

GENERIC DRUG PRICING AND ACCESS IN CANADA: WHAT ARE THE IMPLICATIONS?

A commissioned discussion paper by SECOR Consulting.

JUNE 2010

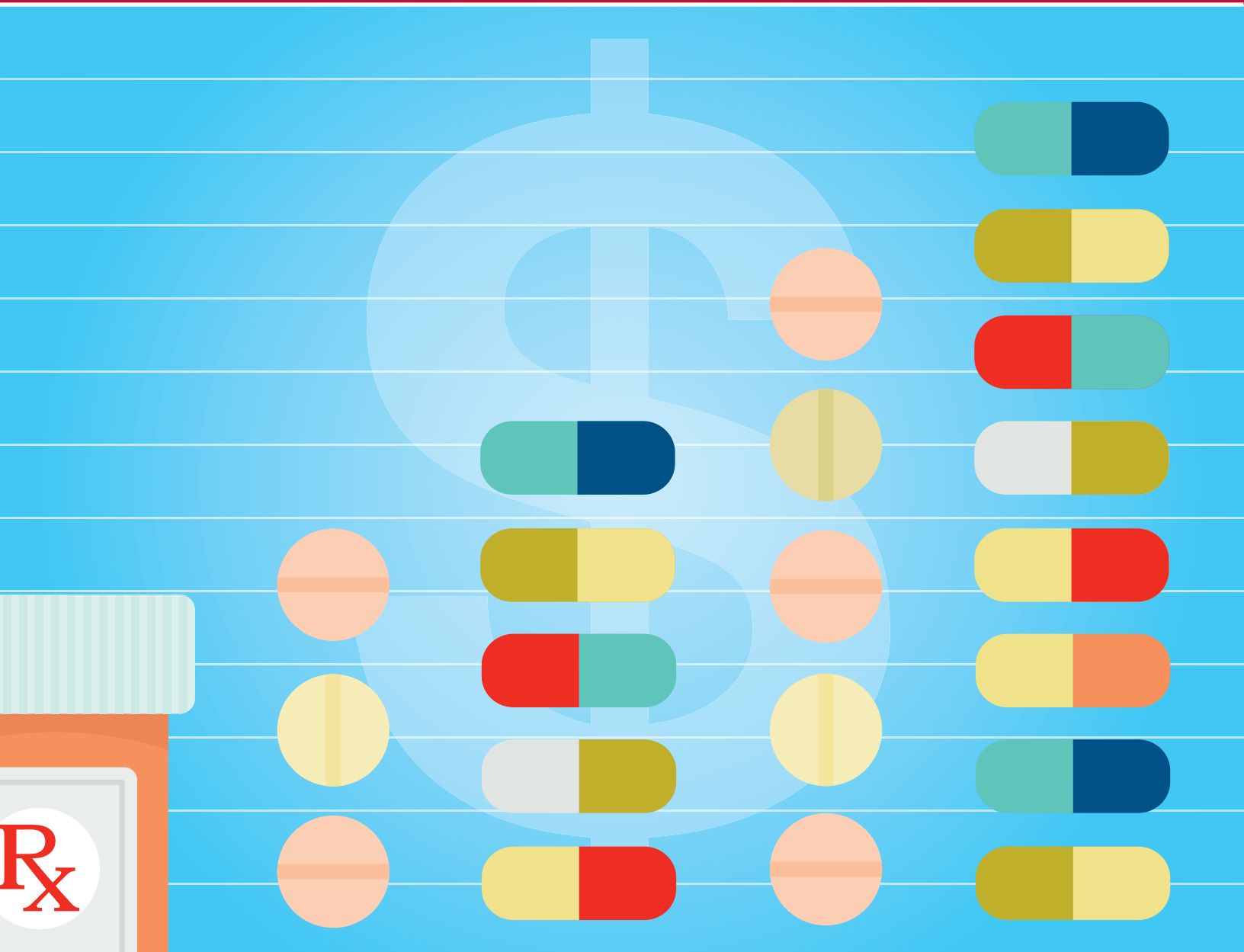


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The Health Council of Canada would like to acknowledge funding support from Health Canada. The views expressed here do not necessarily represent the views of Health Canada.

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Generic Drug Pricing and Access in Canada: What are the Implications?

June 2010

ISBN 978-1-897463-72-7

How to cite this publication:

Bell C, Griller D, Lawson J, Lovren D. (2010). *Generic Drug Pricing and Access in Canada: What are the Implications?* Toronto: Health Council of Canada. www.healthcouncilcanada.ca.

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GENERIC DRUG PRICING AND ACCESS IN CANADA: WHAT ARE THE IMPLICATIONS?

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June 2010

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FOREWORD

Prescription drugs account for an increasing proportion of Canada's growing health care system with rising costs that governments in this country are seeking ways to restrain.

The greater use of generic drugs, for which Canadians pay some of the highest prices in the world, accounts for a significant portion of these rising costs.

The Health Council of Canada commissioned this independent discussion paper to provide Canadians with some further insight into the generic drug sector and potential options to reduce generic drug prices.

Generic drugs are essentially copies made of brand name drugs after their patent protection has expired.

Currently, more than half of the prescriptions written in Canada are for generic drugs — a proportion that is likely to rise as several widely prescribed drugs come off patent in the next few years.

Generic drugs are less expensive than their brand name counterparts and play an important role in helping to improve access to required prescriptions and to contain health care costs.

However, there has been cause for concern for some time about generic drug prices in this country. For example, a 2006 study on non-patented drug prices, conducted by the Patented Medicine Prices Review Board, found average international prices for generic drugs in 10 developed countries to be 15-77% lower than average Canadian prices.

Canada's relatively high generic drug prices contribute to increased health care costs, put a strain on provincial drug program budgets, and can have a negative impact on Canadians' access to medicines and health care.

In recognition of these realities, the 2003 *First Ministers' Accord on Health Care Renewal* pledged to "better manage the costs of all drugs, including generic drugs." As part of the 2004 *10-Year Plan to Strengthen Health Care*, First Ministers further stated that they wanted to "accelerate access to non-patented (generic) drugs and achieve international parity on prices" within the context of a national pharmaceuticals strategy.

Since then, persistent concern about generic drug pricing in Canada prompted the Competition Bureau to publish two reports. The 2007 *Canadian Generic Drug Sector Study* examined the way that generic drugs are marketed in Canada and stated that the design of drug plans "has not resulted in the benefits of ... [generic drug] competition being passed along to Canadians in the form of lower prices." The Bureau's 2008 report, *Benefiting from Generic Drug Competition in Canada: The Way Forward*, suggested some mechanisms to bring down prices and concluded that Canadian taxpayers, consumers, and businesses could save up to \$800 million a year if changes were made to the way that generic drugs are paid for by governments and private plans.

In recent years some provincial governments, which are major payers for prescription drugs, have launched initiatives to bring down generic drug costs. Yet for most Canadians, the issues concerning generic drug pricing remain elusive.

This discussion paper highlights the complex reasons associated with the high cost of generic drugs and the longstanding lack of transparency about how prices are set. Potential options for governments to consider in order to institute reforms, reduce costs, and increase the transparency of generic drug transactions are presented.

Our goal in publishing this discussion paper is to shed light on generic drug pricing issues in order to help Canadians understand what is at stake and to encourage broad public discussion.

Jeanne Besner, RN, PhD
Chair, Health Council of Canada

INTRODUCTION

Rapidly rising expenditures on prescription drugs are of serious concern to individual Canadians and to private and public insurers. Our spending on drugs is growing mainly because we are using more of them. The average age of the population is rising and many Canadians are now living with chronic conditions such as heart disease and diabetes. Drugs are helping us to live longer and to keep us out of hospital but these benefits come at a price.

Faced with tough economic times, provincial and territorial drug plans are looking for ways to restrain their multi-billion-dollar share of the country's annual bill for prescription drugs. Since 2006, some provinces (British Columbia, Alberta, Manitoba, Ontario, Quebec, and Newfoundland and Labrador) have taken steps to rein drug prices in, while improving access.

This discussion paper aims to provide policy-makers, other key stakeholders, and the Canadian public with substantive discussion on the short- and long-term implications of generic drug pricing and reimbursement policies in Canada. The paper shines a light on the issues at play and on related developments within the jurisdictions, and informs Canadians and stakeholders about this important issue against a backdrop of the global economic crisis, growing drug utilization, and a progressively aging population with an increasing percentage of Canadians living with multiple chronic conditions.

SECOR gathered opinions from a broad range of stakeholders and experts, including provincial drug-plan managers, private drug-plan consultants, industry association representatives (manufacturing and pharmacy), patient advocacy representatives, and federal government officials, as well as Canadian and international researchers.

In addition to the insights provided by stakeholders, SECOR conducted an extensive review of the literature on generic drug pricing and access. In particular, two reports published by the Competition Bureau in 2007 (*Canadian Generic Drug Sector Study*), and 2008 (*Benefiting from Generic Drug Competition in Canada*), formed a valuable foundation for the discussion.

EXECUTIVE SUMMARY

Prescription drugs developed over the last 40 years have transformed the practice of medicine. They provide treatments that can cure or help control such conditions as asthma, diabetes, heart disease, bacterial infections, depression, HIV/AIDS, and some forms of cancer. As innovations in prescription drugs have advanced, so has spending on these products, which are now an important component of health care expenditure.

Brand name drug companies conduct the expensive research and development required to bring an innovative (i.e. new) drug to the market. They enjoy the benefit of patent protection for a limited period during which they have market exclusivity, in order to recover their research and development expenditures and make a profit. Then, when patents on innovative drugs expire, generic drug companies are free to make their own versions. These drugs are termed generic drugs and contain the same medicinal ingredients as the original brand name products, but may contain different non-medicinal ingredients.

Both brand name and generic drugs can be sold in Canada only after they have received a Notice of Compliance (NOC) from Health Canada attesting to their safety, quality, and efficacy. In proving the safety and efficacy of their products, generic drug manufacturers are not required to repeat the expensive clinical studies that brand name firms must undertake. Consequently, they are able to charge lower prices for their products.^a

An aging population, along with an increasing number of individuals living with multiple chronic illnesses, means that many more Canadians will require access to prescription medications. Generic drugs play an important role in containing the expenditures on prescription drugs and enhancing accessibility for a cost-sensitive segment of the population who may not be able to afford the more expensive brand name drugs. This increase in accessibility may lead to better adherence to prescribed medication and consequently to improved health outcomes.

Pricing in the generic market is primarily driven by provincial and territorial drug plans. The plans have traditionally reimbursed generic drugs by paying a percentage of the price of the brand name drug or by paying a price quoted by a generic drug manufacturer.

In the early 1990s, government drug plans set prices for generic drugs at a relatively high percentage of the price of the brand name drugs they emulated. Naturally, pharmacies typically billed governments the maximum allowable amounts. Generous profits in the supply chain benefited generic drug manufacturers and encouraged the proliferation of retail pharmacies. Initially, the manufacturers held sway over the pharmacies, and encouraged their purchasing-loyalty by offering them rebates.^b Pharmacies reaped the benefits of reduced drug-acquisition costs and these became an integral part of their retail business model, allowing the number of pharmacies to grow. Over time, the agglomeration of retail pharmacies into franchises, chains, and banner groups shifted the balance of power—these pharmacies could now drive their drug-acquisition costs further down by demanding ever-deeper rebates from the manufacturers. These rebates—also referred to as professional allowances and off-invoice discounts—became the primary lever through which generic firms competed for pharmacy shelf space.

The market dynamics that governments themselves had a hand in creating ultimately became a source of frustration for them. Realizing they were allocating too much profit to the supply chain they began to reduce reimbursement rates. At the same time, governments noted the lack of transparency as to how profits in the supply chain are distributed. They are faced with the challenge of not knowing how much profit can be squeezed from the supply chain through reductions in reimbursement levels before the chain is damaged.

Creating a more sustainable drug system that addresses people's needs at an affordable cost is not simple. Finding solutions that meet this goal and minimize the negative impacts on key stakeholders is an even greater challenge. The impacts of an aging population along with an

^a Generic firms charge lower prices for their products not only due to their relatively low research and development costs, but also due to the effects of competition. Competition puts downward pressure on generic drug prices, but is absent in the patented drug market.

^b The terms "rebates," "professional allowances," and "off-invoice discounts" are used interchangeably throughout the report.

increasing number of individuals living with multiple chronic conditions further compound the problem of creating a sustainable system.

Based on interviews with key stakeholders, researchers, and representatives from other jurisdictions, **six critical success factors** that can improve affordability, accessibility, and sustainability emerged (Figure 3, page 27):

- (A) **Effective pricing strategies** Pricing strategies work well when they reflect the true costs of manufacturing generic drugs and incorporate reasonable profit margins along the supply chain. A 2008 comparison of prices paid by Canadian and international jurisdictions suggests that Canadian payers are reimbursing generic drugs well beyond their true cost, and the excess is being passed along the supply chain to the consumer. Recently proposed changes in Ontario seek to redress the problem, but some commentators suggest they go too far and could actually impact access to pharmacy services through, for example, reduced hours of operation.
- (B) **Appropriate and efficient use of generics** Use of cheaper generic drugs in place of their brand name equivalents is an important source of savings for all payers. Currently, both regulatory and financial incentives in Canada encourage the use of generic pharmaceuticals.
- (C) **Alternative drug distribution channels** Alternative drug-distribution channels offer improved accessibility and are a source of potential cost savings. Most Canadians obtain their prescription medications directly from a pharmacist in a community pharmacy—the prevalence of other drug distribution channels in Canada is currently limited.
- (D) **Diverse offering of pharmacy services** Typical non-dispensing pharmacy services include or could include blood tests, diabetes care, smoking cessation management, vaccinations, the provision of initial treatment for minor ailments, and cholesterol-control consultations, as well as some prescribing privileges. Relatively few Canadian pharmacies offer more than one of these value-added services, even though the scope of the pharmacist's role has recently been expanded to allow the provision of some of these and other basic medical services.
- (E) **High consumer involvement** A higher level of consumer involvement in drug-purchasing decisions could push pharmacy retailers to compete more aggressively on prices. In the current system, consumers have little purchasing power or influence, which allows pharmacies to largely avoid competing on price.
- (F) **Optimal government involvement** Governments are major players in the generic drug market since they are major purchasers of drugs. Through this power and through legislative authority, they can effectively set prices. However, they are also concerned with maintaining an effective supply chain. They want to ensure that all links in the chain can make reasonable but not excessive profits. Given that governments play multiple roles as regulators, price setters, and purchasers, they need to optimize their involvement in the marketplace so that all stakeholders are treated fairly.

In addition to these success factors, the consultations with key stakeholders identified a number of key messages regarding existing trends in Canada:

- While provinces and territories regularly share information with each other, interjurisdictional collaboration on key policy decisions is not as extensive as it could, and needs, to be.
- The gap between public and private insurance costs continues to widen. Many provincial and territorial drug-plan policies on pricing are not extended to private insurance markets.
- The balance of power in the generic drug market has shifted from manufacturers to pharmacy groups, with competition increasing in the manufacturing sector, and with retail pharmacy groups (e.g. chains and franchises) becoming more dominant in the pharmacy sector.
- Benefits of competition at the manufacturing level are absorbed by pharmacies and are not being passed on to consumers and payers.
- A lack of transparency in the system, particularly in determining manufacturer prices net of any off-invoice discounts, has made it difficult for governments to develop effective policies.

- Access to drugs is largely not seen as a significant public policy issue in most Canadian jurisdictions given that most Canadians have some form of drug insurance, even though some may still be facing high out-of-pocket costs.

In the short term, policy-makers could take a number of approaches that would improve affordability, accessibility, sustainability, and transparency, while at the same time minimizing any potential negative impacts on key stakeholders. For example:

- **Drug insurance plans could revisit their maximum reimbursement prices since a body of evidence suggests that Canadian prices are too high.** Drug plans could use Canadian industry information and pricing data from other countries for guidance. This approach mirrors the actions that many provinces are already taking and is basically an extension of the status quo.

If governments are to continue to intervene in the market, they need to ensure that public plans do not achieve lower prices at the expense of private plans. They need to ensure that private plans do not pay more than public plans either by making pricing well-known or through regulation.

- **Reimbursement prices could be set at the pharmacy level.** Governments have constructed reimbursement prices by setting a price for a drug, and by adding distribution costs, profit margins, and dispensing fees for pharmacies. Much to the frustration of governments, manufacturers have competed with each other by offering rebates to pharmacies. Offering discounts and rebates to purchasers is a normal commercial practice that governments have tried without success to suppress. Governments could reimburse pharmacies a single amount, which includes the actual cost of the drug, wholesaler fees, and pharmacy fees for dispensing and counselling.
- **The use of alternative and competing distribution channels could be encouraged.** With more alternatives in the retail market (e.g., mail-order pharmacies and automated dispensaries), competition would increase to the benefit of all payers. Consumer preferences will ultimately dictate how pervasive these channels become and consequently the magnitude of potential impacts. However, regulators should ensure that any barriers to the success of these service-delivery channels are removed.

- **Drug plans, including employer-sponsored plans, could use tiered formularies to encourage their beneficiaries to use low-cost drugs.** Tiered formularies and their associated patient co-payments effectively sensitize the consumer to the cost of medications. However, care must be taken to ensure that patients continue to take appropriate drugs—both for their own benefit and because inferior health outcomes would cost the health system more than any monies saved.

- **Provincial and territorial drug plans could ensure that newly approved drugs are listed on their formularies in a timely manner.** Currently, the formulary listing process can take several months from the time the drug has received its Notice of Compliance from Health Canada. This delay in listing newly approved drugs results, for instance, in public drug plans paying additional money for a brand name drug, even though a lower-cost generic version is available.

