8
3	Hematinics	185.0
4	Hemostatic modifiers	164.4
5	Psychotherapeutics	120.3
6	Biologicals	101.2
7	Anti-virals	91.9
8	Immunologic Agents	72.5

<sup>60</sup> Ringold D.J., Santell J.P., Schneider P.J., Arenberg S. (1999), "ASHP national survey of pharmacy practice in acute care settings: prescribing and transcribing. American Society of Health-System Pharmacists", American Journal of Health System Pharmacy, 56, 142-157.

9	Cardiovasculars	61.9
10	Hormones	56.1
	Top 10 hospital classes	1,602.5

Source: IMS Health.

#### 4.B.2 Role of Hospitals in the Competitive Framework for Generic Drugs

Differences in hospital versus retail pharmacy drug purchases are also reflected in the ranking of generic manufacturers by hospital sales. While diversified producers offer a wide range of products in a variety of forms, others may specialize in injectables or topical application products that are more widely used in hospitals than in retail pharmacies. Table 11 indicates this. The table compares generic manufacturers' rankings for sales to hospitals versus total sales to hospitals and pharmacies for molecules that lost patent protection during the 2001 to 2006 period.

Table 11. Ranking Of Hospital Sales By Generic Manufacturer, 2006

Rank Hospital Sales	Share of Hospital Sales (%)	Manufacturer	Rank Total Sales	Share of Total Sales (%)
1	32.67	Mayne Pharma	8	2.20
2	24.03	Sandoz	7	3.52
3	14.97	Novopharm	2	16.54
4	14.33	Apotex	1	38.61
5	6.92	Pharmascience	5	7.70
6	4.86	Genpharm	3	14.45
7	1.46	Ratiopharm	4	8.07
8	0.42	Taro Pharma	10	1.06
9	0.12	Cobalt	6	4.29
10	0.03	Hospira	17	0.00
	0.18	Others		3.56
	100	Total		100

Data source: IMS Health.

Mayne Pharma Canada was the largest seller of these generic drugs to hospitals in 2006, but was the eighth largest generic manufacturer measured by total sales including both hospitals and retail pharmacies. Sandoz, ranked seventh in total sales, was ranked second measured in hospital sales. Apotex, which had the highest total sales, was ranked fourth in hospital sales only.

Prices for generic drugs used by hospitals are generally determined by negotiations and contracting between the hospitals themselves and the manufacturers. While this may be done on a hospital by hospital basis, it is increasingly being done through group purchasing organizations (GPOs) or Regional Health Authorities (RHAs).

GPOs, such as HealthPro, MedBuy and Contract Management Services, are stand alone operations whose shares are held by hospitals and other health care organizations. They were established by hospitals and other health care facilities to economize on their goods and material costs by providing centralized procurement and obtaining the benefits from buying in higher volumes.

RHAs were established by most provincial governments in the 1980s and 1990s to amalgamate various health services, including hospital services, within regions.<sup>61</sup> Although RHAs may participate in GPO programs, they may also do their own group purchasing.

GPO or RHA contracting processes are normally conducted in a public forum. The GPO or RHA will identify its needs for products, usually by conducting a comprehensive review of the products consumed by each member and their respective annual volumes and unit costs.

A Request for Information (RFI) process may be used, gathering information from members and suppliers. Supplier information is sought later, allowing for an economical value-added benefits analysis. These analyses are usually an integral component of the Request for Proposal.<sup>62</sup>

A Request for Proposal (RFP), outlining the market size, the items and conditions under which the contract will be developed, is issued to all interested suppliers. The contract awarded is often a sole source agreement with the supplier for participation by all of the GPO's members.

Contracts with brand/patented drugs manufacturers often include a right-of-first-refusal clause for cases where a generic drug becomes available during the term of the contract with the brand manufacturer. If the price of the generic drug is lower than the negotiated price for the brand/patented product, the GPO has the opportunity to sever the contract with the brand manufacturer.

In some cases, packaging, colour and/or shape of a drug can play a critical role in purchasing decisions. GPOs will often request a sample of the drug to evaluate its appearance. To minimize medical errors in drug dispensing in hospitals, the appearance of a drug can make a difference for the pharmacist. These factors may, at times, result in the purchase of a higher priced drug product.

As with retail pharmacies, drugs used by hospitals may be obtained through IPDs. By streamlining their pharmaceuticals procurement through an IPD, hospitals can benefit from channel efficiencies, reduced inventory and decreased administrative costs.

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<sup>61</sup> RHAs have been established in all provinces except Ontario. RHAs are described in Organization for Economic Cooperation and Development, *Competition in the Provisions of Hospital Services*, October 27, 2006, pp. 115 – 121, available at [www.oecd.org/dataoecd/39/13/37981547.pdf](http://www.oecd.org/dataoecd/39/13/37981547.pdf).

<sup>62</sup> [www.medbuy.ca](http://www.medbuy.ca).

Competitive contracting processes may be used to obtain IPD services. Key considerations are whether the IPD can:

- Service all members within its membership
- Provide simplified invoicing
- Guarantee delivery times
- Ensure IT system compatibility for logistics management between the IPD and the GPO members.

Since drug prices are negotiated with the manufacturers, the main point of negotiation with IPDs is their mark-up. Distribution and warehousing services are also negotiated.

According to persons contacted for the study, bidding for multiple source generic products can be highly competitive. Rebates off invoice prices are often included in the contract negotiations. In the case of GPOs, manufacturer rebates are sent in a lump sum on a regular basis, usually quarterly, semi-annually or annually.

Table 12 indicates how hospitals pay relatively low invoice prices for generic drugs. The table compares invoice prices paid by hospitals to retail pharmacies for individual generic products, identified by DIN. The table does not reflect any off invoice rebates that may be paid to either retail or hospital pharmacies. For each province, for each drug, the ratio between the retail pharmacy and hospital unit invoice price was calculated.<sup>63</sup>

Table 12. Inter-Provincial Pharmacy/Hospital Price Ratio Analysis, 2006

Generic Drugs	AB	BC	MB	NB	NS	ON	PEI/ NL	QC	SK	Average
Mean	1.38	1.72	1.46	1.72	1.91	1.84	1.71	1.71	1.26	1.64
Median	1.07	1.27	1.14	1.49	1.58	1.54	1.51	1.41	1.00	1.27
Number of Drugs	507	537	474	263	217	680	299	752	400	4129

Data source: IMS Health.

As indicated by the table, retail pharmacy invoice prices tend to be well in excess of hospital invoice prices. On average, pharmacy invoice prices were approximately 39% per cent higher than hospital invoice prices, with differences within provinces ranging from 20% in Saskatchewan to 48% in Nova Scotia.

It was not possible to obtain data on any rebates provided to hospitals that are not accounted for in their invoices. To the extent such rebates are provided, they constitute a further gap between the net price paid by hospitals and the retail pharmacy invoice prices normally reimbursed by private and public drug plans.

<sup>63</sup> The unit invoice prices compared were calculated based on retail pharmacies' and hospitals' drug acquisition costs and do not include off invoice rebates or discounts.

## Chapter 5. The Generic Drug Reimbursement Framework

Public and private drug plans cover about 98% of all Canadians.<sup>64</sup> Provincial plans cover about nine million Canadians with another one million covered by federal plans. These people include many in relatively high use groups, such as seniors and persons suffering from serious illnesses. A further 2/3 of Canada's population is covered by private prescription drug plans obtained through their employer or purchased on an individual basis.<sup>65</sup>

Though covering fewer Canadians than private plans, public drug plans, reflecting the high use groups they cover, are the largest source of funding for retail prescription drug purchases in Canada. Of estimated prescription Canadian drug expenditures of \$21.1 billion in 2006, including pharmacy mark-ups and dispensing fees, public plans accounted for an estimated \$9.6 billion or 45.5%. Private insurers accounted for \$7.6 billion in expenditures or 36%. Out of pocket payments for drugs, co-payments and other prescription drug expenses not covered under either private or public plans accounted for \$3.9 billion in expenditures or 18.5%.<sup>66</sup>

The prevalence of public and private drug plans makes them key determinants of the competitive framework for generic drugs in Canada. This chapter examines relevant features of both categories of drug plans and their implications for the Canadian generic drug competitive framework.

### 5.A. Public Drug Plans

#### 5A.1. Scope and Nature of Public Plans

In 2006, according to CIHI forecasts, the provinces and territories were the main providers of public drug plans in Canada, accounting for about 84.2% of all related expenditures. The remaining public plan expenditures are paid under federal drug benefit plans and social security funds. The federal drug benefit plan accounts for about 6.7% of the total expenditure and social security funds for about 8.8%.<sup>67</sup>

#### *Public Plan Pharmaceutical Product Coverage*

Public plans fully or partially reimburse drugs that are listed on their drug formularies. These are developed in consultation with expert drug advisory committees and reflect

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<sup>64</sup> The remaining 2% of the population that is not covered is concentrated among working age persons in the provinces of Newfoundland and Labrador, Nova Scotia, New Brunswick and Prince Edward Island.

<sup>65</sup> Coverage of persons under public and private drug plans is as reported in Paris, V. And Docteur, E (2006), "Pharmaceutical Pricing And Reimbursement Policies In Canada", OECD, Directorate For Employment, Labour And Social Affairs -Health Committee, DELSA/HEA/WD/HWP (2006) 4, p. 17.

<sup>66</sup> CIHI, *supra*, note 2, pp. 9-11.

<sup>67</sup> *Ibid.* More than 80% of the expenditures under social security funds are provided under the Quebec Drug Insurance Fund for residents who are not otherwise covered by provincial programs or by private health insurance.

individual plans' listing and reimbursement policies.<sup>68</sup> In order for generic products to be considered for formulary listing, the standard filing requirements include the following:

- Consent to access information about the drug from various agencies
- Confirmation from the manufacturer of its ability to supply the drug
- Data indicating bio-equivalence to the brand drug product
- Health Canada NOC
- Price information
- Approved product monograph.<sup>69</sup>

In addition to meeting these filing requirements, generic drugs may also be subject to additional interchangeability requirements in order to be listed on a formulary.

Interchangeability can deal with factors beyond a drug's bio-equivalence to a brand product. For example, bio-equivalent drugs may not be deemed interchangeable with a reference brand product due to:

- Difficult packaging or delivery devices
- A particularly bad taste
- The lack of a marking on a tablet allowing it to be easily divided into two where such a marking exists on the brand reference product.

If these or other characteristics of a generic product could interfere with the proper use or delivery of the drug, the product may not be listed on the formulary.

The timing of the listing of generic drugs on public formularies can vary significantly across provinces, depending on the frequency with which provincial formularies are updated and reviews of generic drug interchangeability are conducted.<sup>70</sup>

### *Public Plan Beneficiaries*

The coverage of public plans can vary substantially from province to province. All provincial and territorial drug plans provide coverage for seniors (New Brunswick and Newfoundland and Labrador apply an income test) as well as residents receiving social assistance.

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<sup>68</sup> Public plans may also provide for drugs to be reimbursed that are not listed on formularies in certain circumstances.

<sup>69</sup> Different information may be required for authorized generics. For example, in lieu of bio-equivalence data, letters may be supplied from the manufacturer of the generic and the manufacturer of the brand drug (possibly the same manufacturer for both) stating that the generic is manufactured under the identical master formula, and manufacturing and quality control specifications as the brand product.

<sup>70</sup> For some provinces (Prince Edward Island, Nova Scotia), the review of applications for listing may take as little as a month. However, in other provinces, the formulary review and update process may be less frequent, for example on a quarterly or semi-annual basis.



Through specific targeted programs, or more generally, through plans available to all residents, all provinces and territories also provide coverage for residents with specific medical conditions and/or who may face exceptionally high drug costs. The specific medical conditions most commonly covered are cystic fibrosis, diabetes, cancer, organ transplant, AIDS/HIV, and multiple sclerosis.

Four provinces offer universal eligibility for drug coverage: British Columbia, Alberta, Saskatchewan and Manitoba. The Ontario Trillium drug plan provides coverage to all residents who are not covered under a private plan and who have high drug costs relative to their income. Quebec maintains cost and income based drug plans that are available to all residents who do not have private drug insurance.<sup>71</sup> New Brunswick, Nova Scotia, P.E.I., Newfoundland and Labrador, and the territories do not provide universal or general cost and income-based programs.

There are six federal drug benefit programs, serving:

- First Nations and Inuit
- Veterans
- Members of the military
- RCMP
- Prisoners in federal correctional facilities
- Refugees

The Non-Insured Health Benefits (NIHB) plan for First Nations and Inuit is the largest of the plans accounting for 65% of all federal plan expenditures in 2005-2006. The plans for Veterans and National Defence are the next largest accounting for 22% and 7%, respectively. The remaining plans collectively account for about 6% of federal spending.<sup>72</sup>

### *Reimbursement*

Drugs covered by public plans are normally acquired by patients from retail pharmacies. The amount reimbursed is determined by the applicable public plan policy on allowable drug costs and pharmacy mark-ups and professional fees, less any applicable patient co-payments and deductibles.

Limited exceptions to the delivery of pharmaceuticals through retail pharmacies apply in the cases of the Department of National Defense (DND) and NIHB. DND delivers drugs through 50 of its own base pharmacies located throughout Canada. Drug supplies are also carried with DND when troops are deployed in foreign theatres. While most NIHB costs are reimbursed through retail pharmacies, the plan also maintains nursing stations on remote reserves which receive supplies obtained through bulk purchasing administered by The Department of Public Works.

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<sup>71</sup> See Paris and Docteur (2006), *supra*, note 65, p. 18.

<sup>72</sup> See, *Federal Healthcare Partnership 2007-2010 Business Plan*, p. 26.

## 5.A.2 Public Plan Generic Drug Related Policies

Public plans may incorporate a variety of policies pertaining directly or indirectly to generic drugs. Key among these are the following:

- Provincial interchangeability laws
- Formulary price caps
- Maximum cost reimbursement
- Net acquisition cost
- Standing offer contracting
- Most favoured nation provisions
- Deductibles and co-payments.

### *Interchangeability Laws*

Interchangeability laws provide the legal basis for interchanging generic products and brand pharmaceuticals. The laws generally apply to all interchangeable products, whether they are dispensed under public or private plans or paid for out-of-pocket. They generally consist of two elements:

- Provisions that allow pharmacists to interchange bio-equivalent products
- Provisions that protect the dispenser of the interchanged drugs against related legal proceedings.

Interchangeability laws may be mandatory, requiring that the lowest cost interchangeable products be dispensed, or, they may be voluntary, permitting, but not requiring, pharmacists to interchange products.

Provinces having mandatory interchange laws include Saskatchewan, Manitoba, Newfoundland and Labrador, and Prince Edward Island. Newfoundland and Labrador and P.E.I. further require that the interchangeable product dispensed be the lowest priced product available.<sup>73</sup>

In the remaining provinces – Nova Scotia, New Brunswick, Quebec, Ontario, Alberta, and B.C. – legislation permits interchange, but does not make it mandatory. Pharmacists may substitute a prescribed drug with an interchangeable drug.<sup>74</sup>

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<sup>73</sup>For Saskatchewan, see *The Pharmacy Act*, 1996, S.S. 1996, c. P-9.1 at sections 54-55. For Newfoundland and Labrador, see *Pharmaceutical Services Act*, S.N.L. 2002, c. P-12.01 at sections 9 and 21. For P.E.I., see the *Interchangeable Drug List Regulations* (EC 287/05) at sections 15-16.

<sup>74</sup>For Ontario, see *Drug Interchangeability and Dispensing Fee Act*, R.S.O. 1990, c. P-23 at sections 4(1) and 5. For Quebec, see *Loi sur la pharmacie L.R.Q.*, chapitre P-10, at s. 21. For Nova Scotia, see *Pharmacy Act*, S.N. 2001, c. 36 at section 28. For Alberta, see *Pharmaceutical Profession Act*, R.S.A. 2000, c. P-12. For New Brunswick, see *Pharmacy Act*, S.N.B. 1983, c. 100 at section 39. For B.C., see *Pharmacists, Pharmacy Operations and Drug Scheduling Act*, R.S.B.C. 1996, c. 363 at section 30.

Most provinces' legislation also provides protection for pharmacists from liability for any legal proceedings stemming from the substitution of an interchangeable drug, provided that substitution is legally allowed in that province.<sup>75</sup> However, in all provinces, physicians can prevent interchange of generic products by indicating that "no substitution" is to be made. This may occur where there is a medical reason why a patient must receive a specific brand of drug. Also, a patient may request "no substitution" and pay any additional drug costs out-of-pocket.

### *Formulary Price Caps*

Under formulary price caps, a generic drug must be priced at or below a maximum price in order to be listed on a public plan formulary. Two provinces, Ontario and Quebec, currently use price caps to limit maximum prices for generic drugs under their provincial formularies.