- **Using the pharmacist to provide additional paid services would moderate the impact of reducing generic drug prices and benefit the health care system.** Given that the Canadian population is aging, the prevalence of chronic disease is increasing, and medical-service demand is growing, expanding the role of the pharmacist could be of great value for both the patient (improved outcomes and access) and the health care system (improved sustainability).

SECTION 1: WHY SHOULD GENERIC DRUGS MATTER TO CANADIANS?

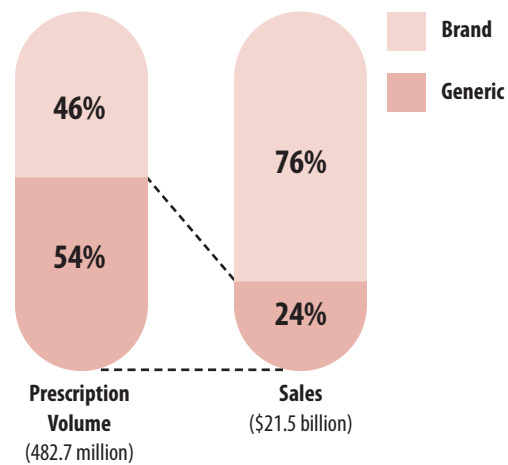
Prescription drugs developed over the last 40 years have transformed the practice of medicine. They provide treatments that can cure or help control such conditions as asthma, diabetes, heart disease, bacterial infections, depression, HIV/AIDS, and some forms of cancer. As innovations in prescription drugs have advanced, so has spending on these products so that they are now an important component of health care expenditure. Spending on prescription drugs in Canada was estimated by the Canadian Institute for Health Information (CIHI) at roughly \$25.4 billion in 2009. The annual growth rate for total drug expenditure outpaced that of total health expenditure from 1985 to 2005 and these rates have been fairly equivalent since. Prescription drugs accounted for 67.5% of total drug spending in 1985, rose to 83.1% in 2007, and are estimated to have accounted for 84.6% of total drug expenditure in 2009.¹

Brand name drug companies conduct the expensive research and development required to bring an innovative drug to market. They enjoy the benefit of patent protection for a limited period (typically 20 years^{2,3})^c during which they have market exclusivity, in order to recover their research and development expenditures and make a profit.

When patents on innovative drugs expire, generic drug companies⁴ are free to make their own versions. These are termed generic drugs and contain the same medicinal ingredients as the original brand name product, but may contain different non-medicinal ingredients. A generic drug must show that it can deliver the same amount of medicinal ingredient in the blood at the same rate as the brand name drug.⁴ The rate and extent of absorption of the drug in the patient’s body must fall within an acceptable range of the brand name product.³

Both brand name and generic drugs can be sold in Canada only after they have received a Notice of Compliance (NOC) from Health Canada attesting to their safety, quality, and efficacy.⁵ Upon patent expiry of the brand name drug, generic manufacturers must demonstrate how the generic product performs in comparison to the brand name product, among other requirements.³ However, in proving the safety and efficacy of their products, generic drug manufacturers are not required to repeat the expensive clinical studies that innovative firms must undertake, and hence are able to charge lower prices for their products.^c

PRESCRIPTION VOLUME AND DRUG SALES IN CANADA (2009)



The price difference between brand name and generic products is best illustrated by examining prescription volume and total drug sales. Generic drugs account for 54% of all prescriptions in Canada, but represent only 24% of prescription drug sales, in terms of total value.⁶

^c Because some manufacturers may obtain more than one patent for a particular drug, the period of patent protection may, in some cases, last more than 20 years. Under these circumstances, the drug will be under patent protection until the last of the filed patents has expired (assuming none of the patents have been proven invalid by another manufacturer).³

^d In some cases, brand name firms also choose to manufacture their own generic drugs. Please see "Brand Name Manufacturers" in Section 4: Key Stakeholders, for further discussion.

^e Please refer to footnote 'a' on page 4.

Generic drugs and the policies that regulate their pricing and accessibility should—and do—matter to Canadians, for the following three reasons:

Generic drugs play an important role in containing expenditures on prescription drugs.

Pharmaceutical products are, in part, paid for by taxpayers whose money funds provincial drug plans and by employers who, in the main, pay for private drug plans.

Generic drugs, as lower-cost alternatives to off-patent brand name drugs, help contain expenditures on pharmaceuticals. While substitution of a generic drug for a brand name drug is not always appropriate,^f in most cases generic drugs do represent a viable alternative.

The use of generic drugs is growing because brand name drugs such as atorvastatin (Lipitor®) and amlodipine (Norvasc®) have come off patent, and will continue to grow as other blockbuster brand name drugs come off patent in the next few years. The projected increase in use of generic drugs will provide a significant source of long-term savings on drug expenditures for all payers.

The importance of containing costs over the long term should not be understated given the projected impact of demographics on drug use. An aging population, along with an increasing number of individuals living with multiple chronic conditions, means that many more Canadians will require access to prescription medications. In fact, individuals

over age 65 account for 41% of retail pharmaceutical spending with individuals between the ages of 45 and 64 accounting for a further 36%.⁷

Generic drugs also play an important role in enhancing accessibility for a cost-sensitive segment of the population who may not be able to afford the more expensive brand name drugs. This increase in accessibility may lead to better adherence to prescribed medication and consequently to improved health outcomes. Generic drug prices also permit drug plans to offer more generous coverage, which may also lead to improved adherence and health outcomes.

Canadians pay too much for generic drugs.

In 2007, Canada was second only to the US in total drug expenditure per capita among 23 Organisation for Economic Co-operation and Development (OECD) comparator countries.¹

Patented brand name prices at the manufacturing level are held in check by the Patented Medicine Prices Review Board (PMPRB).⁸ One price-control mechanism used by the PMPRB is to limit prices of patented drugs in Canada to the median price found in seven industrialized nations.⁹ However, no such mechanisms are in place to regulate generic drug pricing. In other words, price regulation to explicitly ensure that generic prices in Canada are in line with those in other jurisdictions is absent.⁸ Prices of generics in Canada are among the highest in the industrialized world.

AVERAGE FOREIGN-TO-CANADIAN PRICE RATIO AT MARKET EXCHANGE RATES, PATENTED, GENERIC AND NON-PATENTED BRANDED PRESCRIPTION DRUG MARKET SEGMENTS, BY BILATERAL COMPARATOR (2005)

According to a 2006 study by the PMPRB, generic drug prices in Canada are higher, and in most cases substantially higher, than in all 11 countries in the study.¹⁰ Other studies that have examined generic drug prices reached similar conclusions. While generic drug prices in some Canadian jurisdictions have decreased since 2006, they are still higher than in many countries listed in this table.^{8, 11}

Country	Patented	Generic	Non-Patented Branded
Australia	0.78	0.85	0.81
Finland	0.88	0.49	0.75
France	0.85	0.71	0.76
Germany	0.96	0.84	0.91
Italy	0.75	0.76	0.73
Netherlands	0.85	0.80	0.72
New Zealand	0.79	0.23	0.64
Spain	0.73	0.58	0.59
Switzerland	1.09	0.99	1.34
UK	0.90	0.80	0.87
US	1.69	0.65	2.46

^f Generic drug substitution may not always be appropriate given that there are some variations between brand name and generic drugs, as discussed further in Section 2.

⁸ Based on Ontario's reimbursement prices as of 2009.

The generic drug market lacks transparency.^h

Provincial and territorial governments are major payers for pharmaceutical products. As a consequence, their policies have a profound effect on the operation of the Canadian market.ⁱ

As drivers of price in the generic drug market, our public drug plans have traditionally reimbursed generic drugs at a percentage of the brand name price, or at a price quoted by the generic drug manufacturer. Most plans also allow the pharmacist a mark-up and a dispensing fee. However, private drug plans and patients paying for drugs from their own pockets may be charged more or less than public plans for each of these components.

One of the main irritants in the generic market is the way in which the drug reimbursement amount set by the insurer is allocated between manufacturers, wholesalers, and pharmacies. In recent years, retail pharmacy chains and franchises have come to dominate the Canadian sector.³ Exercising considerable purchasing power, they have been able to extract substantial rebates from manufacturers. Independent pharmacies have also been able to extract rebates from manufacturers, though likely not at the same level as pharmacy chains and franchises. Governments have, from time to time, tried to control these practices but with limited success. While individual provincial and territorial drug plans may apply one set of pricing and rebate rules, these can be circumvented by pharmacy retail groups and manufacturers who establish alternate compensation mechanisms through private plans or reimbursement programs in other provinces.

These conditions have led policy-makers to consider the following questions:

- What should Canadians pay for generic drugs?
- What profits should manufacturers, wholesalers, and retail pharmacies capture?
- To what extent should governments intervene in the management of private plans to establish an equitable market?
- Should provinces and territories harmonize their approaches?

The National Pharmaceuticals Strategy (NPS)^j was intended to assist policy-makers in answering some of these questions by developing nationwide sustainable solutions addressing the safety, accessibility, and affordability of drugs. Among other objectives, the NPS aimed to:¹³

- find ways to reduce the costs of prescription medications to governments and individual Canadians;
- ensure that all Canadians have access to the same prescription drugs through their government drug plans, based on a common national formulary; and
- develop options for a nationwide plan for *catastrophic drug coverage* to ensure that Canadians don't face undue financial hardship to pay for prescription medications they need, regardless of where they live (*catastrophic* refers to the impact on a person's finances, not to his or her medical condition).

A 2009 report by the Health Council of Canada found that provincial and territorial governments have proceeded with their own drug reforms, but cooperation among the jurisdictions on a national effort was lost.¹⁴ Since then, both Alberta and Ontario have announced significant reforms to their own policies, but a national strategy is still not in place.

^h A lack of transparency is also an issue in the brand name drug market. For instance, in Ontario, the public drug plan can negotiate secret rebates with brand name manufacturers, allowing the manufacturer to list one price on the formulary and pay secret rebates directly to the Ontario Drug Benefit (ODB) Program. This strategy allows the brand name manufacturer to maintain the ODB prices in the private market and other provinces.¹²

ⁱ Federal reimbursement policies are not discussed in this paper. As stated under "Coverage Policy" in Section 3: Coverage and Reimbursement Policies, federal drug plans cover a relatively small portion of Canadians. Interviews with jurisdictional informants have indicated that federal reimbursement policies typically closely follow the mechanism used by the province or territory where the federal-plan beneficiary resides.

^j The First Ministers recommended a National Pharmaceuticals Strategy as part of their *10-Year Plan to Strengthen Health Care*.

SECTION 2: OVERVIEW OF GENERIC DRUGS

Generic is the term used for a drug that contains the same medicinal ingredients as the original brand name product, but may contain different non-medicinal ingredients. The non-medicinal (inactive) ingredients affect the size and shape of the drug.⁴ Since generic drug manufacturers are not required to carry out expensive chemical, animal, or human studies to prove the safety and efficacy of new products, they can offer their products at lower prices than those charged by brand name firms.^k

Brand name drugs can be sold in Canada only after they have received a NOC from Health Canada attesting to safety, quality, and efficacy.¹⁵ When patents and data protection expire on these products, generic drug firms can enter the market. The generic manufacturers must also obtain a NOC, which requires them to conduct bioavailability studies or to demonstrate how their product performs in comparison to the brand name original.³ Also, of course, they must conform to regulated high-quality manufacturing procedures.¹⁶

Bioequivalence

Health Canada defines *bioequivalence* as a “high degree of similarity in the rate and extent of absorption into the systemic circulation of two comparable pharmaceutical products in the same dose, that are unlikely to produce clinically relevant differences in therapeutic effects or adverse effects, or both.”¹⁶

Comparing the rate and extent of absorption of brand name and generic drug products is usually done through comparative bioavailability studies. These studies typically measure generic drug levels in the blood of healthy human volunteers and compare them with those published for the brand name drug. Some tolerance is allowed for bioavailability difference between the generic and the brand.

Health Canada relies on data that was used by the brand name firm in bringing the original drug to market. This data is protected for a period of eight years (from the time the brand name manufacturer applies for a NOC), during which it cannot be used to prove bioequivalence of generic drugs.^{3,4}

Quality of Manufacturing

Generic drug manufacturers are also subject to Good Manufacturing Practices (GMP) which ensure that drugs are produced consistently. These include the employment of qualified and trained personnel; adequate premises and space; suitable equipment and services; correct materials,

containers, and labels; approved procedures and instructions; adequate testing; and suitable storage and transport. GMP also requires extensive documentation and traceability of all ingredients used and procedures carried out.^{16,17}

Further, “All establishments engaged in fabrication, packaging or labeling, importation, distribution, wholesale, or operation of a testing laboratory for drugs are required to hold an establishment license.” The Health Products and Food Branch (HPFB) of Health Canada is responsible for the inspection of these establishments to verify that they comply with GMP.¹⁶

Comparability with Brand Name Drugs

Even though less effort is typically required for generic drugs to receive a NOC, both brand name and generic drugs are subject to the same safety, quality, and efficacy standards.¹⁵ Hence, for most patients, a generic drug can be substituted for the original brand name drug, without any adverse effects or poorer health outcomes. However, differences between generic and brand name drugs with respect to the make-up of inactive ingredients may make generic substitution inappropriate for some patients.¹⁸

^k Please refer to footnote ‘a’ on page 4.

SECTION 3: COVERAGE AND REIMBURSEMENT POLICIES

Drug insurance plans are designed to help people pay for prescription medications—both brand name and generic—and reduce their financial burden in the event of high or unexpected drug expenses. In fact, they cover roughly 98% of all Canadians, leaving only 2% of the population who must bear all drug costs on their own. These completely uninsured individuals are typically working-age with no employer-sponsored insurance (for instance, self-employed individuals).³ However, even insured individuals may be facing high out-of-pocket expenses.

Coverage Policy

Drug insurance plans are designed to help people pay for prescription medications—both brand name and generic—and reduce their financial burden in the event of high or unexpected drug expenses. In fact, they cover roughly 98% of all Canadians, leaving only 2% of the population who must bear all drug costs on their own. These completely uninsured individuals are typically working-age with no employer-sponsored insurance (for instance, self-employed individuals).³ However, even insured individuals may be facing high out-of-pocket expenses.

Drug plans dictate eligibility requirements and the payments required by their beneficiaries. Eligibility requirements vary greatly among providers and can include any combination of age, place of residence, and income level, among others. Beneficiaries may have to pay premiums, deductibles, or co-payments, and these can vary depending on the beneficiary's level of income.³

Public insurance plans cover roughly one third of the insured population, while private insurance plans cover the remaining two thirds.³ These plans cover the cost of prescription medications outside of hospital settings. Generally, drugs administered in hospitals are provided free of charge under each of the provincial and territorial hospital insurance plans.

Each provincial and territorial government as well as the federal government administers its own drug insurance plan. The federal government provides insurance coverage for about 1 million Canadians including First Nations and Inuit Peoples, veterans, members of the military, the RCMP, prisoners in federal correctional facilities, and refugees.³ Provincial and territorial mandates for drug insurance

are much broader in scope, covering approximately 9 million Canadians including seniors and those requiring social assistance.

Provincial and territorial drug insurance plans vary considerably in eligibility criteria. For example, BC provides universal eligibility for drug coverage.³ In Ontario, the Ontario Drug Benefit (ODB) Program provides coverage for seniors, social-assistance recipients, and residents of long-term care/special care facilities.¹⁹ In general, most provinces and territories offer some form of catastrophic drug coverage,¹ but New Brunswick, PEI, and Yukon do not. The extent of catastrophic drug coverage, in terms of the payment limit for an individual, varies from province to province, in many cases based on family income.^{m,20}

Private drug insurance plans provide coverage for employees of organizations that offer drug benefits to their workers and for individuals who choose to purchase drug insurance independently.³ Most private plans cover not only the employee, but also their family and dependents. Canada's federal and provincial governments—as employers—provide coverage for 3.2 million public servants and their dependents.²²

In addition to eligibility criteria, both public and private plans must determine the cost to be passed on to the beneficiary. Most provincial and territorial plans do not require their beneficiaries to pay premiums. Instead, these plans use deductibles and co-payments to help supplement taxation as a source of funding, with some exceptions.^{n,1} Also, most provincial and territorial plans use income-testing, varying their deductible and co-payment amounts based on the income level of the beneficiary.³ Private plans also use deductibles and co-payments as part of their insurance policies.

¹ *Catastrophic drug coverage* is defined as “the provision of a general level of coverage that protects individuals from drug expenses that threaten their financial security or cause ‘undue financial hardship.’”²⁰

^m In Quebec, the upper payment limit for any individual is fixed at \$954.²¹

ⁿ Deductibles and co-payments also deter people from using drugs unnecessarily.

Currently, public and private insurance plans account for approximately 82% of total prescription drug expenditures in Canada, while patients pay approximately 18% on their own.¹ Table 1 summarizes total drug expenditures and percentage of the total by each of the three groups: public plans, private plans, and out-of-pocket payments.

TABLE 1: PRESCRIPTION DRUG EXPENDITURES BY PAYER IN CANADA (2009 ESTIMATE)

Payer	Total Prescription Drug Expenditures	% of Total
Public Plan	\$11.4 billion	45%
Private Plan	\$9.4 billion	37%
Out-of-Pocket	\$4.6 billion	18%

Source: CIHI (2010).¹

(Note that the above figures do not include drugs paid through hospital budgets.)

It should be noted that public insurance plans, providing coverage for only a third of Canadians, account for a disproportionately large share of expenditures. This may be due to their coverage of many high-use individuals—mainly seniors and people on income support. Provincial and territorial governments are also the insurers for drugs consumed in hospitals and other health care institutions,³ but these expenditures are not reflected in Table 1.

Over the past few years, public-sector prescription drug expenditures as a percentage of total prescription drug expenditures were forecast to have fallen to 45% in 2009 from a 10-year high of 47% in 2005.¹

The share of prescription drug expenditures funded by public insurance plans ranges from 32% in Newfoundland and Labrador to 63% in Nunavut, according to a 2009 estimate.¹ Table 2 shows the public-private split by jurisdiction. The out-of-pocket breakdown was not available at the provincial and territorial level and hence these

expenditures are included under the private share of the market. The large variations among the provinces and territories are partly indicative of differences in eligibility requirements and beneficiary contributions.

Reimbursement Policy

A key decision for provincial and territorial governments is whether their policies will be formulated to apply to both public and private markets, or to public drug insurance plans alone. Currently, Alberta, Quebec, Manitoba, and Newfoundland and Labrador ensure consistent pricing across both spheres,^{23, 24, 25, 26} and the proposed drug reforms in Ontario would also result in regulation for consistency across public and private plans.²⁷ Alberta's new drug strategy will ensure uniformity across public and private plans, whereas Quebec mandates minimum/maximum co-payments and deductibles.^{23, 24, 25} In other jurisdictions, prices paid for the same generic drug may differ, in some cases substantially, between public and private plans.²⁸ Indeed, when governments apply pressure to reduce the costs of public plans, pharmacies may compensate by charging more to private payers, in those provinces where it is permitted.

Reimbursable Drugs

Drug insurance plans may use reimbursement lists, or formularies, to specify which brand name and generic drugs are covered.³ Currently, all provinces use formularies.²⁹ To be listed on provincial and territorial formularies, generic products must have a valid NOC from Health Canada, and confirmation from the manufacturer of its ability to supply the product.³

The actual reimbursement of the drug can occur at either the pharmacy level or the beneficiary level. Under some plans, pharmacies receive payment directly from the insurance provider and, if a co-payment is required, from the beneficiary. Under other plans, beneficiaries pay the pharmacy the entire cost of the prescription and later file a claim with their plan provider.³⁰

TABLE 2: PUBLIC-PRIVATE SPLIT OF PRESCRIPTION DRUG EXPENDITURES BY PROVINCE AND TERRITORY (2009 ESTIMATE)

Market	YT	NT	NU	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL
Public	64%	60%	63%	42%	47%	55%	46%	43%	49%	34%	39%	36%	32%
Private	36%	40%	37%	58%	53%	45%	54%	57%	51%	66%	61%	64%	68%

Source: CIHI (2010).¹

(Note that Private includes both private insurance plan and out-of-pocket expenditures incurred by Canadians.)

In addition to determining which drugs are eligible for reimbursement, policies can also specify the degree of interchangeability between generic and brand name. The designation of generic interchangeability is under provincial jurisdiction and varies greatly across the country. Many provinces have expert advisory committees which review generic drug submissions and determine whether they are interchangeable with the brand comparator. Most jurisdictions accept Health Canada’s Declaration of Equivalence as the primary basis for interchangeability. Some provinces have introduced streamlined review processes for certain generic drugs which involves an administrative rather than a committee review. For example, interchangeability laws can make dispensing of the lowest-cost interchangeable products mandatory. As of 2007, only Saskatchewan, Manitoba, PEI, and Newfoundland and Labrador had mandatory interchangeability. Interchangeability laws can also permit *but not require* pharmacists to interchange products, as was the case in the other six provinces. Pharmacy profits on generic drugs are often greater than on brand name products, so the pharmacy has a financial incentive to substitute generic for brand.³

Table 3 shows the number of generic drug prescriptions as a percentage of total drug prescriptions for each province.⁶ To encourage its brand name pharmaceutical industry, Quebec reimburses the full price of brand name drugs for 15 years after they have been listed on the provincial formulary, even after generic versions have entered the market. This reimbursement policy differs from that of many other provinces, which usually require the patient to pay the difference between the brand name and generic drug.³ As a result, the use of generics versus brand name drugs is lowest in Quebec.

TABLE 3: PERCENTAGE OF GENERIC DRUG PRESCRIPTIONS VS. BRAND NAME IN 2009, BY PROVINCE AS A PERCENTAGE OF TOTAL PRESCRIPTIONS (FOR BOTH HOSPITAL AND RETAIL MARKETS)

	BC	AB	SK	MB	ON	QC	NB	NS	PE/NL
Generic Prescriptions	59%	57%	57%	61%	56%	50%	61%	56%	59%

Source: Canadian Generic Pharmaceutical Association (2009).⁶
 (Note that information for the Northwest Territories, Nunavut and Yukon was not available.)

Over the past five years, the number of generic drug prescriptions as a percentage of total drug prescriptions has grown steadily. For each province, the percentage of generic drug prescriptions was between 10% and 12% higher in 2009 (Table 3) than it was in 2005.⁶

◦ A reference drug is a drug that is considered to produce an equally effective outcome and be the most cost-effective in a particular category of drugs.³²

Several mechanisms are in place to assist public plans in making formulary decisions. The Common Drug Review (CDR), which is funded by the federal, provincial, and territorial governments and conducted by the Canadian Agency for Drugs and Technologies in Health (CADTH), looks at the costs and benefits of drugs on behalf of all Canadian jurisdictions except Quebec. It conducts reviews and makes formulary listing recommendations to public plans based on a clinical efficacy and a value-for-money assessment.³¹ However, there can be long delays between the CDR recommendation and the decision to list on the public drug plan formulary.

Drug Reimbursement Prices

For each generic drug listed on a plan formulary, a set of policies determines the appropriate price for reimbursement. The reimbursement price specified in the formulary directly regulates the price that is charged to the insurance provider.

To determine the drug price specified on the formulary, plan providers typically use one or more of the following approaches:

- capping the formulary price at a percentage of the brand name price;
- specifying a maximum reimbursable cost for a drug or group of interchangeable drugs;
- linking the price to that of a therapeutically equivalent reference drug;[◦] or
- determining the price through a competitive tendering process with manufacturers.

Public and private insurers in Canada use price caps and maximum-reimbursable-cost policies extensively. Very few of them use tendering on a regular basis because pharmacies have the ability to discourage low bidding. Hospitals, however, use tendering extensively to obtain competitive prices for their supply of generic drugs.²⁸

Price Caps

Insurers can set a maximum price for reimbursement by listing each drug on the formulary at or below a percentage of the reference brand name drug price. For example, Alberta, Ontario, Quebec, and Newfoundland and Labrador use this approach by setting the price of generic drugs as a fixed percentage of the brand name prices.^{3, 23, 26} In Alberta, this fixed percentage is 45%. In Ontario, it is currently 50%, but is slated to drop to 25% by 2014 as part of the province’s proposed drug reform.²⁷ As of 2007, reimbursement policies in Quebec and Newfoundland and Labrador follow a similar approach, but incorporate an additional constraint that pegs the reimbursement price for a particular generic to be no more than the lowest price found on any other provincial formulary for the same drug.³

Maximum Reimbursable Cost

Under maximum-reimbursable-cost policies, drug plans use the cost of each generic drug to determine an appropriate formulary price.³³ The cost of each generic drug can be obtained from manufacturers, as is done in Manitoba, Nova Scotia, and other provinces. Manufacturers submit their retail prices to the drug plan, which then determines the appropriate formulary price—usually the lowest price—for an interchangeable group of drugs. Similarly, the cost of each generic drug can be determined based on the pharmacy's average claimed prices, as is the case in British Columbia.³

Manitoba recently implemented an additional requirement for generic manufacturers wanting to be listed on the provincial formulary: they must include a price-benefit analysis of the product, and a declaration that the submitted price is less than or equal to the price of that product in any other province or territory. If a generic company submits a higher price, it must explain the additional benefits the product offers over other products in its interchangeable group.²⁸

Reference Pricing

Reference pricing means using the lowest-priced drug among a group of therapeutically equivalent drugs to set the formulary reimbursement price. Therapeutic equivalence commonly refers to drug products that, when administered to the same person in the equivalent dosage regimen, result in essentially the same therapeutic effect, and/or toxicity.³⁴ British Columbia is one Canadian jurisdiction which has adopted therapeutic-reference pricing for five groups of drugs: non-steroidal anti-inflammatory drugs (NSAIDs); nitrates; histamine-2 blockers; angiotensin-converting enzyme (ACE) inhibitors; and calcium-channel blockers.³⁵

Tendering

Tendering involves the use by drug plans of competitive bidding processes to establish the price that will be reimbursed for a particular drug. The insurer can make the manufacturer with the lowest price the sole supplier of that drug for all plan beneficiaries—or choose more than one manufacturer so as to safeguard supply.^p Only one Canadian provincial plan, Saskatchewan's, practises tendering extensively, using it to determine the price of 91 high-volume interchangeable drug groups.³ Other provinces, including BC and Ontario, have used tendering on a very limited basis.²⁸ For example, BC used the tendering approach to sole-source olanzapine¹² (brand name: Zyprexa®), an off-patent prescription drug for treatment of schizophrenia, bipolar disorder, and related symptoms.³⁶

Other Reimbursable Costs

In addition to reimbursing the cost of the drug, public and private insurance plans also reimburse, to a certain extent, other costs associated with drug-dispensing activities. Dispensing services include checking the prescription for errors, filling the prescription, and providing information on appropriate medication use.³⁷ The fees paid for these services vary from provider to provider.

Insurers may also choose to reimburse a mark-up amount that is proportional to the drug's invoice price. For instance, if the invoice price of a drug is \$25.00 and the allowable mark-up is 10%, the pharmacy will be reimbursed \$27.50 plus the dispensing fee. Mark-ups also tend to vary from provider to provider—some provincial and territorial plans do not reimburse mark-up amounts at all, while others reimburse them at 7–10% of the drug's invoice price.³⁷

Reimbursement for medical counselling fees, as distinct from dispensing fees, is becoming more common among public insurers in Canada. This means remunerating pharmacists for patient-counselling, independent of any dispensing services. For example, Ontario has introduced MedsCheck, a medication review program that compensates pharmacists for reviewing the medication use of patients who have a chronic condition and use three or more prescription drugs.³⁷ Alberta is currently pilot-testing a new pharmacist-compensation model which may introduce separate funding streams for non-dispensing professional services (e.g. counselling and, due to new regulations, prescribing).³⁸

Rebates

Within the existing reimbursement framework, manufacturers have provided pharmacies with rebates^q off invoice prices. Rebates are a by-product of the existing reimbursement framework.³ Over time, however, they have become an important source of revenue for pharmacies. Ontario and Quebec have created policies that specifically target the use of rebates.^{3,12} Quebec initially banned rebates entirely, but has since permitted a rebate equal to 20% of generic sales, provided that this money be used for patient-related professional services. Similarly, *Bill 102* in Ontario replaced rebates with “professional allowances” and capped them at 20% of the drug's invoice price with a similar provision that the allowance must be used to fund patient-related professional services.¹² However, under the Ontario drug reforms announced in April 2010, all rebates or professional allowances would be completely eliminated by 2014.²⁷

^p In reality, supply is unlikely to be an issue. Brand name firms, under patent, are the sole suppliers of innovative drugs. Generic firms, on the other hand, can be one of many suppliers to the market. In an emergency, generic products can be substituted for their brand name equivalents, and vice versa, if supply was ever to become an issue.

^q Rebates are discussed in more detail in Section 4 of this paper.

As mentioned earlier, rebates are almost impossible to police since, for example, a rebate restriction on a public plan can be compensated for by an increased rebate on a private plan, where allowable. Rebates represent a mechanism for partitioning profits between pharmacies and manufacturers. The partitioning reflects the balance of power between the two groups. If drug plans feel they are paying too much for medications and that profits are too high, they can simply reduce the reimbursement price and remain silent on rebates. This strategy would effectively reduce the available margin in the supply chain that can be allocated to rebates.

Patient Case Study

Differences in reimbursement policies are best illustrated by examining the retail drug prices pharmacies charge their customers. Table 4 shows prices paid for Apo-Ramipril obtained from a sample of employer plans in each province (data for Nunavut, Yukon and Northwest Territories was not available, and data from Manitoba could not be confirmed) for the following groups of patients:

1. publicly insured (e.g. seniors);
2. privately insured (e.g. people who have coverage through their employers); and
3. uninsured (e.g. individuals who are not eligible for coverage through their employer or provincial plan).

Apo-Ramipril is a commonly prescribed generic drug that is used to treat high blood pressure.³⁹

An examination of this sample data raises some questions about drug pricing. For example, based on this case study:

- **Costs to public health plans for publicly insured individuals (e.g. seniors) can vary from province to province for the same prescription drug.** For instance, the cost of a 10mg dose of Apo-Ramipril for an individual living in Newfoundland and Labrador is 53% more than for someone in Ontario.
- **Costs to employers for employer-insured individuals can vary within the same province for the same prescription drug.** For instance, in Quebec the cost of a 10mg dose of Apo-Ramipril for an individual receiving coverage through Employer A is \$0.57, while the cost for an individual receiving coverage through Employer B is \$0.90—a difference of 58%.
- **Costs can be higher for uninsured individuals than for either publicly insured or employer-insured individuals, for the same prescription drug.** This difference is most apparent in Ontario, where the cost of a 10mg dose of Apo-Ramipril for some uninsured individuals is more than double the cost for people insured by the ODB Program. Similarly, the cost for some uninsured individuals is 47% more than the cost for some employer-insured individuals.

TABLE 4: RANGE OF UNIT COSTS PAID BY PAYER FOR CANADIANS COVERED UNDER DIFFERENT DRUG PLAN COVERAGE PARAMETERS FOR APO-RAMIPRIL 10mg

Generic Price Comparison:									
Apo-Ramipril 10mg	BC	AB	SK	ON	QC	NB	NS	PE	NL
Provincial Formulary Unit Price¹	0.6700	0.6300	0.6650	0.4750	0.4750	0.6650	0.6650	0.6615	0.7249
Private, Employer-Sponsored Drug Plan Unit Price²									
Minimum	0.6650	0.5796	0.6930	0.4940	0.5700	0.7140	0.6317	0.7178	0.6317
Maximum	0.8571	0.8645	0.8522	0.7320	0.8997	0.8080	0.7470	0.7931	0.8457
Cash-Paying Customer Price³									
Minimum	0.6650	0.5796	0.6930	0.4940	0.5700	0.7140	0.6317	0.7178	0.6317
Maximum	0.9683	0.8645	1.0570	1.0791	0.9703	0.8312	0.7830	0.8604	1.0614

Note: This data was provided to the Health Council of Canada by Cubic Health, an independent analytics and drug plan management company. All provincial data included here is publicly available information from government formularies. Private sector and cash-paying data is based on blinded (i.e. non-personally identifiable), transactional-level drug claims obtained from both pay-direct drug (PDD) and paper-reimbursement employer-sponsored benefit plans in each province. Reimbursement plans are those that require patients to pay cash at the point of sale and be reimbursed by their plan administrator upon submission of the claim. These patients are treated the same as cash paying customers who have no coverage, as opposed to PDD plans that are subjected to point-of-sale pricing controls upon submission of the claim to the claims processor by the pharmacy. This claims data across Canada was taken from a random sample of Canadian employers. This data represents actual private sector drug claim transactions that were paid, and is an illustration of the existing private sector market across Canada.

1. Unit prices as listed in provincial formularies (effective April 2010).
 2. Reflects maximum provincial pricing limitations for private-sector plans enforced by prescription drug plan claims processors.
 3. No pricing limitations enforced, paid out-of-pocket by cash-paying customers directly as charged by pharmacy.

Another implication of the current reimbursement policies is that an employer-insured individual can be charged different amounts for the same generic drug in different pharmacies. This is most apparent in Ontario, but occurs across the country. Prices can be 47% higher in one pharmacy than in another in the same region within a given private-sector plan.⁴⁰

International Jurisdictions

This section examines the pricing and reimbursement policies for five international jurisdictions. Three cost-containment strategies that are not found in Canadian jurisdictions are also briefly described.

Table 5 on page 17 provides a high-level overview of pricing and reimbursement policies for Canada and five other countries—Australia, New Zealand, United Kingdom, France, and Germany.

It should be noted that the US was not included in the table due to the complex nature of its drug insurance market. The share of the private insurance market in both the US and Canada is significant. However, the market for drug insurance in the US is highly fragmented with multiple payers, both public and private, that have their own distinct pricing and reimbursement policies. Hence, a summary analysis of US pricing and reimbursement policies at the national level would not be meaningful. In contrast, each country listed in Table 5, including Canada, has far fewer drug insurance providers, which share many similarities in their overall approach to pricing and reimbursement.

Overall, Canadian pricing and reimbursement policies share many similarities with the policies of the five other countries presented in Table 5. One of the most significant differences between Canada and the others is the actual mechanism used to determine appropriate drug-reimbursement prices. The UK and France rely on negotiations with manufacturers to set their prices, whereas others rely on therapeutic-reference-based pricing, for instance. Most Canadian public plans do not use these approaches and in many cases do not determine pricing levels on a per-product basis, but rather set prices by applying a uniform percentage of brand name prices to all formulary drugs.

Another important difference between Canada and the other jurisdictions can be observed by comparing cost-

containment strategies. In Canada, the provincial and territorial plans have principally relied on decreasing reimbursement prices to contain their costs, whereas France, the UK, and Germany have relied on other techniques, including volume limitations, profit control, and prescription targets.