In Ontario, under the *Transparent Drug System for Patients Act, 2006*, generic drugs normally must be priced at no more than 50% of the reference brand product price in order to be listed on the ODB formulary. There are limited exceptions to this rule. Where there is evidence that the generic product would be the only drug product of its type designated as interchangeable with an original drug product, the drug price may be negotiated between the provincial drug plan and the drug manufacturer. This price may be higher than the 50% maximum, but lower than the price of the original product.<sup>76</sup>

In Quebec, a regime is being implemented under which the price of the first generic drug will be limited to 60% of the price of the reference brand product. The price of subsequent generic drugs will be limited to 54% of the brand-name drug.<sup>77</sup>

In Ontario, after an initial formulary price is established, subsequent price increases are regulated. Changes to the drug benefit price of products on the provincial drug plan formulary are subject to approval by the Executive Officer of Ontario Public Drug Programs.

Quebec implemented a policy in 1994 preventing price increases for drugs listed on the province's formulary, except in certain circumstances.<sup>78</sup> However, the province is in the process of implementing a mechanism to allow drug price increases tied to the province's consumer price index.<sup>79</sup>

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<sup>75</sup> The exceptions are Quebec and Nova Scotia. In Nova Scotia, licensure requirements ensure that all pharmacists have liability coverage when interchanging legally allowable substitutions.

<sup>76</sup> These provisions came into force on October 1st, 2006.

<sup>77</sup> *La politique du médicament*, p. 40. These price caps are due to be put into effect in February 2008. However, Quebec's 'most favoured nation' clause, discussed below, means that Quebec will also benefit from the new Ontario price caps for generic drugs under the *Transparent Drug System for Patients Act 2006*.

<sup>78</sup> *La politique du médicament (Quebec Drug Policy)*, edited by La Direction des communications du ministère de la Santé et des Services sociaux, see section entitled *L'établissement d'un prix juste et raisonnable des médicaments*, p. 7. Note that this policy also applied to wholesalers' mark-ups.

<sup>79</sup> This framework is due to come into effect in February 2008.

### *Maximum Generic Cost Reimbursement*

Maximum generic cost reimbursement policies, generally listed under provincial plans as maximum allowable cost or lowest cost alternative reimbursement policies, do not prevent generic drugs from being listed on public plan registers if they are relatively high priced.<sup>80</sup> Instead, they provide an incentive to dispense low cost generics by stipulating a maximum amount that will be reimbursed for a group of interchangeable products. If a higher cost brand or generic product is dispensed, the difference must be paid by either the patient or the pharmacy.

Maximum cost reimbursement policies apply in all provinces as well as the Yukon.<sup>81</sup> In most cases, maximum cost reimbursement prices are obtained from manufacturers. The exception is B.C., which sets maximum reimbursement cost based on pharmacy prices obtained through its Pharmanet system.

As with interchangeability policies, exceptions may be made to the maximum generic cost reimbursement policies in limited circumstances. For instance, if a patient must receive a particular drug for medical reasons, or the lowest cost product is unavailable due to a supply shortage, provincial drug plans may reimburse the cost of a more expensive product, with no additional cost to the patient.

### *Net Acquisition Cost*

Pharmacies actual acquisition costs of drugs, whether they are patented or no longer patent protected, are used by many provinces as a basis for reimbursing drugs under their public plans, subject to any applicable maximum price or cost reimbursement policies. In these provinces, the maximum amount that can be reimbursed for generic drugs is the lower of the pharmacy actual acquisition cost or the maximum generic cost reimbursement price.

In some provinces, regulations or policies further stipulate that the actual acquisition costs reported by pharmacies should be the net acquisition cost, incorporating the value of any purchase price reduction, rebate, allowance, free products, or discount received by the pharmacy or dispensing physician. These provinces are Nova Scotia, New Brunswick, Quebec, Saskatchewan and British Columbia.<sup>82</sup>

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<sup>80</sup> The term maximum allowable cost has, in some provinces, been applied across therapeutically similar, but not necessarily interchangeable generic drugs. This discussion refers only to cases involving bio-equivalent interchangeable drug products.

<sup>81</sup> In Quebec, however, this policy does not come into effect unless the original brand product has been on the provincial formulary for 15 years.

<sup>82</sup> However, Quebec allows limited rebates for rapid payment.

### *Standing Offer Contracting*

Standing offer contracting involves the use of a competitive bidding process to establish the maximum price that will be reimbursed. The winning manufacturer guarantees delivery of the specific drug at the contracted price. In return, the manufacturer's product is given preference or used exclusively during the contract period.<sup>83</sup>

A number of provinces have attempted or considered using a standing offer contract process. However, Saskatchewan is the only province currently following this approach. The province uses standing offer contracting for 91 high volume interchangeable drug groups.

### *Most Favoured Nation Provisions*

Most favoured nation provisions require that the price offered to a provincial drug plan by a manufacturer for a particular drug product be no more than the lowest amount charged to other provincial drug plans elsewhere in Canada.

Most favoured nation provisions currently apply under the drug plans of two provinces: Quebec and Newfoundland and Labrador.<sup>84</sup> In Quebec, all generic drug manufacturers must sign a commitment that they will submit a guaranteed selling price for any drug they wish to have entered on the list of medications.<sup>85</sup> The guaranteed selling price may "not be higher than any selling price granted by the manufacturer for the same drug under other provincial drug insurance programs."<sup>86</sup>

In Newfoundland and Labrador, in order to have a product listed on the formulary, the manufacturer must provide for a specific period, a guaranteed price for the product that is no higher than the best price available elsewhere in Canada.<sup>87</sup>

### *Deductibles and Co-Payments*

Deductibles are amounts that patients covered by drug plans must spend on prescription drugs before the plan will begin to reimburse costs. Co-payments are amounts that beneficiaries are required to pay for prescription drugs that are partially reimbursed under a drug plan.

Provincial drug plans typically implement deductibles and co-payments as a means to keep overall drug plan costs down and to discourage over-use of prescription drugs. However, with interchangeable generic drugs, significant deductibles and co-payments may also provide incentive for patients to search for lower priced products.

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<sup>83</sup> Exceptions may be allowed for medical or supply reasons.

<sup>84</sup> In Quebec, the regulation with respect to generic drug pricing makes reference to the lowest price offered elsewhere in Canada.

<sup>85</sup> *Regulation Respecting the Conditions on which manufacturers and wholesalers of medications shall be recognized*, R.Q. c. A-29.01, r.1.1

<sup>86</sup> *Ibid.*, see Schedule I.

<sup>87</sup> *Pharmaceutical Services Act*, chapter P-12.01 at section 23.

Co-payments and deductibles are required under many public drug plans. While in many cases they are limited, in some, plan beneficiaries can spend substantial amounts. For example, under the B.C. Universal Fair Pharmacare plan, those under 65 years of age are required to make co-payments of 30% amounting to 2 to 4% of their total family income before pharmaceuticals will be fully reimbursed. Under the Saskatchewan Special Support Program, a deductible of up to 3.4% of annual family income applies. Under Manitoba's Pharmacare program, deductibles are between 2.32% and 5% of adjusted family income. The Ontario Trillium drug program similarly has an income based deductible. The Alberta provincial drug plan requires residents to make co-payments of 30% to a maximum amount of \$25 per prescription.

### 5.A.3 Public Plan Generic Drug Policies Competitive Effects

Despite differences among their generic drug plan policies, reimbursed generic prices tend to vary little between the provinces. The following table indicates this, comparing invoice prices of generic drugs in retail pharmacies. The table compares 2006 average invoice prices for 579 generic drugs sold by prescription in retail pharmacies in nine provinces for which data were available.<sup>88</sup> For each drug, the unit invoice price in each province relative to the national average unit invoice price was calculated.

Table 13. Average Unit Pharmacy Invoice Prices Of generics Relative To Canada Average, 2006

	AB	BC	MB	NB	NL	NS	ON	QC	SK
Mean	0.979	1.021	0.979	1.021	0.992	1.016	1.010	0.972	1.009
Median	0.998	1.031	0.992	0.998	1.000	0.997	1.000	0.985	0.998

Data source: IMS Health.

In all provinces, average generic prices are within 2.5% of the national average. Median prices are within 1.5% of the national average.<sup>89</sup>

Those interviewed for this study generally indicated that there is limited competition in generic drug provincial formulary pricing. Prices in all provinces for initial and successive generic drug products are generally considered to reflect the former maximum price guidelines under Ontario legislation and regulations. Under the guidelines, the first generic listed on the ODB formulary was to be priced at no more than 70% of the brand equivalent. Subsequent generics were to be priced at no more than 90% of the price of the first generic.

<sup>88</sup> The prices partially reflect price changes implemented in October 2006 caused by the lowering of Ontario's maximum ODB formulary generic drug prices to 50% of the brand product price.

<sup>89</sup> The sample does not include generic drug products obtained under the Saskatchewan Standing Offer Contract process, which is discussed further below.

This view exists despite public plans policies designed to ensure that low cost generics are dispensed. These policies are generally considered to have played an important role in ensuring that the lowest priced generic drugs on provincial formularies are dispensed or reimbursed. They also help guarantee a minimum level of cost savings from generic drugs. However, they have not generated strong competition among generic drug manufacturers to reduce their public plan list and formulary prices.

This observation is consistent with incentive structure under most public plan designs. Interchangeability policies, while they provide a basis for substituting lower for higher cost drugs, do not, in themselves, provide incentives for companies to reduce the formulary prices reimbursed by public plans.

Maximum cost reimbursement policies similarly provide limited incentives for generic drug manufacturers to compete on price by offering lower formulary prices. Key competitive features of these policies include:

- The price of the lowest cost product is publicly listed on provincial formularies, or maximum allowable cost or least cost alternative prices lists.
- Competing generic drug manufacturers can protect their competitive positions by matching formulary price decreases offered by other manufacturers.
- Generic drug manufacturers that are the first to offer lower formulary prices are generally not given preference under public plans.

Due to these features, a manufacturer offering a lower formulary price to a public plan may have a limited opportunity to gain significant market share while decreasing its return on sales. Instead, other manufacturers can protect their competitive positions by offering matching formulary price decreases.

Net acquisition cost policies that are aimed at capturing the value of rebates and other such benefits potentially allow public plans to increase their benefits from competition among generic manufacturers. However, the monitoring and auditing capabilities of public plans has traditionally focused on pharmacy invoices that do not capture off invoice rebates, discounts and other benefits.

Establishing a framework to ensure that such benefits are captured would require much more extensive auditing capabilities to allow public officials to broadly examine pharmacies' operations and finances. In designing an effective net acquisition cost policy, an additional concern would be to avoid interfering with efficiency enhancing or normal business terms, such as volume or loyalty discounts and prompt payment rebates.

Public plan maximum formulary price policies require generic drugs to be priced at or below a maximum price relative to their interchangeable branded products. This potentially gives provinces the means to ensure a minimum cost saving for generic drugs. However, these policies do not reflect either the development and supply costs nor the competitive prices of generic drugs. Further price regulation of this nature runs the risk of



preventing the supply of high cost generic drugs for which the development cost is higher than the allowable price.

Most favoured nation policies, while intended to ensure that a province's generic drug prices will be no higher than those of other public plans, can act as a disincentive for manufacturers to compete by offering lower formulary prices to other public plans. They may do this by ensuring that low formulary prices initially offered in one province will be automatically extended to other provinces having most favoured nation policies. Even if the initial offering of the low price conveys a competitive advantage in the first province, this will result in a lower price being received by other provinces with most favoured nation provisions.

As noted, significant deductibles and co-payment requirements apply under various public plans in Canada. However, no indication was provided by research or interviews that these have led to generic drug price competition among pharmacies. In any case, if co-payments and deductibles are increased as an indirect means to promote generic drug competition, the issues of health care quality and access would have to be addressed.<sup>90</sup>

Where it has been possible to apply, standing offer contracting appears to provide significant competitive benefits. As noted, Saskatchewan is the only province obtaining pharmaceuticals through this approach.

Of the 91 drugs for which standing offer contracting is used, information on 37 drugs, which were also sold in other provinces (and were part of provincial reimbursement claims), was available.<sup>91</sup> The following table compares current Saskatchewan generic drug formulary prices for this set of drugs to prices in British Columbia, Saskatchewan, Manitoba, Quebec and Ontario, expressed as a percentage of the brand product price.<sup>92</sup> On average, Saskatchewan pays the lowest percentage of the brand price, about 42%. Ontario has the next lowest average price, 46%, reflecting the recent maximum formulary price caps implemented in the province.

Table 14. Current Formulary Listing Price of Generics Drugs as a Percentage of the Brand Price

	BC	SK	MB	QC	ON
Mean	0.59	0.42	0.58	0.65	0.46
Median	0.61	0.43	0.61	0.63	0.47
Number of Drugs	37	37	37	36	34

Data source: Brogan Inc.

<sup>90</sup> For discussion of these concerns, see, for example, Paris and Docteur (2006), *supra*, note 65, pp. 35-38.

<sup>91</sup> It may be noted that all of Saskatchewan's 91 standing offer contracts are supplied by two companies, Dominion Pharmacal and Nu-Pharm, which sell these drugs exclusively in the province.

<sup>92</sup> In the case of Ontario, prices are based on the revised maximum formulary price formula implemented in January 2007.

While increased direct contracting by public plans may have the potential to increase their benefits from competition among manufacturers, parties with whom this matter was discussed pointed to a number of related obstacles and issues to be addressed. They include:

- Ensuring that such contracting promotes or sustains competition among generic manufacturers, rather than results in a concentrated and uncompetitive generic drug supply sector.
- The need to effectively and efficiently integrate contracting practices and pharmacy operations.

In addressing the first of these issues, it would be important to ensure that competitive contracting is designed to protect competition through successive rounds of contracting. Processes that result in the exit of manufacturers over time may ultimately lead to a loss of effective competition.

On the second issue, in effectively integrating contracting practices and pharmacy operations, it is important to consider how to deal with existing inventory when there is a change in contracted manufacturers. A further consideration may be ensuring that different interchangeable products remain available to deal with circumstances where a contracted generic product cannot be used by a patient for medical reasons.

Reliance on competitive contracting also places greater emphasis on successful bidders being able to supply the market, and mechanisms to ensure that alternative sources are available where a contractor is unable to meet demand.

The practices noted above are not the only ones that might be considered to shift the focus of generic competition to public plans. Others might involve, for example, restricting access to formularies as a means to encourage price reductions.

Practices shifting the focus of generic competition to public plans, away from pharmacies, in any case, would increase emphasis on the regulation of pharmacy professional fees and mark-ups. As these practices would limit the potential to provide rebates or professional allowances by generic drug manufacturers, they would tend to make pharmacies more reliant on professional fees and mark-ups, and would make the pharmacy net returns more transparent.

## **5.B Private Drug Plans**

### **5.B.1 Overview**

Private drug plans generally complement public plans by covering persons or costs not covered by the public plans. As noted, about two-thirds of Canadian residents are covered by private insurance. According to the CIHI, private insurers, including group and

individual insurance, paid \$7.6 billion for prescription drugs in Canada in 2006 representing 35.8% of total prescribed drug expenditures.<sup>93</sup>

This section describes the private drug plans sector in Canada and its role within the competitive framework for the generic drugs in Canada.

### **5.B.2 The Canadian Private Drug Plans Sector**

While individuals may purchase private drug insurance, group benefit plans provide approximately 95% of private coverage in Canada.<sup>94</sup> These plans are normally sponsored by or organized by employers, or professional orders or associations. In choosing the level and type of coverage to provide, plan sponsors look for a balance between more comprehensive coverage (desired by plan members), managing their risk exposure, and minimizing their drug coverage or insurance premium costs.

Plan sponsors have the option of providing either fixed cost (insured), or uninsured plans for their members.

#### *Insured Plans*

Under insured plans, drug costs are principally reimbursed by the drug plan provider. These groups pay a "premium" per employee or family. Smaller groups usually choose the premium method of funding as a means to manage their risk. Premiums include the cost of anticipated claims expense, administration costs, a charge for risk and an estimate for claim cost increase. At renewal time the claims experience is analyzed. If the rate varies from what was anticipated, this may be reflected in either higher or lower rates on renewal.

#### *Administrative Services Only*

Larger groups are more likely to sponsor uninsured or administrative services only (ASO) plans as the size of their membership can adequately diversify their exposure to risk. These groups choose to "self insure" which means they pay the claim costs plus a percentage or per claim fixed charge for administration. Since the group assumes the "risk" of large claims, no risk charge needs to be incorporated.