In France, price-volume contracting is used to control pharmaceutical expenditures. Under this system, the government sets annual limits on growth in drug expenditures. If these limits are exceeded, a volume-based formula is used to determine rebates that drug manufacturers and health care service providers must pay back to health insurance funds. In effect, this policy works to shift a portion of the financial risk to the manufacturers.^{41, 44}

In the UK, the Department of Health regulates not only the price of generic drugs, but also the margins at all levels of the supply chain. For instance, prices that are used to reimburse pharmacies for generic drugs have a built-in profit margin, which is defined as the difference between the reimbursement price and the actual cost of acquisition. This profit margin is essentially a profit target that is negotiated between the pharmacies and government. Selected pharmacy invoices are surveyed quarterly to determine the difference between actual and target margins. If the actual margins are not in line with the target, reimbursement prices are adjusted accordingly in the next quarter.^{41, 43}

In Germany, negotiated prescription limits (volume targets) are in place to limit the number of medications prescribed by physicians. Those who exceed these limits by more than 25% are required to pay a penalty to a regional sickness fund. The penalty can be avoided if the physician can prove that the prescriptions were medically necessary and that the prescribed drugs were of the lowest-possible price. In addition to volume targets, Germany also employs individual cost limits. If a physician exceeds the cost limit by more than 25%, he or she may have to repay the excess amount to the regional sickness fund. To inform prescribing behaviour, physicians are provided with a performance report that compares their individual prescription volumes to the regional average for groups within their specialization.⁴⁷

Potential applications of these cost-containment strategies and their relevance within the Canadian context are further described in Section 5.

TABLE 5: HIGH-LEVEL OVERVIEW OF PRICING AND REIMBURSEMENT POLICIES FOR PUBLIC PLANS IN SIX COUNTRIES

	CANADA	AUSTRALIA	NEW ZEALAND	UK	FRANCE	GERMANY
Formularies	Drugs must be listed on provincial and territorial formularies to be reimbursable	Drugs must be listed on the formulary to be reimbursable ⁴¹	Drugs must be listed on the formulary to be reimbursable, with only one drug for a wide range of conditions ⁴²	All drugs that are authorized for sale are fully reimbursable—exceptions are included on a negative list ^{41,43}	Drugs must be listed on the formulary to be reimbursable ⁴⁴	All drugs that are authorized for sale are fully reimbursable—exceptions are included on a negative list ⁴¹
Inter-changeability	Interchangeability by the pharmacist is allowed and mandatory in some provinces, but prescribers can request “no substitution” where appropriate	Interchangeability by the pharmacist is allowed but patients are permitted to refuse substitution ⁴¹		Interchangeability by pharmacists and other dispensers is allowed, but prescribers can request “no substitution” where appropriate ⁴³	Interchangeability by the pharmacist is allowed and incented, but not mandatory ⁴⁴	Interchangeability by the pharmacist is allowed ⁴¹
Pricing	Prices are based on a percentage of the brand name price in some provinces, while other provinces use a maximum-reimbursable-cost approach (therapeutic-reference-based pricing is also used in BC)	Prices are based on pharmacoeconomic evaluations. ⁴⁵ Therapeutic-reference-based pricing is also used ⁴¹	Therapeutic-reference-based pricing is used extensively ⁴¹	Prices for readily available medicines: ⁴³ <ul style="list-style-type: none"> • Category M are based on manufacturer retail prices plus a discount • Category A are based on list prices of a basket of 2 wholesalers and 3 manufacturers • Category C are not readily available and are based on a particular brand/manufacturer 	Formulary prices are based on the prices negotiated with the manufacturers ⁴⁴	Reference prices are set for drugs “with the same or similar substances or with comparable efficacy” with typically 1/3 ^{4d} of the drugs available at or below the reference price ⁴⁷
Tendering	Tendering used extensively in Saskatchewan and sporadically in other jurisdictions		Generic drugs are procured exclusively through a sole-source tendering process ⁴²			
Dispensing Fees	Pharmacies receive dispensing fees which vary from province to province	Pharmacies receive a fixed professional fee of \$5.15 per prescription (on most drugs) ⁴⁶		Pharmacies receive fees and allowances based on dispensing volumes ⁴³	Patients pay a fixed out-of-pocket fee of €0.5 per package with an annual ceiling of €50 ⁴⁴	Pharmacies are paid a flat rate payment of €8.10 plus a fixed margin of 3% ⁴⁷
Pharmacy Mark-ups	Pharmacies receive mark-ups at 7–10% of the drug’s invoice price in most provinces	Pharmacy mark-ups are regulated at 10% of the pharmacy purchase price (on most drugs) ⁴⁶		Mark-ups are negotiated profit margins that are monitored regularly ⁴³	Pharmacy mark-ups are regulated in a regressive mark-up scheme that ranges from 26.1% for ex-factory prices that are less than €22.90 to 6% for ex-factory prices greater than €150 ⁴⁴	Pharmacy mark-ups are regulated in a regressive mark-up scheme that ranges from 68% for ex-factory prices that are less than €1.22 to 8.3% for ex-factory prices greater than €543.91 ⁴⁷
Medical Counselling Fees	Medical counselling fees are used in Ontario and Nova Scotia			Pharmacists receive payments for specific services (e.g. Medicine Use Reviews) ⁴³		
Rebates and Discounts	Rebates with no restrictions are allowed in all provinces except Ontario and Quebec			Rebates are negotiated between the manufacturer, wholesaler, and pharmacy with no restrictions ⁴³	Rebates are allowed, but restricted to 17% of the manufacturer price ⁴⁴	Cash discounts can be negotiated between manufacturers, wholesalers, and pharmacies ⁴⁷
Volume Limitations		Under price-volume contracting, remuneration to manufacturers is reduced if volume threshold is exceeded ⁴¹	Under price-volume contracting, manufacturers are vulnerable to financial risk if forecasted volumes are exceeded ⁴¹		Targets are set for growth in expenditures, with manufacturers paying rebates to health-insurance funds if targets are exceeded ^{41,44}	
Profit Control				Reimbursement prices are frequently adjusted to control profits at various points in the supply chain ⁴³		
Prescription Targets			Prescription budgets are set for many physician groups ⁴¹	Prescription budgets are set for physician groups and individual physicians ⁴¹		Prescription budgets are set for physician groups and individual physicians ⁴¹

Note 1: Data was collected from the most recent country-specific, publicly-available documents found and confirmed by international experts.

Note 2: All the information in this table refers to generic drugs, but may inherently be true of all drugs. Rows that apply only to generic drugs are: Pricing, Tendering, Rebates and Discounts, Volume Limitations, and Profit Control.

Note 3: Blank cells indicate that the policy is not being pursued in the jurisdiction at the time of writing.

SECTION 4: KEY STAKEHOLDERS

To properly assess the impact that policy changes or the actions of individual stakeholders have on the patient and on the broader system, it is first necessary to understand the incentives of each stakeholder. This section profiles the key stakeholders by describing their role in the generic drug system, key incentives that drive their decision-making, and recent trends.

Patients

Patients are the consumers and end-users of prescription medication but those covered by private or public plans do not pay directly for medications or, at most, make co-payments. They are often price-insensitive unless they are among the 2% of Canadians who lack any form of drug insurance coverage. Patients can choose where to have their prescriptions filled.[†] Otherwise, their purchasing power is limited, i.e. their ability to choose a particular drug is limited to the extent that they can influence the prescribing behaviour of their physician, or change their drug coverage. In some jurisdictions, however, people can request an interchangeable product at the pharmacy counter.⁴⁸

In large urban centres the choice of pharmacies may be abundant with multiple pharmacies within a small radius, while in rural communities there may only be the local independently owned pharmacy. Based on proposed regulatory changes in Ontario, people there may soon have the option of obtaining their medications from an automated dispensary.⁴⁹

The choice of where to fill prescriptions is driven by four factors: quality of services (i.e. dispensing, counselling, and other patient-care services), location and hours of operation, retail price of medication, and selection of consumer goods.^{37,5} Each of these factors has a different level of importance from the perspective of the patient.

The quality of services and pharmacy location are considered to be the two most important factors in determining where patients fill their prescriptions. In fact, the majority of respondents to a consumer survey indicated that provision of information on appropriate medication use, pharmacist's

access to the patient's prescription history, and the availability of the prescribed medication—all characteristics of the quality of dispensing services—to be very important characteristics of their consumer experience. Location, defined as physical proximity to the pharmacy, was deemed to be the second most important factor.³⁷

The retail price of prescription medication was one of the least important factors in influencing patients' decisions in choosing a pharmacy.³⁷ As mentioned earlier, 98% of Canadians have some form of drug insurance, which partially or fully subsidizes the cost.³ Even though many people share in the costs of filling their prescriptions through co-payments, these are small compared to the costs of prescriptions. It stands to reason that the small minority who lack any form of drug insurance would see price as an important consideration, but a large majority of Canadians would not see the retail price of their medications as a significant factor when choosing a pharmacy.³⁷

Provincial and Territorial Drug Plans

Provincial and territorial plans need to balance two competing objectives: access to medications and cost containment. The policies and approaches outlined in Section 3 are designed to strike a balance between these two objectives. While there seems to be little evidence to suggest that timely and convenient access to generic drugs is a problem, studies have shown that Canadian drug insurance plans (for example, in Ontario) pay significantly higher prices for generic drugs, as compared to drug plans in many other OECD countries.¹¹ In response, some provinces and territories have already undertaken significant reform to their generic drug pricing strategies.^{3,23}

[†] Patients in hospitals typically receive drugs free of charge through provincial and territorial hospital insurance plans. In this section we focus on people outside the hospital environment.

⁵ Consumer goods include items that are sold exclusively in pharmacies, as well as other typical retail goods such as groceries, health and personal care items, and giftware, among many others. Items sold exclusively in pharmacies include prescription and some over-the-counter medicines.³⁷

Given that all provincial and territorial plans regulate their generic drug prices through either price caps or maximum-reimbursable-cost policies, they have the power to determine the price of each generic drug that is paid by their plan. However, the degree of price control under each plan can vary greatly.

In the wake of increasing cost pressures on public drug plans, price caps appear to be the most effective mechanism for cost containment. Three of the four largest provinces (Alberta, Ontario, and Quebec) employ a price-cap policy that sets the price of the generic at a fixed percentage of the brand name drug. Periodically, all three have attempted to achieve savings for their drug plans by lowering this percentage.^{3,38} On the other hand, interviewees who contributed to this paper suggested that policies which rely on manufacturer retail prices (i.e. maximum-reimbursable-cost policies) may

not be translating to lower formulary prices. For instance, these interviewees indicated that the prices of generics in the Atlantic Provinces, which follow the maximum-reimbursable-cost approach, are consistently higher than in Ontario and Alberta.[†]

Income testing is another strategy that provincial and territorial drug plans have used to curb their costs. Indeed, one component of Alberta's new drug strategy is the introduction of monthly premiums and co-payments, dependent on income, for seniors.³⁸ Many provinces have some form of income testing for seniors.³ Under an income-tested coverage policy, beneficiaries with higher incomes share in the costs of their prescriptions at a proportionately higher rate than individuals with lower income levels. This approach allows the insurer to shift some of the cost to the patient.³⁸

SUMMARY OF BILL 102 (ONTARIO) AND BILL 130 (QUEBEC)

Ontario first made significant changes to its generic drug policies in 2006 with the *Transparent Drug System for Patients Act*, more commonly known as *Bill 102*. Under *Bill 102*, the price that the ODB Program paid pharmacies for generic drugs was reduced from 63% to 50% of the equivalent brand name drug price, resulting in savings for the public plan.¹² However, *Bill 102* did not extend these prices to drugs purchased under private plans. As a result, the price gap between the public and private markets widened considerably. According to an article published in CMAJ, “a generic version of a brand name drug priced at \$100 would now cost the province \$61 and private plans \$87, compared to prices of \$75.41 and \$79.30 before the 2006 Act.”^{50,41}

In addition to reducing the reimbursement price for ODB-purchased generic drugs, *Bill 102* capped manufacturer rebates at 20% of the drug cost, but once again only for ODB-purchased drugs. This discrepancy in regulation between the public and private markets means that pharmacies can demand higher manufacturer rebates for privately purchased drugs, potentially offsetting their reduced profit margins on ODB-purchased drugs.

In a similar vein, Quebec decreased its generic drug reimbursement prices under the 2006 *Loi sur l'assurance médicaments (Bill 130)*. As per *Bill 130*, when there was more than one generic product, prices of generic drugs were set at 54% of the equivalent brand name drug price. However, Quebec has a ‘most-favoured-nation’ clause, which ensures that generic drugs under its public plan are reimbursed at a price that is no higher than in the lowest-priced Canadian jurisdiction. In theory, this clause means that Quebec's public plan will reimburse generic drugs at a price less than the 54% set in *Bill 130* because Ontario's prices are set at only 50%.¹²

Generic drug prices under Quebec's public plan decreased by 21% after the legislation, partly as a result of the price reductions in Ontario.²⁸ However, just as in Ontario, Quebec's legislation did not extend the public-plan prices to the private insurance market, resulting in much higher prices for private payers. One notable difference between *Bill 102* and *Bill 130* is that Quebec's legislation capped rebates at 20% of the invoice price for both publicly and privately purchased drugs.¹²

In April 2010, new generic drug regulations were proposed in Ontario. These regulations and their impacts on stakeholders are further discussed in Section 6.

[†] The Atlantic Provinces have relatively smaller populations and therefore less purchasing power.

⁴¹ Prices include mark-ups and dispensing fees.

Private Drug Plans

Private insurance companies in Canada provide drug coverage as well as administrative services to their customers, who consist primarily of employers and individuals. The private drug insurance industry is a mix of for-profit and not-for-profit organizations and varies from province to province with some insurers having a stronger foothold in certain regions.³

While individuals may obtain drug coverage through private insurers, employers are the major purchasers (approximately 95%) of private coverage in Canada. Employers that choose to obtain coverage for their employees through a third-party insurer typically pay a premium for each employee. In turn, the insurer reimburses fully or partially each employee's prescription drug costs. The amount of the premium is structured to cover anticipated drug costs, administrative costs, and a margin to compensate the insurer for the risk incurred. Premium rates are renewed at regular intervals to ensure that premiums are in line with actual costs.³ In effect, normal insurance pooling of risk is limited and firms pay premiums that reflect the costs they impose on the plan plus an administration fee.

In addition to offering benefit plans, insurance companies also offer administrative services to larger employer groups that choose to provide their own insurance coverage to employees. These groups typically need assistance with the technical aspects of providing drug insurance, such as processing and adjudicating claims. These tasks are complex and technical in nature. As a result, many for-profit insurers, in turn, further outsource these duties to companies such as ESI Canada and TELUS Health Solutions (formerly Emergis), which specialize in health-claims management.³

Within the existing payment structure for private plans, insurance companies would have little interest in seeing drug costs lowered. Indeed, the fees they charge employers for administering their drug plans are computed as a percentage of the drug plan's total costs, or on a per-claim basis. Furthermore, only 17% of private payers have *managed plans*—those in which a cost-benefit analysis of drug coverage is undertaken.⁵⁰

Employers

Employers and other employee representatives^v can choose to provide drug insurance as part of their benefits package. They can either create their own insurance plan or enroll employees with an existing third-party insurer.

Larger employers typically create their own plans and are in effect self-insured. In other words, claim costs are paid by the employer and not an insurance company. Smaller employers typically enroll their employees with an insurance company that offers drug-benefit plans, as described above.³

Interviewees contributing to this report noted that most employers do not have reimbursement policies as sophisticated as those developed by public drug plans. Well-developed formularies with price-control mechanisms are not common. Further, these interviewees indicated that many existing employer-group reimbursement policies are outdated and have been unchanged since they were first negotiated. As a result, generic drug prices for private plans have remained largely unchanged over the years while the same drugs have often decreased in price for public plans. Employers in some provinces are also paying higher dispensing fees than their public-plan counterparts.^{12, 50}

Generic Drug Manufacturers

Generic drug manufacturers provide a lower-priced alternative to brand name drugs after patent expiry, selling their products to pharmacies and hospitals.³ The generic pharmaceutical market reached \$5.2 billion in gross sales^w in 2009—approximately 24% of Canada's total prescription-drug market. In terms of dispensing volume, the generic market accounted for 54% (or 263 million) of all prescriptions in Canada.⁵¹

More than 15 manufacturers supply generic drugs to the Canadian market. Among these companies, 13 have manufacturing facilities here. The largest Canadian manufacturer, Apotex, is domestically owned. However, many Canadian manufacturers are foreign-owned or have a parent company that is foreign-based.³ Apotex and Teva Canada, the two largest manufacturers, had a combined market share of nearly 51% in 2008, based on their total sales to pharmacies and hospitals. The top five manufacturers had a combined share of 77% of the generic pharmaceutical market in Canada.⁵¹

The generic drug manufacturing industry in Canada contributes to both employment and exports. In 2008, the industry employed approximately 12,000 Canadians. The majority of these jobs are in manufacturing. Unlike brand name products, the majority of generic drugs sold in Canada are also produced here. In addition, Canadian generic manufacturers export a substantial percentage of their goods to other countries—approximately 40% of their total sales volume.⁵¹

^v Employee representatives include unions and professional orders and associations.

^w It should be noted that net sales of the market are likely considerably lower, once rebates are factored in.

When deciding to bring a new product to market, generic manufacturers are typically faced with a key consideration: the length of time to formulate the product and to obtain regulatory approval. Development and approval costs play an important role in the decision-making.³

Patent litigation is perhaps the most important consideration for generic firms because it is both expensive and risky. A patented drug usually has more than one patent to its name.¹² In fact, brand name manufacturers can secure additional patents for a specific drug to prolong the period of market exclusivity.⁵² As a result, for any particular drug, it is not often the case that all patents expire prior to generic entry. Instead, generic drugs become available when all remaining patents on a brand name drug are found invalid or not infringed. Hence, in bringing a product to market, generic firms must determine the likelihood of success in litigation, in the event that the brand name manufacturer files a patent-infringement lawsuit.¹²

Timing is also a key consideration for generic drug manufacturers. A generic firm that is involved in patent litigation faces a threat from other generic firms that wait for the litigation to finish and enter the market immediately thereafter, without incurring any litigation costs.¹² Timing is especially important given that pharmacies are less likely to switch generic manufacturers once they have a generic product stocked. As a result, the majority of generic first-to-market entrants continue to capture the largest share of the market even after other firms have entered with their own version of the drug.³

In some jurisdictions, first generic entrants may also have a price advantage over subsequent entrants. In Ontario, prior to *Bill 102*, the price for the first entrant was set at 70% of the brand name drug price, while the price of subsequent entrants was set at 63%.³ Similarly, first entrants in the US have an advantage because they are granted a six-month period of market exclusivity. These policies provide an additional incentive for generic drug manufacturers; however, they have generally not been used across the provinces and territories.