Insured and ASO drug plans are provided in Canada by both for-profit insurers, such as Great-West Life, Manulife and Sun-Life, and not-for-profit companies, such as Green Shield Canada, Alberta Blue Cross and Medavie Blue Cross.

The administration of these plans is complex and highly technical. It requires:

- Maintaining and updating drug formularies
- Developing and maintaining a network of pharmacies

<sup>93</sup> See CIHI, *supra*, note 2.

<sup>94</sup> Paris and Docteur (2006), *supra*, note 65, p.18.

- Claims adjudication
- The manual and electronic processing and settlement of drug claims
- Expertise in the analysis and assessment of claims information
- Expertise in the development of coverage and reimbursement policies
- Expertise in the development of flexible software solutions
- Coordination with provincial plans.

Non-profit drug plan providers, such as Blue Cross and Green Shield Canada, have developed capabilities to provide these services for their own and other group plans that they administer.<sup>95</sup> For-profit drug plan providers widely contract out the electronic processing and settlement of claims to third party pharmacy benefits managers (PBMs).

PBMs serve as intermediaries between the plan provider and the pharmacy to settle claims. They may also provide other pharmacy benefit management services listed above. In some cases, PBMs may deal directly with employer or other plan sponsors rather than through a plan provider. ESI Canada and Emergis are the two largest PBMs in Canada. Other Canadian PBMs include ClaimSecure and NexgenRx.

### **5.B.3 The Role of Private Drug Plans in the Generic Drug Competitive Framework**

Private plans may adopt similar policies to those used by public plans on generic drug pricing and interchangeability. It has been stated that in Canada, provincial government drug plans have structured the pricing and gross margins that both public and private plans pay.<sup>96</sup>

The view is supported by the following table comparing generic drug costs reimbursed by provincial plans in comparison to private plans. Drugs covered in the table include both generics and brand-name drugs that have lost patent protection. They were both public and private plans reimbursement claims in 2006.

Prices used for constructing the table include both drug costs and pharmacy mark-ups reimbursed. For each drug, the average unit price in Canada was calculated. The ratio between the national average unit price paid by a public plan and the unit price paid by a third party payer was computed. The table shows descriptive statistics of the ratios between the unit prices paid by the provinces on average and the private plans.

For both brand-name and generic drugs, the prices paid by private plans tend to be higher than the price paid by the public plans. On average in 2006, non-patented brand, per unit, cost public plans about 90% of the cost of private plans. For generic drugs only, the ratio was 93%.

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<sup>95</sup> These companies may also provide related services to provincial drug plans.

<sup>96</sup> CIBC Report, *supra*, note 38, p. 61.

Table 15. Public Plans versus Private Plans Unit Price Ratio, 2006

	Non-patented Brand-name Drugs	Generic Drugs
Mean	0.90	0.93
Median	0.93	0.93
Standard Deviation	0.11	0.05
Minimum	0.40	0.62
Maximum	1.22	1.19
Number of Drugs	378	245

Data source: Brogan Inc.

The higher prices paid, on average, by private plans versus public plans may reflect the granting of higher mark-ups by private plans or their payment of higher drug prices than the provinces.<sup>97</sup>

This relationship between public and private plan generic drug prices is undergoing change. Although Ontario legislation has capped generic drug prices under ODB plans at 50% of the brand price where more than one generic is available, these prices are not being provided to private plans in Ontario. Consequently, a two-tiered price structure exists in the province for generic drugs. Further concern has been expressed that not only private plans do not currently benefit from lower generic prices in Ontario, private plan prices may increase to compensate for the lost revenues on ODB sales under the reduced ODB maximum generic drug prices.

The limited role of insurers and PBMs in seeking lower cost generic drugs is an important difference between the generic drug competitive frameworks in the US and Canada. In the US, insurer owned and independent PBMs are highly active in negotiating generic drug rebates or discounts from manufacturers. These can provide important savings on drugs costs for plan sponsors.<sup>98</sup> Determining the reasons for this difference between the Canadian and Us generic drug sectors was beyond the scope of this study.

<sup>97</sup> Higher private plan prices may occur, for example, where the price of brand and generic drugs on a provincial formulary is frozen over time but the price for other parties is allowed to increase.

<sup>98</sup> 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 PBMs of, on average, 62% off the manufacturer's wholesale price.

## Chapter 6: Summary of Key Findings

Generic drugs play an important role in helping to manage Canada's health care costs. Generics are developed and manufactured to be substitutable for branded drugs. Their role is to provide competition for patented drugs when their patent protection ends due either to the end of their period of patent protection or when the patents are found to be invalid.

Competition between generic and brand pharmaceuticals takes place within a unique competitive framework. Key elements of this framework are as follows.

### *Demand*

Demand for prescription drugs is determined by a prescribing physician. Physicians' main concern selecting a drug is its perceived effectiveness in treating a condition. The physician does not have a direct financial interest in the drug that is eventually supplied.

Patients normally obtain their prescribed drugs from retail pharmacies located in the community. Many patients are insensitive to the price they pay for generic drugs as they bear none or only a small portion of their drug costs under their public and private drug plans. An estimated 98% of Canadians are covered by these plans.

### *Dispensing*

The choice of which generic product to dispense, except in cases where a prescribing physician indicates that no substitution is permitted, is generally made by the pharmacist from products in stock in the pharmacy. This choice is subject to provincial laws, regulations or policies allowing brand products and their generic products to be dispensed interchangeably. In some cases, patients may play a role where they wish to obtain the brand product or a particular generic product.

Pharmacies' decision of which generics to stock and dispense reflects a number of considerations. Pharmacies stock one or a small number of generic products to keep inventory management costs down. The decision regarding which generic(s) to stock takes into account the invoice price of the product net of any rebates or allowances. Other terms and conditions, such as reliability of supply, or possible benefits of dealing with suppliers providing a broad range rather than a small number of products are also taken into account.

The net pharmacy price has traditionally been a major determinant of product selection in most jurisdictions in Canada. However, recent legislation in Ontario restricting the granting of off invoice rebates and allowances is likely to increase the importance of other considerations, such as the breadth of product portfolio, particularly for sales under Ontario Drug Benefit plans. Rebates have been prohibited for a number of years in Quebec and have recently been the subject of a number of court cases.

Reimbursement of the price paid by consumers for generics dispensed by retail pharmacies is based on public and private drug plans' formulary and reimbursement practices. Private plans' practices tend to mirror or complement public plans' practices. These practices typically base the amount that is reimbursed on the lowest priced generic product on the formulary. These prices generally reflect invoice or list prices and do not include off invoice rebates. Ontario has maximum formulary price restrictions for its public drug plans. In October 2006, the province reduced maximum reimbursement prices for generic prices to a norm of 50% of brand prices. The previous formula stated that most products could be priced at no more than 63% of the brand price.<sup>99</sup>

Hospital pharmacies account for a significant share of generic drugs demand, particularly for drugs normally provided on an in-patient basis. They obtain much of their needed pharmaceuticals through competitive tendering processes. Hospitals pay for these products out of their budgets and they are dispensed to patients free of charge under the public health care system.

### *Distribution*

Generic drugs are distributed to pharmacies and hospitals either through independent pharmacy wholesalers and distributors (IPDs), self distribution to pharmacy groups such as chains, banners store and franchises, or manufacturer direct shipments. IPDs are becoming an increasingly important means for distributing products. They offer services to all manufacturers providing them with an alternative means, besides direct distribution, for getting their products to pharmacies that do not self distribute.

### *Manufacturing*

Manufacturing of independent generic drugs involves significant development and regulatory approval costs. Researchers work to develop a drug that is bio-equivalent to the brand-name reference product. Regulatory approval to sell an independent generic drug in Canada involves obtaining a NOC from Health Canada addressing related patent claims and the bio-equivalency of the generic drug with the brand product. According to those contacted for this study, from the time a decision is made to introduce a generic product, manufacturers may require between three to six years to bring the product to market. Sunk costs may be in the range of \$3.5 million (including costs for bio-equivalence studies, development and regulatory approval) for a small molecule. Costs can vary widely depending on the complexity of the product, the potential to spread development costs across international markets, the scope and nature of any associated patent litigation and the cost for bio-equivalence or clinical studies. Obtaining approval to supply authorized generics (AGs) involves much lower costs as these products are the same as the brand product already being supplied.

Key determinants in whether to supply a generic product include:

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<sup>99</sup> Quebec has also established maximum price regulations. However they are not due to come into effect until February 2008 and their effect has been mitigated by the revised Ontario formulary prices that will be automatically adopted under Quebec's formulary policies.