While many manufacturers supply generic drugs to the Canadian market, only the larger ones have sizeable and diversified product portfolios. Smaller manufacturers create a very limited but specialized set of pharmaceuticals,³ which they can produce at a lower cost. Since the existing retail market is dominated by pharmacy groups that exert substantial buying power to obtain lower drug prices, generic manufacturers are not necessarily required to offer

a wide range of products to succeed. They can thrive by providing a few products at relatively low prices.

The level of competition among generic manufacturers is higher in the US than in Canada.⁵³ While the number of generic manufacturers in Canada has increased over the past few years, many of the recent entrants to the Canadian market offer a limited portfolio of drugs. Hence, a typical generic drug is not likely to have more than a few suppliers. In contrast, in the US market, a typical generic is likely to have many suppliers competing for market share.

Since prices of generic drugs are basically regulated in Canada, manufacturers use non-price means such as rebates to compete for shelf space in pharmacies. Since the early 1970s they have competed by offering rebates and other incentives that function to reduce the pharmacy's actual cost of acquisition to less than the amount reimbursed by the drug plans.³⁷ However, Ontario's proposed drug reform would eliminate these rebates, likely changing how manufacturers compete to get their drugs into pharmacies. They would probably become more focused on price competition.

One difference between brand name and generic manufacturers is the extent of sales and promotion activity. Generic manufacturers employ relatively few sales representatives, as compared to brand name manufacturers. Brand name firms compete by marketing drugs to prescribers and hence a substantial sales force is required to reach out to each physician and prescriber across the country. On the other hand, generic manufacturers compete primarily through their rebates to pharmacies.

Brand Name Manufacturers

Since the entry of a generic version of a brand name drug typically erodes a substantial amount of the original drug's market share, brand name manufacturers have a strong incentive to participate in the generic drug market. They compete with generic manufacturers through two principal means: patent-infringement litigation and the use of authorized generics. Usually they do not lower the price of their brand name product when a generic version appears because many consumers will still choose the higher-priced brand name drug¹²—whether due to a good tolerance for its formulation ingredients, brand loyalty, or other reasons.

Under existing regulations, a brand name firm may seek a two-year injunction against a Health Canada approval of a generic drug on the basis that its patent has been infringed. If the courts find such an allegation valid, generic entry is

effectively delayed for up to 24 months. The brand name manufacturer can file a patent-infringement lawsuit even after a generic drug has received Health Canada approval and is being sold. If successful, the manufacturer may be awarded damages for its lost revenue.³ However, recent regulatory changes^x have made it more difficult for brand name firms to appeal Health Canada decisions.⁵⁴

Brand name manufacturers may decide to compete for a share of the generic drug market by choosing to release their own *authorized* generic versions of a drug. An authorized generic typically has the same compound as the brand name drug, but is “labeled and priced as a generic.” Authorized generics may be sold by a licensee or by a subsidiary of the brand name manufacturer. Many licensees are in fact generic firms. Although estimates show that authorized generics are available for 40% of drugs,^y they only account for about 7% of generic sales value in Canada. One reason for this discrepancy could be that many authorized generics—from a sample of 26 drug markets studied—were not the first to enter the market, and hence were at a disadvantage in capturing a substantial market share.^{3, 12, 55}

Authorized generics are an appealing strategy for brand name firms for two reasons. First, they discourage entry from unlicensed (i.e. independent) generics. Second, they allow the brand name firm to continue its revenue stream by capturing a share of the generic drug market, either through direct sales or a license agreement, while still making profits from the sales of its higher-priced brand name drug.¹² Dr. Reddy’s Laboratories manufacturing generic versions of Merck’s Zocor® is an example of an authorized generic deal. At the time of patent expiry in 2005, Zocor® had total global sales of USD \$4.5 billion.⁵⁶

Distributors

Generic manufacturers distribute their products through three channels: independent pharmacy distributors (IPDs), retail pharmacy group self-distributors, and direct shipments. IPDs and pharmacy self-distributors are the two primary means of generic drug distribution. In 2006 IPDs accounted for 57% of generic pharmaceuticals distributed in Canada (other than to Walmart), while self-distributors accounted for about 34%. Manufacturer direct shipments to pharmacies are less common, and becoming increasingly less so—with only 9% in 2006, down from 19% in 2002.³

IPDs provide a wide range of services, including product delivery on a daily or sometimes twice-daily basis, inventory management, electronic ordering, and storage. In some cases, IPDs also provide financing services to their customers. As with any organization that specializes in supply-chain management, costs include storage and warehousing, transportation, and electronic information systems.³

McKesson Canada and AmerisourceBergen Canada are the two largest IPDs, with 16 and 12 distribution centres, respectively. McKesson alone provides distribution of prescription drugs and pharmacy retail products for more than 800 manufacturers to over 6,500 pharmacies and over 1,300 hospitals and other health care institutions.³

Self-distributors are retail pharmacy groups that maintain their own distribution centres for supplying products to their pharmacies. For example, Shoppers Drug Mart and Pharmacie Jean Coutu, two retail pharmacy franchises, both have their own distribution capabilities.³

Traditionally, drugs have been distributed through pharmacies. In Ontario, however, recent innovation and regulatory changes may soon allow a remote dispensing machine—currently being tested in a hospital setting—to distribute pharmaceuticals directly to patients in their communities. PCA Services, a Canadian drug distributor, has developed the PharmaTrust™ MedCentre remote dispensing system. According to PCA Services, “The PharmaTrust dispensary can stock up to 220 types of prescription drugs, including pre-packaged oral and topical medications, which are picked by its sophisticated robotic system, after the pharmacist processes the prescription.”⁵⁷ This functionality, along with a feature that allows users to communicate with the pharmacist through a two-way video link, enables the direct distribution of drugs.

With the threat of some Ontario pharmacies closing or reducing their hours due to proposed new legislation, the automated dispensary offers a potential solution to ensure that patient access is not compromised in these areas. “As drugstore chains say they can no longer afford to keep some shops open, the \$80,000 machines are poised to fill the gap,” says President and COO of PCA Services Peter Suma.⁵⁸ The distributor also operates a home delivery pharmacy, which allows patients to order refill prescriptions over the phone.⁵⁷

^x Regulations amending the Patented Medicines (Notice of Compliance) Regulations, under the Patent Act.

^y Based on a sample of 83 generic drugs that entered the Canadian market between 1998 and 2004.⁵⁵

Pharmacies

Pharmacies in Canada can be categorized in five types: independent, banner, franchise, chain, and food and mass-merchandise pharmacies:

- Independent pharmacies are independently owned and not affiliated with a banner, franchise, or chain corporate entity.
- Banner pharmacies are independently owned but affiliated with a central office that directs all marketing and buying procedures, among other things.
- Franchise pharmacies are not independently owned; the franchisee pays a fee to the franchisor for the right to open and operate the pharmacy.
- Chain pharmacies are part of a corporate entity that owns five or more stores and employs salaried managers to run the pharmacy.
- Food and mass-merchandise pharmacies are located in supermarkets and large department stores and also employ salaried managers to run the pharmacy department.³⁷

Banner, franchise, and chain pharmacies are commonly grouped together under the term *retail pharmacy groups*.³

Among the 7,905 community pharmacies reported in Canada in 2006,^z retail pharmacy groups collectively accounted for 58%. The remaining pharmacies were split almost evenly between independent and mass-merchandise. Over the past few years, the proportion of independent pharmacies has steadily declined—from 24% (1,718 pharmacies) in 2002 to 21% (1,705 pharmacies) in 2008. The proportion of mass-merchandise pharmacies and retail pharmacy groups grew by 3% and by less than 1%, respectively, during the same period.^{3, 60}

The Katz Group (Rexall) and Shoppers Drug Mart are the two largest pharmacy groups, with over 1,100 and 800 outlets, respectively. These two retail pharmacy groups account for nearly 25% of all community pharmacies in Canada. The five major pharmacy groups, which also include Loblaw's, Pharmasave and Jean Coutu, account for nearly 40% of all community pharmacies in Canada.³

On average, there are 2.5 pharmacies per 10,000 people. Pharmacy density varies from province to province with Newfoundland and Labrador having the highest density at 3.8 and Quebec having the lowest at 2.2 per 10,000 people.⁵⁹ Pharmacy density in Ontario is roughly equal to the average in a sample of European countries, but nearly double the density in the US.¹¹

The distribution of pharmacies across urban and rural areas is an important aspect of the system. In rural areas, independent pharmacies are prevalent since they are willing to serve smaller populations, while retail pharmacy groups and mass-merchandise pharmacies are typically clustered in urban areas.

The business model used by independent pharmacies differs greatly from the one used by retail pharmacy groups and mass-merchandise pharmacies. Prescription sales account for a much larger proportion of total revenues for independents (80%) than for retail pharmacy groups (as low as 56% for franchises and 52% for mass-merchandise pharmacies).⁶¹ Also, independent pharmacies operate shorter hours on average, and have much less reliance on—and make less money from—consumer goods.³⁷ However, the profits of all pharmacy types are strongly dependent on prescribing generic drugs.

The net prescription-based revenue of any pharmacy in Canada consists of three components: mark-ups proportional to the drug's invoice price, dispensing fees, and rebates. Based on the 2006 average retail price of a generic prescription (\$25),³⁷ it is estimated that the average Canadian pharmacy^{aa} earned \$250,000 in dispensing fees and mark-ups^{bb} and an additional \$250,000 in rebates.^{cc} Hence, half of the \$500,000 in net revenue earned by a pharmacy filling 30,000 generic prescriptions per year consists of rebates.

Estimating the impact of the proposed Ontario drug reforms, the net revenue of the average Ontario pharmacy from the above example would decrease by between \$130,000^{dd} and \$220,000.^{ee} In other words, net revenues would drop by between 26% and 44%. Other predictions suggest that the

^z 2009 data indicates there are now about 8,428 community pharmacies.⁵⁹

^{aa} The average pharmacy in Canada fills 30,000 generic prescriptions per year.³⁷

^{bb} Assuming a mark-up of 8% and an average dispensing fee of \$7.⁶²

^{cc} Assuming an average rebate of 50% of drug price.³⁷

^{dd} Assuming a \$4 dispensing-fee increase, which translates into an extra \$120,000 (\$4 x 30,000) of revenue. This amount would partially offset the \$250,000 loss in rebates, for a net revenue decrease of \$130,000 (\$250,000 minus \$120,000) for the pharmacy.²⁸

^{ee} Assuming a \$1 dispensing-fee increase, which translates into an extra \$30,000 (\$1 x 30,000) of revenue. This amount would partially offset the \$250,000 loss in rebates, for a net revenue decrease of \$220,000 (\$250,000 minus \$30,000) for the pharmacy.²⁸

impact of these reforms on a typical Ontario pharmacy could be even greater. Mark Dickson, Chair of the Canadian Association of Chain Drug Stores, has said that “the funding cuts translate into an average annual revenue decrease of more than \$300,000 per pharmacy.”⁶³

The loss in revenue would be partly mitigated by an increase in dispensing fees as illustrated in the example above. This increase in dispensing fees has been promised by the Ontario government, starting with a \$1 increase for every ODB prescription filled and with subsequent annual increases. Dispensing fees in rural and under-serviced areas would increase by up to \$4 under the reforms.²⁷ In addition, Ontario has earmarked \$150 million in funding for compensating professional services, further reducing the negative impact of the decrease in drug price. As will be described further in Section 6, the proposed reforms should generate savings for taxpayers, employers, employees, and out-of-pocket patients.

The retail price of a generic drug charged to the patient is another major lever that pharmacies can use to increase their net revenues. It consists of the drug invoice cost, a proportional mark-up, and the dispensing fee.³⁷ As discussed in Section 3, each drug plan will likely reimburse different amounts for drug ingredient costs, mark-ups, and dispensing fees. Hence, within the existing reimbursement structures, pharmacies have the ability to invoice different prices to different patients for the same drug.

In addition to dispensing drugs, pharmacies may also provide other professional services—blood tests, vaccinations, diabetes care, smoking cessation programs, weight management programs, cholesterol-control consultations, and many others. The provision of these value-added services varies greatly from pharmacy to pharmacy. According to the *Community Pharmacy 2008* report, 58% of pharmacies in Ontario, for example, provide one or more of these services today.¹¹ One likely hypothesis for the inconsistent provision of these services across Canada is that mechanisms for funding them have yet to be fully developed by the provinces and territories.

Hospitals

As of 2006, only 12% of all drugs sold in Canada were purchased by hospitals.³

Hospital committees, many of which are physician-driven, are responsible for determining the products that will be listed on the hospital formulary. The formularies tend to

be fairly similar from hospital to hospital within the same province or territory, but can vary significantly from one jurisdiction to another. The differences are most stark for expensive therapies such as cancer treatments.³

The drugs listed on hospital formularies are more specialized than those on provincial and territorial plan formularies. For example, certain intravenous drugs must be provided only on an inpatient basis, and hence are found only on hospital formularies. As a result, the therapeutic drug classes dispensed in hospitals differ greatly from those dispensed in community pharmacies. Cancer drugs, for example, constitute the largest proportion of hospital drug purchases, but are not even among the 10 most-purchased therapeutic drug classes for community pharmacies, in terms of dollar value. The two generic manufacturers that dominate the hospital market, Mayne Pharma and Sandoz, are not among those that dominate the retail pharmacy market.³

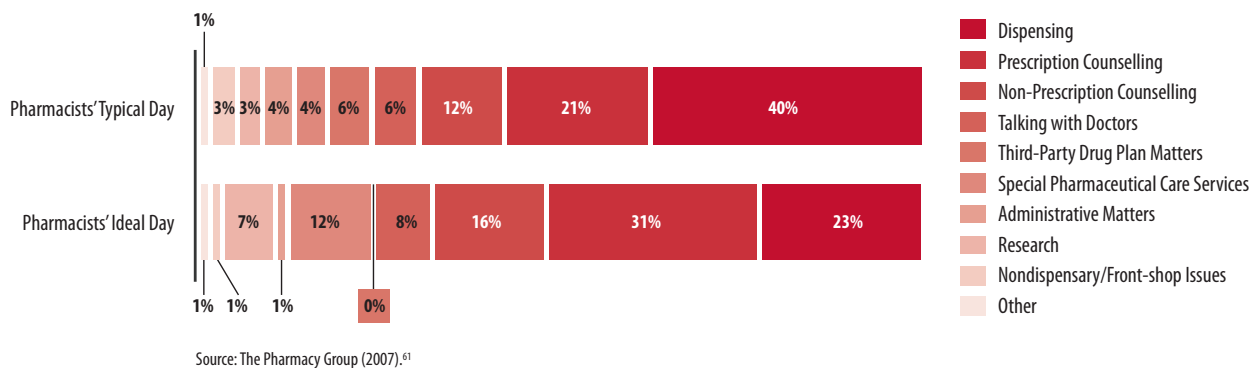
Hospitals primarily use tendering to purchase their generic drugs. Many hospitals use group purchasing organizations (GPOs) or their regional health organizations to garner the potential cost savings that can be realized by buying in higher volume.³ Some GPOs purchase drugs for hospitals in more than one province. For example, some hospitals in Alberta and British Columbia procure their drugs jointly through the same GPO.⁶⁴

Since hospitals rely on a competitive bidding process and negotiate directly with manufacturers, they are typically able to obtain lower invoice prices than community pharmacies. However, these findings do not necessarily suggest that the net prices paid by hospitals are lower than those paid by pharmacies—due to the prevalence of off-invoice discounts.³

Pharmacists

With recent regulatory changes across Canada, the role of the pharmacist as a health care professional has been rapidly expanding.^{65,66} These changes were triggered by observations that pharmacists’ expertise was not being fully leveraged and patients were not receiving higher levels of service despite increased spending. The results of a survey of pharmacy owners and managers reinforced the notion that pharmacists could be used to provide a more balanced set of services that would shift the focus away from dispensing activities.⁶¹

FIGURE 1: BREAKDOWN OF PHARMACISTS' TYPICAL AND IDEAL DAY



As Figure 1 illustrates, pharmacists currently spend a considerable portion of their day on dispensing activities and administrative duties, including front-shop and third-party drug-plan issues. However, based on the survey results, pharmacists would prefer to spend significantly more time counselling patients and providing special pharmaceutical care services.⁶¹

The current dispensing-oriented system is a direct reflection of the fee-for-service compensation model that focuses primarily on dispensing fees as a means to remunerate pharmacies. Some Canadian jurisdictions have created fees that are designed to compensate other professional services such as patient counselling.⁶² In addition, recent regulatory changes have extended the right to prescribe medicine—for many years the exclusive right of physicians and dentists—to other professions including nurse practitioners, optometrists, midwives, podiatrists, and, most pertinent to this discussion, pharmacists.⁶⁶

Ontario offers the most recent example of provincial legislation that extends prescribing privileges. The province passed legislation in December 2009 that permits pharmacists to extend, adapt, and adjust prescriptions, and to dispense medications remotely.⁶⁵

Prescribers

There is a lack of consistent legislation across the provinces and territories to determine which professionals can prescribe drugs, and *which* drugs, and the conditions for which they can prescribe them. As a result, the scope of prescribers' practice varies greatly across Canadian jurisdictions. For example, pharmacists can prescribe continuing-care medication in Manitoba, New Brunswick, and Nova Scotia, but not in any other province or territory.⁶⁸

Similarly, podiatrists can prescribe antibiotics and antifungal agents, but only in Alberta.⁶⁴ While changes to the scope of prescribers' practice are underway across Canada, physicians continue to write the majority of prescriptions.