- Demand size and competitors: The projected aggregate demand size of the reference brand product as well as the related therapeutic class play an important role. First, the generic manufacturers take into consideration how many manufacturers are expected to introduce competing generic versions of the targeted molecule. Second, branded companies may in some cases provide added competition to the generic manufacturer by introducing: (i) a competing drug within the same therapeutic class, or (ii) brand extensions to replace older formulations whose patents are about to expire. Brand extensions may reduce the potential demand size available to the generic industry once the original drug loses patent protection with a proportion of patients being prescribed the new version.
- Development and approval costs: An important part of the entry decision is the evaluation of the total costs of introducing a generic drug to the market. These costs include drug development, bio-equivalence and/or clinical studies and federal and provincial approvals.
- Timing: The length of time it would take to develop the product and obtain approval from Health Canada is a crucial consideration. This is particularly so if it results in the late release of a generic product following the loss of patent protection by the relevant brand product.
- Specialization and product portfolio: The manufacturer may have been involved in some related work, or it may specialize in producing drugs within a certain therapeutic class or specialize in certain dosage forms (creams, ointments, injectables), thereby benefiting from economies of scale or scope in production. On the other hand, manufacturers may wish to supply a molecule to make their product portfolio more attractive to customers.
- Legal challenge costs: Challenging brand patents, can be a costly and time-consuming process. A generic manufacturer already involved in legal challenges may decide not to enter into another challenge.

While it has not been possible to conduct a full assessment of generic competition, within this framework it appears that strong competition takes place among manufacturers in the supply of many generic drugs in Canada, particularly those products having high annual sales. Whereas in the past the industry was dominated by two large Canada based suppliers, there are now 15 generic drug suppliers in Canada. Many have ownership and other relations with major global generic drug manufacturers. The ending of patent protection for a drug can result in the entry of multiple suppliers.

Granting of off invoice rebates to pharmacies has traditionally been the principal means by which manufacturers have competed with each other.<sup>100</sup> It has not been possible to obtain detailed evidence regarding the size of these rebates. However, public sources and information provided by parties interviewed for the study indicate that net pharmacy prices have been, on average, at least 40% below the invoice price, and as much as 80% lower in some cases. These rebates have provided incentives for pharmacies to substitute generic drugs for brand products and have been an important source of income for them. It may be noted that competition in the form of rebates, by its nature, is not reflected in price studies comparing invoice prices in Canada versus other countries.

Off invoice rebates provided to pharmacies have typically not resulted in lower prices to consumers nor to public and private drug plans. While the plans may incorporate specific generic drug related policies, they provide limited incentive for pharmacies or manufacturers to compete to supply the plans through lower formulary and reimbursement prices. Rather, these prices, in all provinces, have tended to reflect maximum allowable prices under the Ontario's former ODB maximum price regulations. Other than the ODB sales that are covered by Ontario's new maximum price regulations, this pricing is continuing. Consequently, in Ontario a two-tiered pricing framework exists for ODB plan sales versus sales of drugs for private plans or persons paying out-of-pocket.<sup>101</sup>

Alternative public and private drug plan approaches that focus competition on reimbursers, could result in important cost savings for insurers. However, further consideration of these approaches is required in order to assess the barriers to their implementation, how they may be integrated into the current pharmacy and drug plan framework, and how they may be designed to promote and sustain effective competition among manufacturers.

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<sup>100</sup> While they are not inherently anti-competitive, in certain circumstances, such as where they are used by a dominant firm to induce exclusive supply, rebates may have anti-competitive effects.

<sup>101</sup> However, Quebec's public plan formulary prices are due to be adjusted in February 2008 to reflect the new Ontario maximum price level.

## Appendix 1: Federal Regulatory Framework for Pharmaceutical Products

### Overview

All drugs that are marketed in Canada are subject to the *Food and Drugs Act*<sup>102</sup> and *Food and Drug Regulations*.<sup>103</sup> The *Food and Drugs Act* defines a drug as in part as “any substance or mixture of substances manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms... , restoring, correcting, or modifying organic functions ... , or disinfection in premises in which food is manufactured, prepared or kept”.<sup>104</sup>

Whether a product is categorized as a “drug” depends on its composition (medicinal value leading to a pharmacological effect), and/or what claims are made for the product.

Part C of the *Food and Drug Regulations* requires a manufacturer to obtain a Drug Identification Number (DIN) prior to selling a drug in Canada.<sup>105</sup> A manufacturer or distributor is defined as “a person, including an association or partnership, who under their own name, or under a trade-design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug”.

In regulatory terms, the “manufacturer” of a drug is not necessarily the company that makes the product, but the company to which the product is registered at the time of approval. The manufacturer may be located outside Canada, but there must be someone in Canada who is responsible for the sale of the drug.

Health Canada is responsible for ensuring compliance with the regulations and non-compliant products are subject to action.

### Pre-Market Drug Submission Requirements

New drugs can be sold in Canada once they have successfully passed a review process to assess their safety, efficacy and quality. Health Canada's Health Products and Food Branch (HPFB) is responsible for this review process.<sup>106</sup>

A drug may be regulated as a new drug when it has not been on the market in Canada for long enough or in sufficient quantity to have proven its safety and effectiveness under conditions of use. As well as a DIN, a new drug must have a Notice of Compliance (NOC) with Part C of the *Food and Drug Regulations* issued before it can be sold in Canada.

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<sup>102</sup> R.S.C. 1985, c. F-27, available at [laws.justice.gc.ca/en/F-27/](http://laws.justice.gc.ca/en/F-27/).

<sup>103</sup> C.R.C., c. 870, available at [laws.justice.gc.ca/en/F-27/](http://laws.justice.gc.ca/en/F-27/).

<sup>104</sup> *Food and Drugs Act*, s. 2.

<sup>105</sup> The DIN is an eight-digit number located on the label of prescription and non-prescription drug products authorized for sale in Canada.

<sup>106</sup> See [www.hc-sc.gc.ca/hpfb-dgpsa/](http://www.hc-sc.gc.ca/hpfb-dgpsa/).

A New Drug Submission (NDS) typically involves between 100 and 800 binders of data, containing scientific information about the product's safety, efficacy and quality. It includes:

- The results of both the pre-clinical and clinical studies
- Details on the production of the drug and its packaging and labeling
- Information about its claimed therapeutic value
- Information about its conditions for use and side effects.

A clinical trial does not have to be performed in Canada for a New Drug Submission or a DIN Application.

When a generic drug enters the market, Part C of the *Food and Drug Regulations* allows the manufacturer to file an Abbreviated New Drug Submission (ANDS). The ANDS contains data that demonstrate the drug's bio-equivalence with a Canadian reference product. A Canadian reference product is defined as a drug which has been issued an NOC and which is marketed in Canada by the innovator of the drug. Where the innovative drug ("brand-name" drug) is no longer marketed in Canada, a drug acceptable to the Ministry of Health can be used to demonstrate bio-equivalence.

The ANDS must meet the same quality standards as an NDS and the generic product must be shown to be as safe and effective as the brand-name product. An ANDS typically involves between 10 and 20 binders of data. It includes scientific information on the generic product's performance compared with the brand-name product, and provides details on the production of the generic drug, its packaging and labeling.

Generics do not have to replicate the extensive clinical trials that have already been done when the original, brand-name drug was developed. Those trials usually involve a few hundred to a few thousand patients. Since the safety and efficacy of the brand-name product has already been well established in clinical testing and often many years of patient use, it is not scientifically necessary, and would be unethical, to require that such extensive testing be repeated for each generic drug that a firm wishes to market. Instead, generic applicants must scientifically demonstrate that their product is bio-equivalent (i.e., performs in the same manner) as the pioneer drug, within an acceptable range.

One way scientists demonstrate bio-equivalence is to measure the time it takes the generic drug to reach the bloodstream and its concentration in the bloodstreams of 24 to 36 healthy, normal volunteers. This gives them the rate and extent of absorption or bio-availability of the generic drug, which they then compare to that of the pioneer drug. The generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the pioneer drug.

A Supplemental NDS (SNDS) must be filed by a brand-name or generic manufacturer if certain changes are made to an already-authorized product. Such changes might include:

- The dosage form or strength of the drug

- The formulation
- The method of manufacture, labeling or recommended route of administration.
- An expansion of the claim or conditions of use for the drug.

A DIN application must be filed for those products that do not meet the definition of a 'new drug'. This happens when a substance has been sold in Canada for long enough and in sufficient quantities to have established its safety and effectiveness for use as a drug.