As described in Section 3, regardless of the drug indicated on the prescription, pharmacists have the option and in some cases are required to substitute an interchangeable drug. However, prescribers have the ability to prevent this substitution by writing “no substitution” on the prescription.³ In addition, as stated earlier, some provinces allow the patient to request an interchangeable product at the pharmacy counter.

The length of the drug supply, which is specified on the prescription, can vary from drug to drug. For acute symptoms, drugs are prescribed for the specific number of days required to treat the condition. For chronic symptoms, prescriptions are typically for either a 30-day or 90-day supply.³

Taxpayers

Provincial and territorial drug plans are funded through taxes. Hence, generic drug pricing policies have a direct impact on how money collected from taxes is allocated to the government's health care priorities.

It is important to recognize that savings achieved through drug reforms may not necessarily translate to lower taxes. Instead, government drug plans could take the savings they achieve by lowering generic drug reimbursement prices, and redirect them to other priorities. These priorities could include funding new cancer drugs, expanding provincial formularies to include more generic drugs, and improving access in under-served areas.

⁶¹ See Section 5(D) for further discussion on pharmacy services.

⁶⁸ Pharmacists in Newfoundland and Labrador will also be able to authorize continuing-care medication in the near future.²⁶

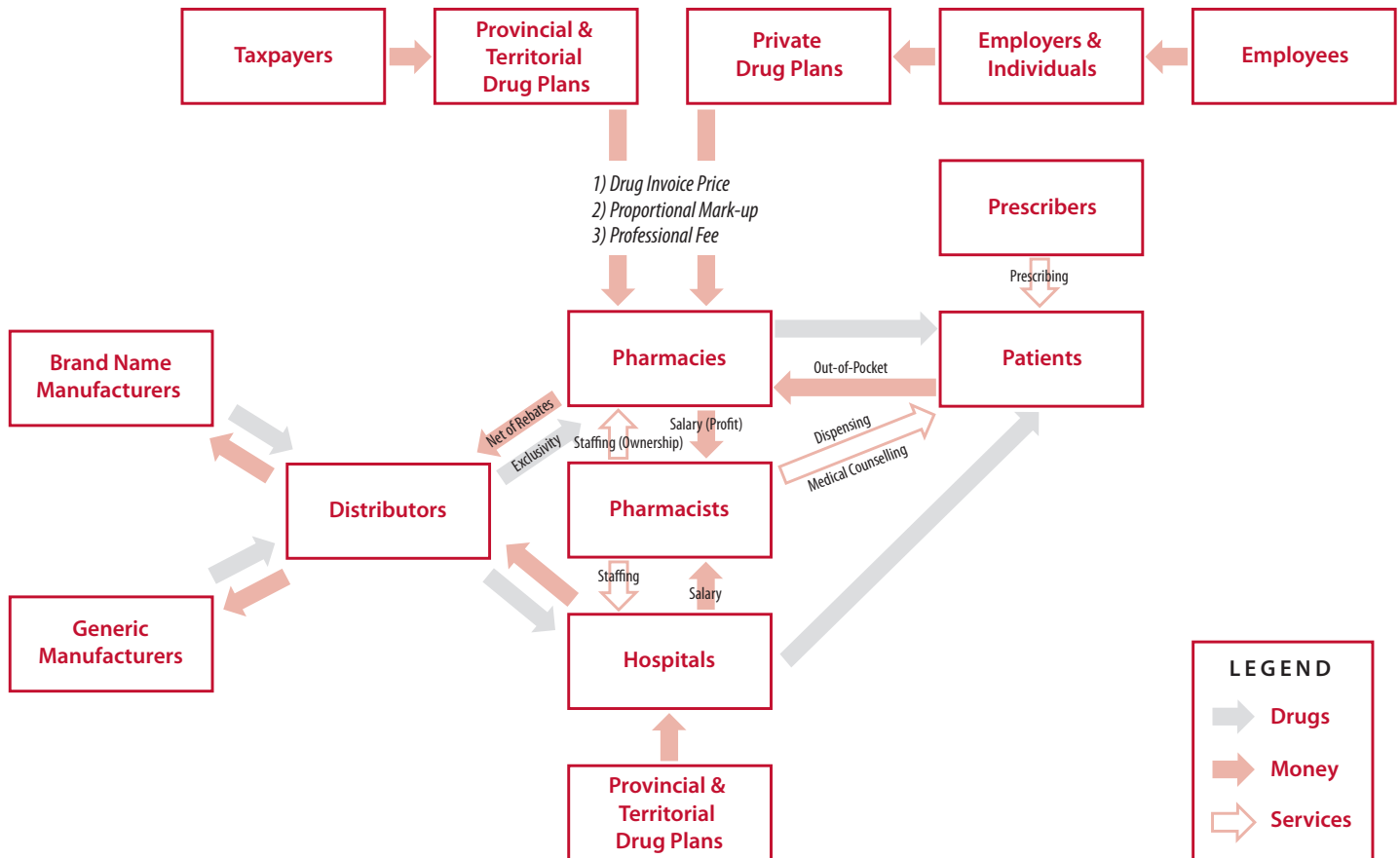
Employees

Private drug plans are funded, in part, by employees, albeit indirectly. An employer that offers drug insurance for its workers is either self-insured or pays a per-employee premium to an insurance provider, as described earlier in this section. Regardless of the mechanism, from the employer’s perspective drug insurance is an additional cost of employing a person. Hence, it can translate to

lower wages for employees.¹² Some employee sponsored plans require the employees to share in the premiums.

Similar to public-plan beneficiaries, insured employees can face out-of-pocket expenses through co-payments and deductibles.

FIGURE 2: OVERVIEW OF KEY STAKEHOLDERS



The generic drug system is complex. Many stakeholders are involved in ensuring that patients receive appropriate medication at a reasonable cost to the payer. The relationships between these stakeholders are driven by their individual incentives. However, these relationships are often not easily understood, as each stakeholder can have multiple—and

sometimes competing—incentives. The diagram above depicts the stakeholders involved in the generic drug system and provides a simplified view of their interactions by tracing the flow of drugs from manufacturer to patient and the flow of money from payer to manufacturer.

SECTION 5: CRITICAL SUCCESS FACTORS AND OPTIONS FOR ACHIEVING THEM

The effectiveness of generic drug policies can be evaluated across three dimensions:

- **Affordability**⁶⁷ — the total cost of generic drugs and professional services to all payers;
- **Accessibility**⁶⁷ — the ease of access to generic drugs and pharmaceutical services; and
- **Sustainability**⁶⁸ — the ongoing, long-term affordability and accessibility of coverage.

The goal of any drug-policy reform should be to create an environment that addresses the needs of patients at an affordable cost that can be sustained over the long term.^{hh}

With many Canadian jurisdictions facing increasing budgetary pressures, the affordability and sustainability of the existing system is being cast into doubt. Indeed, many Canadian jurisdictions are currently reforming their generic drug policies in hope of addressing these concerns.

With 98% of Canadians covered by some form of drug insurance, access to drugs has generally not been seen as a significant public issue.³ However, it should be noted that having some form of coverage does not necessarily mean that people are not facing high out-of-pocket costs.

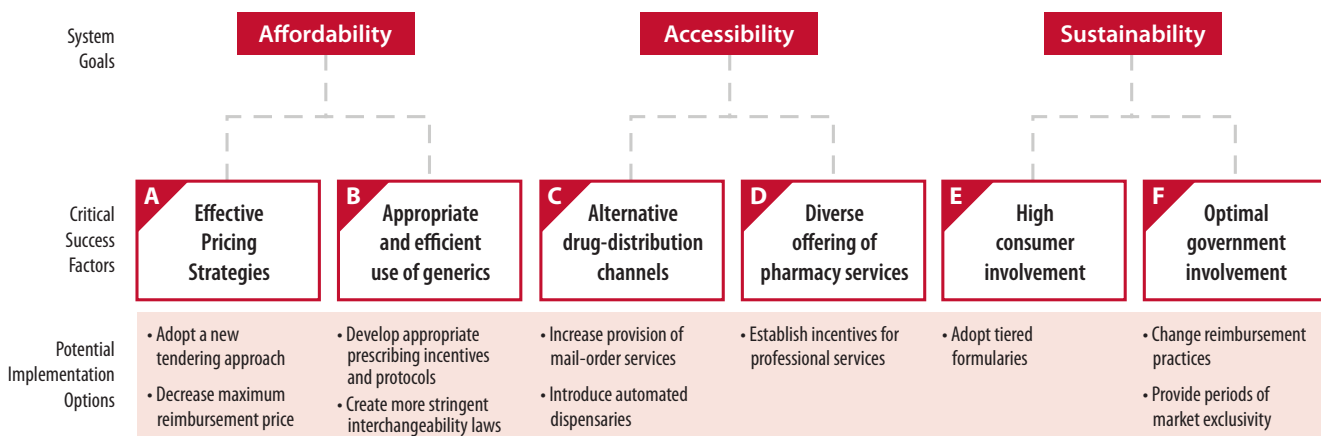
Most Canadians, including those living in rural areas, have reasonable access to pharmacies. Nonetheless, access to pharmacy services is a key feature of the reform policies currently being discussed. A growing consensus suggests that the skills and expertise of pharmacists are not being fully leveraged in the current system. Hence, many provinces

are discussing ways to better utilize the pharmacist to provide enhanced services and to improve outcomes.

Based on interviews with key stakeholders, researchers, and representatives from several jurisdictions, six critical success factors have emerged that can improve affordability, accessibility, and sustainability. These six factors, and potential implementation options for achieving them, are illustrated in Figure 3, below.

Each success factor outlined in Figure 3 corresponds to one of the three system goals—affordability, accessibility, or sustainability. However, most have implications for all three. For example, multiple drug-distribution channels enhance accessibility, but may also improve the affordability and long-term sustainability of the system by offering a lower-cost alternative to traditional drugstores, especially for refills on maintenance drugs.

FIGURE 3: SYSTEM GOALS, CRITICAL SUCCESS FACTORS AND POTENTIAL IMPLEMENTATION OPTIONS



^{hh} Quality of generic drugs is another important system goal. However, as discussed in Section 2 of this paper, generic drugs are subject to the same quality, safety, and efficacy standards as brand name drugs. Health Canada regulations ensure that each generic drug meets high standards of quality. As a result, the quality of generic products has not been a policy issue and is thus not further discussed in this paper.

(A) Effective Pricing Strategies

Effective pricing strategies reflect the true costs of manufacturing generic drugs and incorporate a reasonable margin along the supply chain. Provinces and territories are the dominant payers for generic pharmaceutical products and they have significant influence on pricing. Retail pharmacy groups are the dominant providers at the retail level and they exert considerable influence on the market.³ As a consequence, normal market forces do not serve as the mechanism for optimizing prices at the retail level. However, competition between manufacturers in their efforts to sell to pharmacies seems to be thriving.

In the absence of normal market mechanisms at the retail level, understanding how profits are made in the supply chain and determining what prices should be paid for generics tends to dominate the public-policy discussion.

A comparison of prices paid by Canadian and international jurisdictions suggests that Canadians are reimbursing generic drugs well beyond their true cost and reasonable margin levels. In Ontario, for instance, the top 20 generic drugs reimbursed by the ODB Program cost taxpayers more—in some cases substantially more—than those same drugs in the US, Italy, Germany, Spain, Sweden, or the UK. The average price of the top 20 generic drugs in these countries is from 11% (in Italy) to 77% (in the UK) lower than in Ontario.¹¹ As a further example, a 10-mg dose of enalapril—a generic drug that treats high blood pressure—costs 80% more in Ontario than in the US, and the price of a 500-mg dose of metformin—a drug that treats type 2 diabetes—costs 29% more.⁶²

Given that manufacturer wholesale prices in Canada are similar to those of other nations, our significantly higher reimbursement price would suggest that a large portion of the extra funds is flowing to other parts of the supply chain (i.e. distributors and pharmacies). Since distributors receive an average mark-up of only 5%,³ the majority is likely flowing to the pharmacies. A large majority of the stakeholders interviewed for this paper support this conclusion.

The Competition Bureau projects savings of \$800 million per year for all payers in Canada if public and private plans redesign their compensation policies appropriately.²⁸

Below are potential implementation options for developing effective pricing strategies:

Adopt a new tendering approach

In a market with many players, tendering or competitive bidding may offer the best mechanism to achieve prices that are a true reflection of costs. In the generic drug market, the first issue to be addressed is, who should tender? The general assumption is that manufacturers should tender to provincial and territorial drug plans and that pharmacies should charge governments separately for their services.

However, this perspective overlooks the power aggregated by pharmacies consolidated into retail pharmacy groups. Aggregation has allowed pharmacies to extract rents from manufacturers in the form of rebates. While efforts have been made to stop this practice they have not been particularly successful. Ontario's proposed drug reform has pledged to completely eliminate rebates for both publicly and privately purchased drugs.²⁷

Most Canadian drug plans have not been able to achieve the benefits of tendering at the manufacturer level and will likely not be able to do so under existing regulations and market conditions. Currently, pharmacy retail groups are able to exercise their large buying power by putting pressure on manufacturers to submit high bids that in turn leave room for off-invoice rebates. As a result, manufacturers do not have an incentive to submit low bids or even to participate in the bidding, for fear of large pharmacy groups refusing to stock their products.

In light of these challenges, it should arguably be the pharmacies and not the manufacturers that bid to supply drugs. This practice is emerging in the US and parts of Canada as pharmacy retail groups contract to supply drugs and basic medical services to major employers.⁶⁹

Tendering by pharmacies to insurance plans might encourage more price competition among pharmacies—an element which is absent in the current system. Such price competition would likely cause pharmacies to put pressure on manufacturers to lower their prices. Thus, payers would ultimately reap the benefits of competition at both manufacturer and pharmacy levels. However, tendering by pharmacies is not without its challenges:

- The pharmacy that wins the tender would likely be the preferred provider for beneficiaries of the insurance plan. In other words, patients would either be required to fill their prescriptions exclusively from this pharmacy or face higher co-payments if they chose to fill them elsewhere.

- The role of independent pharmacies would have to be re-evaluated, given that an independent does not have the geographical coverage of a group of pharmacies and would likely win no bids on its own.
- Retail pharmacy groups, powerful in general, are also concentrated in specific regions of the country and have disproportionate power in those regions.

Decrease maximum reimbursement price

Decreasing the maximum reimbursement price for generic drugs is perhaps the easiest option to implement. For jurisdictions that already have price caps—Alberta, Ontario, Quebec, and Newfoundland and Labrador^{3, 23, 26}—reducing the reimbursement price is simply a matter of reducing the fixed percentage of the brand name price that is used to reimburse generic drugs. For other jurisdictions, reducing the maximum price would require more effort: either creating a price-cap structure of their own or finding ways to lower the price of each generic class under existing maximum-allowable-cost policies.

Reducing maximum prices would achieve the end goal of improving the affordability of generic drugs for public plans, and ultimately for taxpayers. However, the impacts on private plans, their sponsors, and out-of-pocket patients would likely differ across jurisdictions. For example, if a jurisdiction chooses to only impose price caps on the reimbursement prices for public plans, it leaves open the possibility of pharmacies recouping their lost revenue through private payers. They could increase either the drug price or dispensing fee they charge to private plans and out-of-pocket patients.

Even if pharmacies were permitted to—and did—charge higher prices to private payers, it is unlikely they could recoup all the profits they had lost from the public sector. As a result, they might seek other ways to generate revenue or decrease costs, including:

- increasing their front-store revenues, thereby shifting towards the business model employed by chain, banner and franchise pharmacies;³⁷
- merging with other pharmacies to improve their purchasing power and hence drive down their net acquisition costs;
- eliminating the cost of distributors by sourcing products directly from the manufacturer or using their own distribution channels;
- integrating vertically by acquiring or partnering with a generic manufacturer to produce pharmacy-brand generics; and
- cutting costs by shutting down stores or reducing hours of operation.

Pharmacies in Ontario are already proclaiming significant changes to their business model, including cost-cutting, as a response to the reimbursement-price cuts recently proposed by the provincial government. Shoppers Drug Mart CEO Jurgen Schreiber has indicated that the pharmacy chain will be “moving ahead with reductions in store hours, staff and services at Shoppers even before legislation is enacted.”⁷⁰

The impact on rural pharmacies would likely be more severe than on those in urban centres. Recall from Section 4 that for independent pharmacies—which constitute the majority of pharmacies in rural areas—prescriptions in general, including generic drug rebates, are an even-more-significant source of revenue than it is for other pharmacies. Decreasing the maximum reimbursable price would likely result in a reduction in rebates to pharmacies. Hence, pharmacies in rural areas with relatively low dispensing volumes could be seriously impacted.³⁷ Any pricing strategy must ensure that adequate funding is provided to rural pharmacies, as is the case in Alberta.²³ As discussed in Section 4, Ontario has also indicated a dispensing-fee premium for pharmacies in rural or under-served areas.

Manufacturers, when faced with increasing pressure from pharmacies to reduce their net prices, would focus primarily on increasing efficiency and decreasing their costs of production. This type of environment would favour firms that manufacture a very limited but specific set of products, since specialized firms may be more able to produce drugs at a lower cost than firms that manufacture a broad array of products. In addition to becoming more specialized, manufacturers might also consider transferring their production to countries such as India and China. (The largest Canadian generic manufacturer, Apotex, already has a manufacturing facility in India.)⁷¹

(B) Appropriate and Efficient Use of Generics

Use of cheaper generic drugs in place of their brand name equivalents is an important source of savings for all payers. Maximizing generic use, in addition to developing effective pricing strategies, is a critical factor in ensuring the affordability of prescription drugs.

In a 2006 comparison of 22 European countries, the generic drug share of the market (by volume) was less than 50% in 13 countries,⁷² compared to 54.4% in Canada.⁶ This would indicate that there are some incentives within the Canadian market (and others) to dispense generic pharmaceuticals. Clearly, the presence of rebates on generic drugs may—for the moment, at least—be one of these incentives.²⁸ Any drug-policy reform must ensure that proper incentives are in place to dispense generic drugs, because a drop in generic drug rebates could make the dispensing of brand name products a more profitable option for some pharmacies. To ensure that incentives to dispense generics are in place, Canadian jurisdictions can focus on influencing either the prescribing behaviour of physicians or the dispensing behaviour of pharmacies.

Below are potential implementation options for achieving appropriate and efficient use of generics:

Develop appropriate prescribing incentives and protocols

In many countries, the decision between dispensing a generic or brand name drug is physician-driven. As shown on Table 5 in Section 3, prescription targets are set for physicians in countries such as Germany and New Zealand. These targets, especially cost targets, serve as an incentive for them to prescribe lower-cost alternatives to brand name drugs, where appropriate. Similarly, in the UK, physicians have financial incentives that are designed to encourage cost-effective prescribing, in an effort to maximize generic substitution.^{73,74}

Kaiser Permanente in the US is an example of an organization implementing prescribing protocols that encourage generic use.^{75,ii} Similarly, the US company Pitney Bowes has adopted a value-based insurance-design approach to prescribing and has achieved improvements in health outcomes and remarkable savings in the management of chronic disease.^{76,77}

Create more stringent interchangeability laws

Unlike the other countries studied, Canadian provinces and territories have traditionally relied on pharmacies rather than physicians to drive generic utilization. As a result, all Canadian jurisdictions have interchangeability laws that require or allow pharmacists to substitute generic drugs in place of brand name. The interchangeability law alone does not serve as an incentive to dispense generics. However, as stated in Section 3, four provinces (Saskatchewan, Manitoba, PEI, and Newfoundland and Labrador) have mandatory interchange laws.³ This provision creates the necessary incentive for pharmacists to dispense lower cost generic drugs.^{jj}

Given that interchangeability policies and regulations already exist in all provinces and territories, it would be relatively simple for drug plans to implement a pharmacist-driven approach that makes substitution mandatory in those jurisdictions where it is now optional, and that specifies substitution of the lowest-cost product.^{kk} On the other hand, creating a physician-driven market using such incentives as prescription targets would be much harder to accomplish, given the absence of any such models within the existing system.

Moreover, limiting a physician's ability to prescribe by applying budgetary constraints, or mandating a physician to prescribe the lowest-cost medication in a class of drugs, may result in poorer health outcomes for the patient and potentially higher costs for the health care system. (The impact would differ from that of placing the same restrictions on pharmacists, because when restrictions are applied at the pharmacist level, as suggested above, the physician retains the right to override the rule by specifying, “no substitutions.”) Prescribing appropriate drugs is generally the least expensive health care intervention, and having choice among drugs is important since patients may respond to different products in different ways. Some may work where others fail and some may cause adverse effects where others do not. Hence, an approach that relies on prescribing protocols rather than strict cost targets (i.e. drug budgets) may be a more suitable strategy for ensuring appropriate and efficient use of generic drugs.

ⁱⁱ Brand name drugs are only covered when there is no available generic equivalent, or when prescribed by a physician.⁷⁵

^{jj} However, as noted in Section 3, patients can still request a brand name product in some Canadian jurisdictions.

^{kk} Even under mandatory substitution laws, physicians could still enforce the prescription of a brand name drug where it is more appropriate for the patient (i.e. in cases where the brand and generic drug do not have an identical effect on the patient).

(C) Alternative Drug-Distribution Channels

Most Canadians obtain their prescription medications directly from a pharmacist in a community pharmacy. The prevalence of other drug-distribution channels in Canada is limited when compared to other countries, especially the US. In the US, mail-order pharmacies, in particular, are emerging as a viable distribution channel. This is also one of the fastest-growing segments of the market in terms of sales revenue.^{78, 79}

The primary benefit of alternative drug-distribution channels is improved accessibility. As described in Section 4, patients view pharmacy location, and thereby convenience, as one of the most important factors in determining where to fill a prescription. Features that improve convenience, such as home delivery and 24-hour access, are likely to be well-received. However, accessibility is not the only benefit of alternative distribution channels. They may also be a source of potential savings for the system.

Below are potential implementation options for providing alternative drug-distribution channels:

Increase provision of mail-order services

The benefits of mail-order pharmacies or online pharmacies have been well-chronicled:

- 24-hour availability that allows patients to order refill prescriptions any time of day;⁸⁰
- home delivery that saves patients travel time to the pharmacy and wait times;⁸¹
- telephone services that allow patients to ask sensitive questions in private;⁸⁰ and
- automatic dispensing of repeat prescriptions, ensuring that refills are obtained on time.⁸⁰

In addition to these benefits, mail-order pharmacies have the potential to save money for the system as a whole. They have a more favourable cost structure than traditional community pharmacies, primarily due to lower overhead and greater efficiency. The ability to serve a large catchment area from one location (i.e. a warehouse) allows them to save the overhead costs of operating retail locations. Mail-order pharmacies also have the ability to automate their dispensing practices and streamline the workload of their pharmacists. Evidence from the US suggests that lower overhead and greater efficiency allow mail-order pharmacies to charge lower dispensing fees than traditional pharmacies.⁸²

Mail-order is available in Canada but a stronger mail-order presence here could represent a source of potential savings. Pharmacy-benefit managers, who manage insurance benefits for many private plans, have encouraged the growing utilization of mail-order pharmacies in the US.⁸³ A similar move by the largest employer groups in Canada could trigger more widespread adoption of the mail-order channel, and ultimately lead to savings for private payers. Public payers would undoubtedly follow suit.

However, any growth in the mail-order segment would likely be met with great resistance by community pharmacies, and could decrease the revenue they generate. The lower dispensing fees typically charged by mail-order pharmacies could trigger some price competition between the two groups in the long term, further eroding the profitability of community pharmacies.

As a preemptive strategy, some retail pharmacy groups have already established their own mail-order pharmacies. For instance, the Sobeys Pharmacy Group, which has over 200 pharmacy locations across Canada, offers a home-delivery service for prescription medications that can be ordered by phone, online, by e-mail, or post mail.⁸⁴

One of the most important features of the mail-order pharmacy is its potential to increase competition at the retail level. New operators can enter the business with a relatively small investment, thereby challenging the dominant position of retail pharmacy groups. However, it should be noted that mail-order pharmacies and other alternative distribution channels are best suited for refill prescriptions of long-term medications (e.g. medications for chronic disease),⁸² and not necessarily for acute needs (e.g. prescriptions for antibiotics).

Introduce automated dispensaries

The automated dispensary is another service-delivery channel that has recently had success in the US, where many retail pharmacy groups and mass merchandisers have installed vending machines that automatically dispense prescription drugs. These machines allow patients to retrieve their refill prescriptions even when the pharmacy is not open. They also allow patients to avoid waiting at the pharmacy counter.⁸⁵

Perhaps one of the more subtle benefits of this service-delivery channel is that it frees pharmacists up to spend more time on non-dispensing activities.⁸⁵ In fact, these machines may be one of two key enablers for pharmacists to provide more value-added professional services.⁸⁶ (The other key enabler,

⁸⁶ Many pharmacies, of course, use technicians to assist in dispensing-related activities and thereby achieve the same impact. For these pharmacies, a vending machine would not free up a significant amount of pharmacist time.

which is discussed in the following sub-section, is a funding model that provides an incentive for pharmacists to perform these value-added services.)

The PharmaTrust™ MedCentre remote dispensing system is the next generation of automated dispensary. Unlike the aforementioned vending machines in the US, the PharmaTrust machine does not require patients to order their refills in advance. Instead, the machine allows the user to communicate with a pharmacist via a two-way video conference, after scanning the prescription. The pharmacist then fills the prescription remotely and triggers the machine to dispense the appropriate medication.⁸⁶

The PharmaTrust dispensary offers numerous benefits:

- Patients not only have 24-hour access to dispensing services, but also 24-hour access to counselling services.
- Smaller communities, which sometimes have difficulty attracting pharmacists, can offer both dispensing and counselling services to their residents without having a pharmacist in the community.
- Family health clinics, shopping malls, grocery stores, and other locations can begin offering pharmacy services to their customers, thereby improving overall accessibility.⁴⁹

Like mail-order pharmacies, dispensing machines have the potential to save money for the system. The automation of dispensing activities and streamlining of patient-counselling services are the two main drivers of any potential savings from this avenue.

Despite safety concerns raised by the Ontario College of Pharmacists, the PharmaTrust remote dispensing system has already cleared a number of legislative hurdles. In fact, the machines have already been in use in a few Ontario hospitals, and PCA Services, the developer of PharmaTrust, plans to deploy them in malls, grocery stores, and other locations across Ontario later this year.⁴⁹ Depending on patient response to these machines, pharmacies may be significantly impacted and suffer reduced revenues. To counter this, pharmacies may look to extend their reach by installing their own dispensing machines to compete directly with PharmaTrust. Regardless of the pharmacy response, all payers are likely to benefit financially with more competition at the retail level.

(D) Diverse Offering of Pharmacy Services

As described earlier in this section, the role of the pharmacist as a health care professional, in general, is not being fully leveraged within the existing Canadian system. The provision of non-dispensing, value-added professional services remains relatively low, and patients have a very limited portfolio of such services to choose from in most pharmacies. This is illustrated in Table 6, using Ontario as an example. The most common non-dispensing, value-added service provided in Ontario pharmacies is blood testing, with only 36% of pharmacies offering it. Most services shown in Table 6 are offered at no more than 15% of Ontario pharmacies. Moreover, 42% of pharmacies provide none of the services shown.¹¹

TABLE 6: NON-DISPENSING PHARMACY SERVICES OFFERED IN ONTARIO

Service	% of Ontario Pharmacies Offering Service
Blood tests	36
Diabetes care	30
Smoking-cessation management	26
Vaccination	14
Cholesterol-control consultations	14
Asthma management	14
Hypertension management	13
Pain management	10
Home visits	9
Women's health programs	8
Weight management programs	7
Arthritis management	6
Anticoagulation management	5

Source: Sapsford (2009).¹¹

Much of the policy-making to date has focused on expanding the scope of practice for pharmacists. Attention is only now shifting toward finding appropriate incentives for pharmacies to begin offering the services their pharmacists are authorized to provide. Without specific financial incentives in place for non-dispensing services, pharmacies are likely to continue emphasizing dispensing-related activities.

An expanded role for the pharmacist is especially important given the increasing number of individuals living with chronic conditions. Compliance and disease-management programs at the pharmacy level could be beneficial in light of

this.⁸⁷ Team-based models of patient care—with pharmacists included—offer another lever in successfully treating the increasing number of people living with chronic conditions.

Studies have found that a team approach, with clear roles for pharmacists and other health care professionals, results in better-coordinated and more comprehensive care than can be offered by a single health care provider. A pharmacist, as part of an interprofessional team, can play a very valuable role in educating patients and helping them manage chronic conditions more effectively. A focus on team-based care would ultimately improve patient health outcomes and quality of life, and save money for the broader health system, as patients in team-based environments typically make fewer trips to hospital.⁸⁸

Below is a potential implementation option for providing a diverse offering of pharmacy services:

Establish incentives for professional services

The provision of non-dispensing services is being encouraged through government subsidies.³⁷ Alberta is currently in a transition period during which it will aim to create a funding model that reimburses pharmacists for non-dispensing activities.³⁸ Developing such a model will first require consideration of different compensation structures (fee-for-service, salaried, or fixed payment per patient), followed by setting actual payment amounts that will be sufficient to change pharmacist behaviour.

The recent drug reforms announced by the Ontario government indicate that new funding would be available to compensate value-added professional services. Health Minister Deb Matthews has said, “If pharmacists do embrace the model, if they do provide services like vaccinations, like chronic-disease management ... then that’s an area that I think we’d look very closely at.”⁸⁹ As part of the proposed reforms, \$150 million has been earmarked for compensating professional services that pharmacists would provide to Ontarians.²⁷

There is precedent in Ontario for these types of professional services. In 2007, the province introduced MedsCheck, a service that allows patients with chronic conditions, using three or more prescriptions, to schedule a 30-minute discussion with a pharmacist (a comprehensive review of their medications).⁹⁰ The pharmacist receives \$50 for the 30-minute consultation³⁷—a fee that may provide scant incentive for pharmacists to shift away from dispensing-related activities.

With an average dispensing fee of \$10.50 in Ontario, pharmacists would need to fill only five prescriptions in 30 minutes to surpass the amount they would earn from a MedsCheck consultation.⁹¹ Our interviewees suggested that pharmacists typically fill many more prescriptions in 30 minutes, and thereby earn their pharmacies much greater revenue by focusing on dispensing activities. Considering this, it is likely that Ontario would revisit the funding level of the MedsCheck service as part of its new drug strategy.

Nova Scotia launched a similar service, called Medication Review Service, in 2007. To be eligible, a patient must be enrolled in the province’s Seniors’ Pharmacare Program, be on four or more medications (as compared to three or more in Ontario) or on one of seven specified drugs, and must have one of seven medical conditions, such as diabetes or hypertension. The pharmacy receives \$150 for rendering this service.⁹²

(E) High Consumer Involvement

In the current system, most consumers have little incentive to comparison-shop for their prescription drugs. As described in Section 4, those with drug insurance tend to disregard price concerns, and seek out the pharmacy that is closest to their home or workplace. Moreover, the lack of competition between pharmacies suggests to the consumer that prices are standardized and that only minimal savings could be realized (either for themselves, through co-payments, or for the system as a whole) by comparison shopping. The Canadian situation contrasts sharply with that in the US, where retailers compete aggressively and publicly for generic drug sales.⁵³

To make consumers more engaged in their purchasing decisions, transparency and clarity of price information is necessary. Price information effectively allows consumers to exert pressure on pharmacies to lower their retail prices.⁹³

Below is a potential implementation option for encouraging high consumer involvement:

Adopt tiered formularies

Some drug insurance plans group the drugs listed in their formularies into tiers, with each tier having a different level of co-payment. This is to provide a financial incentive for the consumer to purchase one drug over another, thereby increasing the consumer’s involvement in the purchasing decision. Logically, these drug plans will often group low-cost drugs into the tier which has the lowest co-payment amount.^{94,95} In doing so, they encourage the consumer

to purchase low-cost drugs over more expensive alternatives—a strategy which saves the drug plan money.

Many jurisdictions, including most Canadian public drug plans, already use tiered formularies to encourage consumers to purchase generic drugs instead of brand name. Consumers have the option of purchasing the more expensive brand name drug, but must pay the amount in excess of the generic price out-of-pocket.³ In other words, the insurer reimburses only the amount that is equivalent to the cost of the generic drug, and patients choosing the more expensive brand name drug will only be partially reimbursed.

In addition to determining which drugs are eligible for reimbursement, policies can specify the degree of interchangeability between generic and brand name pharmaceuticals. For example, interchangeability laws can make dispensing of the lowest-cost interchangeable product mandatory. Currently, only Saskatchewan, Manitoba, PEI, and Newfoundland and Labrador have *mandatory* interchangeability.^{mm} Interchangeability laws can also permit *but not require* pharmacists to interchange products, as is the case in the other six provinces.³ In any case, pharmacy profits on generic drugs have often been greater than on brand name products, giving the pharmacist a financial incentive to substitute generic for brand. However, the proposed Ontario reforms which aim to eliminate rebates may in fact make the dispensing of brand name products more profitable for some pharmacies.

Despite the prevalence of tiered formularies in Canada, research conducted to prepare this paper did not reveal any Canadian drug plans (public or private) that have extended the tiered approach to a tiering of pharmacies, based on the prices they charge consumers. A drug plan could choose to fully reimburse the cost of a drug purchased in one pharmacy, but only partially reimburse the cost of that same drug from another, more expensive pharmacy. A patient choosing the more expensive retailer would have to pay the difference.

The benefit of extending the tiered-formularies approach is clear: pharmacies would begin competing on price, or risk losing those customers who wanted to avoid or minimize their co-payments. The challenge for insurers would be to determine the lowest-cost pharmacy for each generic drug or group of generic drugs. This would require some form of continuous monitoring of pharmacy prices and frequent formulary updates. One impact on price-sensitive consumers

would be that they might have to travel longer distances to obtain their medications. Also, this model would not work in smaller communities where people may have access to only one pharmacy.

(F) Optimal Government Involvement

Governments are major players in the generic drug market since they are major purchasers of drugs. In most provinces they dominate to the extent that they approach single-purchaser (monopsony) power. Through this power and through legislative authority, they can effectively set prices. But governments are concerned to maintain an effective supply chain. They want to ensure that all links in the chain can make reasonable but not excessive profits. Governments can also apply pressure to the supply chain so as to drive efficiency.

In the early 1990s, government drug plans set reimbursement levels for generic drugs at a relatively high percentage of the price of the brand name drugs they emulated.^{96,97} Naturally, pharmacies typically billed governments the maximum allowable amounts. Generous profits in the supply chain benefited generic drug manufacturers and encouraged the proliferation of retail pharmacies.³ Initially, generic drug manufacturers with large portfolios of drugs held sway over the pharmacies, and encouraged their purchasing-loyalty by offering them off-invoice discounts. Pharmacies reaped the benefits of reduced drug-acquisition costs and this became an integral part of their retail business model, allowing the number of pharmacies to grow.³⁷ In effect, these discounts became the primary lever through which generic firms competed for pharmacy shelf space.