#### *The Review Process*

If, at the completion of a new drug review, HPFB concludes that the benefits outweigh the risks and that the risks can be mitigated and/or managed, the product is issued a Notice of Compliance (NOC) and a Drug Identification Number (DIN), as required in the Food and Drugs Act and Regulations. This allows the manufacturer to sell the product in Canada.

Filing an ANDS as opposed to an NDS is less demanding for a generic drug manufacturer because many of the safety and efficacy concerns were addressed when the reference product was approved. The generic product goes through a screening process, which HPFB tries to complete in 45 days. If anything is unclear in the file, the manufacturer has 15 days to clarify the issue. If it fails to clarify, a Notice of Non-Compliance (NON) is issued and the company has three months to reply. Also, if there are deficiencies in the file, a Notice of Deficiency (NOD) is issued, although this is not very common.

If the submission is complete, it enters the formal review process, which HPFB attempts to complete in 180 days (it may take much longer). Three reviews are performed to determine if the drug complies with the *Food and Drugs Act*:

- Chemistry and manufacturing
- Safety and efficacy.
- Product information.

If, on completing its review, HPFB finds that the submission does not comply with the requirements of the *Food and Drugs Act and Regulations*, it will issue a Notice of Non-Compliance (NON). This notice outlines HPFB's concerns and generally asks for more information. The manufacturer must respond by a specified date. If the submission does comply, a NOC is issued.

#### *The Patented Medicines (Notice of Compliance) Regulations*

The *Patented Medicines (Notice of Compliance) Regulations (NOC Regulations)*<sup>107</sup> are the link between the *Patent Act*<sup>108</sup> and the review process under the *Food and Drugs Act*

<sup>107</sup> SOR/93-133, available at [laws.justice.gc.ca/en/p-4/sor-93-133/164296.html](http://laws.justice.gc.ca/en/p-4/sor-93-133/164296.html).

<sup>108</sup> R.S.C. 1985, c. P-4.

*and Regulations.* The dual purpose of the *NOC Regulations* is to ensure that, on the one hand, the timely access to Canadians of lower cost medicines and, on the other hand, the “early working” exception to patent infringement is not abused by second entry manufacturers.

The Therapeutic Products Directorate of Health Canada maintains a patent register consisting of patent lists submitted by first persons (innovators). The Patent Register<sup>109</sup> is an alphabetical listing of medicines and the associated patents, patent expiry dates and other related information, established in accordance with the *NOC Regulations*. When a generic or second entry manufacturer seeks approval of a drug in Canada based on a previously approved drug, it must address all patents listed on this register concerning that drug.

After a generic manufacturer files an ANDS on a drug covered by a patent on the Patent Register, and while the safety and efficacy are being reviewed, the applicant must either:

- Advise HPFB that it will accept that the *NOC* will not be issued until the patent expires or
- File a statement claiming that the person who filed the patent list is not the patent owner (or acting with the owner's consent) or
- File a statement that the patent has either expired, is not valid, or is not infringed (a Notice of Allegation, or *NOA*).<sup>110</sup>

The *NOA* must be served on the person who submitted the patent list (generally the holder of the original *NOC*). That person then may, within 45 days, apply for a court order prohibiting HPFB from issuing an *NOC* for the second-entry (generic) product.

If it receives notice of such a court application, HPFB cannot issue a *NOC* for 24 months, or until the court makes a determination regarding the allegations in the *NOA*, whichever comes first. The court may shorten the 24-month period or extend it if the parties consent, or if the court finds that one or both of the parties has failed to reasonably co-operate in expediting the application.

The generic manufacturer must address all patents on the patent list given by the patentee to Health Canada. Prior to October 2006, a patentee was able to re-start the 24 month automatic stay by listing new patents for formulations or uses after a generic company filed its ANDS. This practice would extend market exclusivity long after the initial patent or patents on it had expired.

The new patents could be added at any time, and in some cases, new patents were added days before the original patent on the active ingredient expired. Under the October 2006 amendments to the *NOC Regulations*, a generic manufacturer who files a submission or supplement for an *NOC* for a generic version of an innovative drug need address only the

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<sup>109</sup> The Therapeutic Products Directorate has developed a web-accessible version of the Patent Register available at: [www.patentregister.ca/](http://www.patentregister.ca/).

<sup>110</sup> *NOC Regulations*, s. 5.

patents, on the Register as of that filing date. Patents added to the register after that filing date would not have to be addressed. The register is "frozen" for the generic manufacturer.<sup>111</sup>

If the person who submitted a patent list applies for a court order, an NOC cannot be issued for the generic product until either:

- The 24 month stay expires or
- The patent expires or
- The court declares there would be no patent infringement or
- The court application is withdrawn, discontinued or dismissed.<sup>112</sup>

If the patentee wins the case, the NOC cannot be issued until the final patent expires. If the generic wins, an NOC can be issued as soon as Health Canada has completed its review for safety and efficacy.

### **Filing and Management of Drug Submissions**

All drug submissions must be accompanied by:

- A completed drug submission application form
- A submission evaluation fee form
- A copy of the proposed label(s)
- The appropriate drug submission certification form.

New drugs must have a copy of the product monograph. Drug submissions are processed according to the *Management of Drug Submissions Policy*, which also identifies the performance targets for review time frames for different types of submissions.

The *Submission Evaluation Fees Guide* identifies the evaluation fee and the timing of payment for different types of pre-market drug submissions. Fees are charged for the following services linked to the regulation of drugs:

- Drug Submission Evaluation
- Drug Master File Registration
- Issuance of Export Certificates (for non-controlled drugs).

In addition to the fee for evaluating the safety, efficacy and quality of a product, HPFB levies other user fees<sup>113</sup> for drug therapeutic product regulatory activities:

- Fees for maintaining the right to market a product (an annual fee must be paid for each Drug Identification Number (DIN) that pertains to a drug)

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<sup>111</sup> *Ibid.*, s. 5(4).

<sup>112</sup> *Ibid.*, s. 7.

<sup>113</sup> More information available at [www.hc-sc.gc.ca/dhp-mps/prodpharma/fees-frais/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/fees-frais/index_e.html).

- A fee for an establishment license that certifies the type of operations and category of products that the establishment is authorized to handle.

### *Product Labelling*

Once a drug is approved for the Canadian market, it must be packaged and distributed with information that will help consumers make an informed choice about its use. The general labeling requirements are outlined in Part C of the *Food and Drug Regulations*.

### *Good Manufacturing Practices (GMP)*

All drugs marketed in Canada are subject to good manufacturing practices (GMP) as outlined in Part C of the *Food and Drug Regulations*. The GMP and establishment licensing requirements apply to drugs in dosage form and to most bulk intermediates. The *Food and Drug Regulations* make it mandatory for fabricators, packagers/labelers, importers and distributors to have detailed information available about drug products for sale in Canada. All facilities involved in these activities are licensed and inspected by Health Canada to ensure that the GMP standards are met.

### *Environmental Assessment*

All products regulated under the *Food and Drugs Act* are subject to the *Canadian Environmental Protection Act, 1999*<sup>114</sup> and the *New Substances Notification Regulations*.<sup>115</sup> Pharmaceuticals, cosmetics, veterinary drugs, food additives, novel foods, biologicals (including genetic therapies), radio-pharmaceuticals, medical devices, and natural health products are all included. Before importing or manufacturing a new substance in Canada, importers or manufacturers must provide additional data to Health Canada so that an environmental assessment can be conducted.

### *Establishment Licenses*

Establishment licenses ensure that manufacturers comply with good manufacturing practices (GMP) or equivalent standards for drugs and natural health products. All establishments that fabricate, package, label, import, distribute or wholesale these products, or operate a testing laboratory for them, must have an establishment license, unless they are expressly exempted under the *Food and Drugs Act and Regulations*.

HPFB also inspects manufacturing plants and other sites where products covered under the *Food and Drugs Act* are handled to verify compliance with regulatory requirements. Establishment licenses, issued by Health Canada, are renewed on a yearly basis. Establishment license holders are inspected every three years. Traditional medicines, homeopathic preparations, and vitamin and mineral supplements, when in dosage form and intended for self-medication, are currently exempt from this requirement.

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<sup>114</sup> S.C. 1999, c. 33.

<sup>115</sup> SOR 2005/247 and SOR 2005/248.



### *Imported Products*

It is mandatory that a person in Canada be responsible for imported drug products. Importers usually must hold an establishment license and have evidence available that the imported products meet Canadian GMP or equivalent standards.