The market dynamics that governments themselves had a hand in creating ultimately became a source of frustration for them. Realizing they were allocating too much profit to the supply chain, some jurisdictions began to reduce reimbursement rates.⁵⁰ At the same time, governments have grown frustrated by the lack of transparency as to how profits are distributed in the supply chain. They are faced with the challenge of not knowing how much profit can be squeezed from the supply chain through reductions in reimbursement levels before the chain is damaged.

The UK has partially solved this problem by monitoring pharmacy margins and resetting prices on a regular basis. In any quarter, enterprising pharmacists can seek the lowest-cost generics from manufacturers and wholesalers. The lowest price obtained then becomes the dominant reimbursement price for the following quarter, and

^{mm} All provinces have interchangeability laws, but only these four have mandatory interchangeability laws.

government may impose profit claw-backs on pharmacies for excess profits made in the previous quarter.⁴³

In addition to setting reimbursement levels, Canadian governments have tried to intervene in other ways. For example, Ontario and Quebec have attempted to regulate off-invoice discounts, and many other provinces have at least considered a similar approach.³ As explained in Section 3, these discounts represent a substantial source of profits for pharmacies, and bans and limits are difficult to enforce.

Below are potential implementation options for achieving optimal government involvement:

Change reimbursement practices

Much of the frustration for payers comes from government's efforts to control pricing at different levels in the generic drug supply chain. Governments attempt to control the manufacturers' prices by setting a reimbursement rate for drugs. They also try to control retail prices by specifying dispensing fees and mark-ups at the pharmacy level. As previously explained, pharmacies have compensated by pushing for deeper discounts from manufacturers and charging higher prices to private insurance plans and out-of-pocket customers. Governments' efforts to ban the use of discounts have been largely unsuccessful simply because market dynamics are, in this instance, more powerful than government edicts.

To simplify the situation, governments could set a reimbursement price at the pharmacy level. For example, the reimbursement paid to a pharmacy for dispensing a 90-day supply of drug X would be \$Y. Initially \$Y could be the total of the current reimbursement price, the pharmacist's mark-up, wholesaler fees, and acquisition cost of the drug. \$Y could be decreased if government felt that profits in the supply chain were too high. Governments would also need to consider publishing these prices so that private insurers were aware of them, or to regulate them so that the same prices applied to the private market.

Prices could be adjusted so as to influence behaviour. For example, 90-day prescriptions could be encouraged by making them more attractive to the pharmacist, from a cash-flow perspective, than three 30-day prescriptions. The pharmacist might accept a lesser profit if it came more quickly. In addition, pricing could be adjusted to encourage generic use over equivalent brand name use. Pharmacies could compete for business by offering to reduce or eliminate co-payments, for example, or by giving customers coupons to buy other goods.

In this environment, mail-order pharmacies would likely grow as a distribution channel because they are intrinsically less expensive than brick-and-mortar retail outlets, and this would further enhance the competitive environment.

An extension of this concept is for governments to call for tenders from pharmacies as described in Section 5(A).

The interviews carried out for this paper suggest that manufacturers' profit margins are already being squeezed, and therefore any downward trend in reimbursement would predominantly hit pharmacies. To compensate, governments could introduce a practice now being tested by some provinces, particularly Alberta and Ontario. These two provinces have indicated that they will allow pharmacists to provide initial prescriptions for common minor ailments such as backache and sore throat, as mentioned previously in this section. They will compensate the pharmacists at a lower rate than is paid to doctors. The work of doctors would not diminish, but would be redirected toward more serious cases requiring their professional skill set.

Overall, governments would enhance access to health care—and the negative impact of drug-system reform on pharmacies would be reduced because their lower profits on generic drugs would be partly compensated for by the fees-for-services they would receive. From the pharmacist's perspective, treating minor ailments would be an attractive addition to providing drug consultations such as MedsCheck.

Provide periods of market exclusivity

Governments can also intervene to encourage the development of generic versions of drugs. Ontario, for example, used to provide a higher reimbursement rate for the first company to launch a generic version of a drug in the province.¹² In the US, an enormously valuable 180-day market-exclusivity period is granted to the first generic entrant for certain applicants.⁹⁸ A similar practice could be put in place in Canada. In formulating such an approach, governments would need to consider that brand name firms are increasingly releasing generic versions of their own drugs. Governments might want to provide a period of exclusivity to the first two generic versions to enter the market.

To ensure that the competitive benefits of market exclusivity were realized, governments could ban deals between generic companies and brand name companies in which payment is made to slow the entry of a generic to the market. The reported deal between Ranbaxy and Pfizer to slow the entry of the generic form of Lipitor® is perhaps the most publicized example of this type of arrangement.⁹⁹

The implementation options discussed above represent a set of potential mechanisms that can help jurisdictions achieve greater effectiveness across the three critical dimensions—affordability, accessibility, and sustainability—and also to achieve greater transparency. The options are not exclusive of each other, and in many cases two or more could be bundled together (e.g. tiered formularies and mail-order services). However, not all options will be feasible or appropriate for all jurisdictions.

Based on these options, Section 6 provides a set of policy options that may be most appropriate for Canadian jurisdictions to consider at this time.

SECTION 6: OPTIONS FOR POLICY-MAKERS

Creating a more sustainable drug system that addresses the needs of patients at an affordable cost is not simple. Finding solutions that meet this goal and minimize the negative impacts on key stakeholders is an even greater challenge. The impacts of an aging population along with an increasing number of individuals living with multiple chronic conditions further compound the problem of creating a sustainable system.

In light of these circumstances, many governments, both in Canada and abroad, are continuously changing their generic drug policies in hopes of finding successful long-lasting solutions. Over the past few years, a number of trends have emerged and should be taken into account when considering future changes to the Canadian generic drug system:

- While provinces and territories regularly share information with each other, interjurisdictional collaboration on key policy decisions is not as extensive as it could, and needs, to be.
- The gap between public and private insurance costs continues to widen. Many provincial and territorial drug-plan policies on pricing are not extended to private insurance markets.
- The balance of power in the generic drug market has shifted from manufacturers to pharmacies, with competition increasing in the manufacturing sector, and with retail groups (e.g. chains and franchises) becoming more dominant in the pharmacy sector.
- Benefits of competition at the manufacturing level are absorbed by pharmacies and are not being passed on to consumers and payers.
- A lack of transparency in the system, particularly in determining manufacturer prices net of any off-invoice discounts, has made it difficult for governments to develop effective policies.
- Access to drugs is largely not seen as a significant public policy issue in most Canadian jurisdictions given that most Canadians have some form of drug insurance (even though insured patients may still face high out-of-pocket expenditures).
- **Drug insurance plans could revisit maximum reimbursement prices since a body of evidence suggests that Canadian prices are too high.** Drug plans could use Canadian industry information and pricing data from other countries for guidance. This approach mirrors the actions that many provinces are already taking and is basically an extension of the status quo.

If governments are to continue to intervene in the market, they need to ensure that public plans do not achieve lower prices at the expense of private plans. They need to ensure that private plans do not pay more than public plans either by making pricing well-known or through regulation.

- **Reimbursement prices could be set at the pharmacy level.** Governments have constructed reimbursement prices by setting a price for a drug, and by adding distribution cost, profit margins, and dispensing fees for pharmacies. Much to the frustration of governments, manufacturers have competed with each other by offering rebates to pharmacies. Offering discounts and rebates to purchasers is a normal commercial practice that governments have tried without success to suppress. Governments could reimburse pharmacies a single amount, which would include the actual cost of the drug, wholesaler fees, and pharmacy fees for dispensing and counselling.

- **The use of alternative and competing distribution channels could be encouraged.** With more alternatives in the retail market (e.g., mail-order pharmacies and automated dispensaries), competition would increase to the benefit of all payers. Consumer preferences will ultimately dictate how pervasive these channels become and consequently the magnitude of potential impacts. However, regulators should ensure that any barriers to the success of these service delivery channels are removed.

In the short term, policy-makers and drug-plan managers could take a number of approaches that would improve affordability, accessibility, sustainability, and transparency, while at the same time minimizing potential negative impacts on key stakeholders. The approaches listed below are a subset of the most feasible options discussed in Section 5. It should be noted that not all of these approaches can be implemented concurrently.

- **Drug plans, including employer-sponsored plans, could use tiered formularies to encourage their beneficiaries to use low-cost drugs.** Tiered formularies with associated patient co-payments effectively sensitize the consumer to the cost of medications. However, care must be taken to ensure that patients continue to take appropriate medications—both for their own benefit and because inferior health outcomes could cost the health system more than any monies saved.
- **Provincial and territorial drug plans could ensure that newly approved drugs are listed on their formularies in a timely manner.** Currently, the formulary listing process can take several months from the time the drug has received its NOC from Health Canada. This delay in listing newly approved drugs results, for instance, in public drug plans paying additional money for a brand name drug, even though a lower-cost generic version is available.
- **Using the pharmacist to provide additional paid services would moderate the impact of reducing generic drug prices and benefit the health care system.** Given that the Canadian population is aging, the prevalence of chronic disease is increasing, and medical-service demand is growing, expanding the role of the pharmacist could be of great value for both the patient (improved outcomes and access) and the health care system (improved sustainability).

APPENDIX: RECENTLY PROPOSED CHANGES TO ONTARIO'S GENERIC DRUG POLICIES AND REGULATIONS

As we were completing this discussion paper, the Government of Ontario proposed changes to the way it regulates reimbursement and prescribing fees for generic drugs. These are summarized below.

Ontario first made significant changes to its generic drug policies in 2006 with the *Transparent Drug System for Patients Act*, more commonly known as *Bill 102*. This legislation decreased the prices the provincial government was paying for generic drugs covered under its public drug plan and aimed to curtail the practice of manufacturers providing off-invoice discounts to pharmacies.

On April 7, 2010, Ontario announced that it would pursue further reforms to its generic drug pricing and reimbursement policies.¹⁹⁹ Highlights of the announced reforms include:²⁷

- decreasing the price of all generic drugs purchased in Ontario by at least 50% by 2014, effectively ensuring that neither public nor private insurers would pay more than 25% of the cost of the original brand name drug;
- eliminating the practice of professional allowances (also known as rebates or off-invoice discounts) paid to pharmacies by manufacturers, by 2014;
- increasing the funding available for pharmacists' compensation by raising dispensing fees and earmarking \$150 million for other professional services; and
- paying pharmacies in rural or under-served areas a higher dispensing fee than would be paid to their counterparts in urban areas for prescriptions covered by the ODB Program.

The benefits of these reforms for public payers are clear. The Ontario public drug plan, and by extension taxpayers, could save an estimated \$500 million per year by implementing these reforms. These savings would amount to approximately 12% of the ODB Program's annual budget. However, the benefits for private plans, and by extension for employers and for consumers paying out-of-pocket, are less certain, but could be very significant.²⁰⁰

Savings for the public sector could be important in ensuring not only the immediate affordability of generic drugs, but

also the long-term sustainability of the system, especially in light of the increasing number of individuals who will require access to prescription drugs. Also, these savings could be used to give Ontarians more generous drug coverage, thereby improving health outcomes and reducing costs for the health care system.

In anticipation of reduced revenues, some pharmacies are already signaling cut-backs in store hours, thus raising concerns about accessibility to medication for some consumers. While some risk does exist, most patients could be unaffected. As noted above, in areas where the risk is greatest—i.e. rural or under-served—pharmacies would receive a higher dispensing fee than their counterparts in other areas for prescriptions covered by the ODB program. This would help keep these pharmacies viable and thus mitigate the risk of accessibility issues. Further, any potential drop in accessibility could be partially countered by a recent innovation: the automated dispensary, as discussed in Section 5.

In terms of out-of-pocket savings, patients might see a decrease in their drug costs depending on how their insurers had structured their premiums, deductibles, and co-payments. Savings for privately insured and uninsured individuals have an additional element of complexity since the reforms do not extend to mark-ups and dispensing fees charged by pharmacies to the private market. As noted above, pharmacists might increase these to help offset other losses in revenue. Therefore, the impact of the reforms on out-of-pocket savings remains to be seen, especially for privately insured and uninsured people.

Assuming that some out-of-pocket savings were achieved, an improvement in health outcomes might follow. A study based on 2007 data showed that an estimated 8% of Canadians are affected by cost-related non-adherence to prescriptions.¹⁰⁰ In other words, they risk adverse health outcomes to save money or because they cannot afford the

¹⁹⁹ Detailed at: http://health.gov.on.ca/english/public/legislation/drugs/regulation_935.pdf.

²⁰⁰ Given that private insurers pay higher prices for generic drugs and have higher total drug expenditures, as compared to the Ontario public drug plan.

drugs. Lower out-of-pocket costs for patients could lead to improved adherence to prescriptions, and consequently to improved health outcomes.

Both the equity and future earnings of pharmacies could be impacted by the proposed reforms, with some actually going out of business. This is mainly because pharmacy revenue growth over the past few years has been funded, in large part, by rebates from generic drug manufacturers. Hence, these reforms could ignite a significant shift in the business model of pharmacies.

The impacts of the reforms could lead pharmacies to enact cost-cutting measures, consolidate into larger pharmacy groups, and even find new sources of revenue.^{PP} Pharmacy chains, franchises, and banner groups are better positioned than independent pharmacies are to absorb reduced income from generic drug sales, partly because much of their revenue is already derived from other sources. The impact on independent pharmacies could be deeper since they tend to focus on prescribing as their major source of revenue. These independents could be hard-pressed to find cost-saving opportunities or new sources of revenue, given that most of them are pharmacist-owned and have limited front-shop space.

To mitigate the impact on pharmacies, the Ontario government would dedicate a portion of the savings it achieved to other pharmacist services (for instance, flu shots), in effect offering pharmacies a new source of revenue, and giving patients improved access to basic health care services. The challenge with this approach is finding an appropriate funding level that will encourage pharmacists to perform more non-dispensing activities. Nonetheless, increasing the funding that is available for these services in a manner that provides appropriate incentives for pharmacists could benefit both patients and pharmacies.

From the perspective of manufacturers, if profits are squeezed out of the supply chain as the changes in regulation intend, manufacturers may seek more cost-effective means of producing their drugs and may even relocate or shift some of their production to countries with lower labour and operating costs.

In addition to the stakeholder-impacts described above, the reforms could also give rise to the following:

- **An increase in mark-ups and dispensing fees for private payers** While the reforms would regulate drug costs across both public and private markets, dispensing fees and mark-ups for private payers would remain uncapped. Indeed, pharmacies might increase these to help compensate for other revenue reductions.
- **An increase in rebates in other provinces and territories** Pharmacy groups with outlets outside Ontario may try to compensate by seeking additional rebates from manufacturers for goods supplied in other provinces or territories. Since Quebec is the only other province with rebate caps, this outcome could be likely, especially among franchises and chains with a pan-Canadian presence.
- **The development of alternative rebate practices** Regulating rebates may not be a straightforward undertaking. Manufacturers and pharmacies may find other ways to continue the practice (i.e. by providing discounts for bulk purchases).

The proposed Ontario reforms could have a ripple effect in other provinces and territories. Quebec and Newfoundland and Labrador could be the first to follow suit since their public plans are mandated to match the price of the lowest-priced Canadian jurisdiction for each generic drug. Other provinces and territories might follow, especially since many of them are already contemplating changes to their drug-pricing strategies.

As described in Section 1, Canadian jurisdictions are paying relatively high prices for generic drugs, as compared to many industrialized nations. In response to this price differential, the cornerstone of Ontario's proposed approach is an attempt to bring prices more in line with those found in international jurisdictions. Other components of the reform are designed to reduce the impact of these price reductions on the supply chain, and to ensure that patient access to prescription drugs is not compromised. As such, these reforms could be an important step in making generic drugs more affordable and accessible for patients.

Furthermore, ensuring that affordability is sustained into the future was no doubt a major consideration in constructing these reforms. An aging population and an increasing number of people living with chronic conditions means that drug consumption will likely increase in the near future. The proposed changes could be essential in preparing for this projected demand and creating a more sustainable system.

^{PP} A natural response of pharmacy groups could be to vertically integrate generic drug manufacturing but this too is prohibited under the proposed changes in regulation.

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About the Health Council of Canada

Canada's First Ministers established the Health Council of Canada in the 2003 *Accord on Health Care Renewal* and enhanced our role in the 2004 *10-Year Plan to Strengthen Health Care*. We report on the progress of health care renewal, on the health status of Canadians, and on the health outcomes of our system. Our goal is to provide a system-wide perspective on health care reform for the Canadian public, with particular attention to accountability and transparency.

The participating jurisdictions have named Councillors representing each of their governments and also Councillors with expertise and broad experience in areas such as community care, Aboriginal health, nursing, health education and administration, finance, medicine, and pharmacy. Participating jurisdictions include British Columbia, Saskatchewan, Manitoba, Ontario, Prince Edward Island, Nova Scotia, New Brunswick, Newfoundland and Labrador, Yukon, the Northwest Territories, Nunavut, and the federal government.

Funded by Health Canada, the Health Council operates as an independent non-profit agency, with members of the corporation being the ministers of health of the participating jurisdictions.

The Council's vision

An informed and healthy Canadian public, confident in the effectiveness, sustainability and capacity of the Canadian health care system to promote their health and meet their health care needs.

The Council's mission

The Health Council of Canada fosters accountability and transparency by assessing progress in improving the quality, effectiveness and sustainability of the health care system. Through insightful monitoring, public reporting, and facilitating informed discussion, the Council shines a light on what helps or hinders health care renewal and the well-being of Canadians.

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