Where a drug is registered in the name of a company not located in Canada, the name of the importer and the business address of the person in Canada responsible for its sale must appear on the inner and outer labels of the drug. Importers must provide evidence that their products meet the same standards as those manufactured domestically, before they can become available in Canada. This may involve inspection of specific incoming shipments and close cooperation with the Canada Border Services Agency.

An establishment license is not required if:

- The importer is a practitioner, pharmacist or a person under the supervision of a practitioner
- The drug is imported for a prescription
- The drug is not commercially available in Canada.

To determine whether imported drugs meet Canada's GMP regulatory requirements, Health Canada uses reports from its own inspectors or from recognized partner countries under the terms of Mutual Recognition Agreements (MRAs)<sup>116</sup> and the Pharmaceutical Inspection Cooperation Scheme (PIC/S). It also uses inspection reports from the United States Food and Drug Administration.

The use of inspection reports from recognized partner countries is based on a rigorous process that has established equivalency of both GMP standards and compliance inspection procedures and reports between the two countries.

### *Distribution*

Schedule F to the *Food and Drug Regulations* identifies those drugs that are authorized for sale on condition that they are prescribed by a physician. The distribution of drug products for human use is governed by the Provinces.

### *Compliance and Enforcement*

HPFB has inspectors who verify compliance with the *Food and Drugs Act and Regulations*. Where necessary, they take steps to enforce the prohibitions outlined in these laws. Under the authority of the *Food and Drugs Act*, inspectors can enter and

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<sup>116</sup> Canada has established MRAs with Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom. An MRA is also being finalized with Australia. The Pharmaceutical Inspection Cooperation Scheme members include the MRA countries listed above, as well as: Czech Republic, Hungary, Malaysia, Romania, Singapore, Slovak Republic and Latvia.

inspect places where drugs are manufactured, prepared, preserved, packaged or stored. If any non-compliance is found, appropriate actions are taken.

## Appendix 2. Data Description

The data in this study refer only to prescription drugs sold in Canada. Non-prescription or over-the-counter (OTC) drugs are excluded. Brand-name and generic drug-product data were sourced from IMS Health and Brogan Inc.

### *IMS Health - Canadian Drug Store and Hospital Purchases Audit*

Canadian Drug Store and Hospital Purchases Audit (CDH) from IMS collects data on dollar value and unit volume of pharmaceutical products purchased by retail pharmacies and hospitals, from a representative sample of over 2,000 drugstores and 563 hospitals. The sample data is projected to the universe of drugstores and hospitals to reflect all purchases in Canada. Drug purchase data are collected electronically and include the following data items: corporation/manufacturer, molecule/chemical, product name, launch date, strength, package size, dollar sales, units, and prescriptions. Data take into account the purchases of drugstores and hospitals regardless of whether purchases were made directly from manufacturers or through wholesalers. Therefore, it includes markup by wholesalers for the volume moving through wholesalers.

The data set used in this report contains information on 108 molecules on the Canadian market that lost patent protection between 2001 and 2006. For each strength and dosage format, by province/region, on a monthly basis, the following information was available: molecule name, product name, therapeutic class level three, manufacturer, strength, product form, launch date, number of prescriptions, number of extended units purchased and price of purchase.

The extended unit may be pills (for oral solids), millilitres (for liquids), doses (for some inhalers) and grams (for powders).

### *Brogan Inc. - Public and Private Drug Plans Database*

Provincial data from Brogan Inc. covers British Columbia, Alberta, Manitoba, Ontario, Quebec, New Brunswick, Nova Scotia, Prince Edward Island, and Newfoundland and Labrador. Brogan provincial data provide information on drug utilization metrics for molecules available in Canada whose patent expired between 1998 and 2005.

The data set used in this report contains information on OTC and prescription drugs for 283 molecules available in Canada that lost patent protection between 1998 and 2005. Of these, 200 molecules were sold by prescription only. For each molecule, by province, the following information was available: DIN, molecule name, product name, therapeutic class, manufacturer, strength, product form, patent expiry date for branded drugs, NOC issue date, launch date, formulary listing date, formulary listing price, number of claims, number of units dispensed and cost of claims.

In every province except Newfoundland and Labrador, the cost element includes the drug ingredient cost and the pharmacy mark-up. In Newfoundland and Labrador the cost

consists of: drug ingredient cost + pharmacy mark-up + pharmacy dispensing fee (for some plans) – patient co-payment.

The average pharmacy mark-up was 7% in Alberta, British Columbia and Manitoba, 8% in New Brunswick and Nova Scotia, 15% in Newfoundland and Labrador, 10% in Ontario, 12.95% in Prince Edward Island and up to 9% in Quebec. In Saskatchewan the pharmacy mark-up is 30% for a drug cost up to \$6.30, 15% for a drug cost between \$6.31 and \$15.80, and 10% for a drug cost of \$15.81 to \$200.00, up to a maximum of \$20.00 for drug cost over \$200.00. The private plans allowed for an average mark-up of 10%.

The following version of each provincial formulary was used to obtain information on formulary list prices.

Table 16. Sources of Provincial Formulary Prices

	Alberta HWDBL Full list, January 2007 and Alberta Additions, March 2007
BC	Up to Bulletin of March 21 2007
MB	Manitoba Interchangeable Formulary, December 2006
NL	Interchangeable Drug Formulary, March 2007
NB	New Brunswick: MAP List, March 2007
NS	MAC List, July 2006 and update MAC, February 2007
PEI	MAC List, May 2006
ON	ODB Edition 39 and updates, March 2007
QC	Liste de Medicaments, February 2007
SK	Formulary of February 2006 and many bulletins until January 2007

### Appendix 3. List of Acronyms

AB:	Alberta
AG:	Authorized (or licensed) Generics
ANDS:	Abbreviated New Drug Submission
API:	Active Pharmaceutical Ingredient
ASHP:	American Society of Health-System Pharmacists
BC:	British Columbia
CAPDM:	Canadian Association for Pharmacy Distribution Management
CDH:	Canadian Drug Store and Hospital Purchases Audit
CGPA:	Canadian Generic Pharmaceuticals Association
CHA:	Canada Health Act
CIBC:	Canadian Imperial Bank of Commerce
CIHI:	Canadian Institute for Health Information
CMDB:	Canadian Management Information Systems Database
DC:	Distribution Channel
DIN:	Drug Identification Number
DND:	Department of National Defense
GJC:	Groupe Jean Coutu
GMP:	Good Manufacturing Practices
GPO:	Group Purchasing Organizations
HBM:	Health Benefit Managers
HPA:	Health Plan Administrator
HPFB:	Health Products and Food Branch (Health Canada)
ICES:	Institute for Clinical Evaluative Sciences
IDA:	Independent Druggists' Association
IG:	Independent Generic
IMS:	Intercontinental Medical Statistics
IPD:	Independent Pharmacy Distributors
IT :	Information Technology
IV:	Intravenous
MB:	Manitoba
MRA:	Mutual Recognition Agreement
NB:	New Brunswick
NDS:	New Drug Submission
NIHB:	Non-Insured Health Benefits
NL:	Newfoundland & Labrador
NOA:	Notice of Allegation
NOC:	Notice of Compliance
NOD:	Notice of Deficiency
NON:	Notice of Non-Compliance
NPS:	National Pharmaceutical Strategy
NS:	Nova Scotia
OCOTH:	Ontario Council of Teaching Hospitals
OCP:	Ontario College of Pharmacists
ODB:	Ontario Drug Benefit

OECD: Organization for Economic Co-operation and Development  
ON: Ontario  
OTC: Over The Counter  
PBM: Pharmacy Benefit Manager  
PBM/HBM: Pharmaceutical/Health Benefit Managers  
PDCI: Palmer D'Angelo Consulting Inc.  
PEI: Prince Edward Island  
PIC/S: Pharmaceutical Inspection Cooperation Scheme  
NOC: Patented Medicines Notice of Compliance  
PMPRB: Patented Medicines Price Review Board  
POS: Point of Sale  
P&T: Pharmacy and Therapeutics  
QC: Quebec  
RCMP: Royal Canadian Mounted Police  
R&D: Research and Development  
RHA: Regional Health Authority  
RFI: Request for Information  
RFP: Request for Proposal  
Rx: Prescriptions  
SK: Saskatchewan  
SNDS: Supplemental New Drug submission  
TPD: Therapeutic Products Directorate  
TPP: Third Party Providers  
US: United States

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