Generic Drug Pricing Policy in Quebec

June 2013

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Publisher
Commissaire à la santé et au bien-être

This report was prepared by independent researchers. As such, they are fully responsible for its content. The views expressed by the authors do not necessarily reflect those of the publisher, the Commissaire à la santé et au bien-être.

The Commissioner thanks Alberta’s Ministry of Health for its support in the translation of this paper.

This report is available in the Publications section of the Commissioner's website: www.csbe.gouv.qc.ca.

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Preface

The *Generic Drug Pricing Policy in Quebec* report was prepared for the Commissaire à la santé et au bien-être [Quebec commissioner of health and well-being] to assist him with his evaluation of the effectiveness of the health and social services system as it relates to medications.

This report discusses the pricing policies for drugs reimbursed by Quebec’s public drug insurance plan and potential changes to these policies. During the reference period selected, the mechanisms used by Quebec’s prescription drug insurance plan to regulate generic and brand-name drug prices underwent major changes. Although the impact estimation model was adapted accordingly, the scope of this report is limited in that it does not address the cost or ways to implement the policies discussed.

Acknowledgements

The research team would like to thank all those who agreed to be interviewed for this study and those who contributed relevant information. This study could not have been carried out without them.

The research team would also like to express its sincere gratitude to the Commissaire à la santé et au bien-être for sponsoring this project.
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### Acronyms and abbreviations

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<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>AAC</td>
<td>Average Annual Change</td>
</tr>
<tr>
<td>AQPP</td>
<td>Association québécoise des pharmaciens propriétaires [Quebec Association of Owner-Pharmacists]</td>
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<tr>
<td>BC</td>
<td>British Columbia</td>
</tr>
<tr>
<td>BGMA</td>
<td>British Generic Manufacturing Association</td>
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<tr>
<td>CBC</td>
<td>Competition Bureau of Canada</td>
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<tr>
<td>CGPA</td>
<td>Canadian Generic Pharmaceutical Association</td>
</tr>
<tr>
<td>CSBE</td>
<td>Commissaire à la santé et au bien-être [Commissioner of Health and Well-Being]</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>GDP</td>
<td>Gross Domestic Product</td>
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<tr>
<td>GOP</td>
<td>Group purchasing organization</td>
</tr>
<tr>
<td>GSP</td>
<td>Guaranteed Selling Price</td>
</tr>
<tr>
<td>INESSS</td>
<td>Institut national d’excellence en santé et en services sociaux [National Institute of Excellence in Health and Social Services]</td>
</tr>
<tr>
<td>MSSS</td>
<td>Ministère de la Santé et des Services sociaux [Ministry of Health and Social Services]</td>
</tr>
<tr>
<td>MSSS-SDI</td>
<td>Ministère de la Santé et des Services sociaux, Service de développement de l’information [Ministry of Health and Social Services, Information Development Department]</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
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<tr>
<td>ODB</td>
<td>Ontario Drug Benefit Program</td>
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<tr>
<td>OECD</td>
<td>Organization for Economic Cooperation and Development</td>
</tr>
<tr>
<td>PMPR</td>
<td>Patented Medicine Prices Review Board</td>
</tr>
<tr>
<td>QPDIP</td>
<td>Quebec Prescription Drug Insurance Plan</td>
</tr>
<tr>
<td>QPPDIP</td>
<td>Quebec Public Prescription Drug Insurance Plan</td>
</tr>
<tr>
<td>RAMQ</td>
<td>Régie de l’assurance maladie du Québec [Quebec Health Insurance Board]</td>
</tr>
<tr>
<td>SOC</td>
<td>Standing Offer Contract</td>
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Glossary

Actual purchase price
Price paid by the Régie de l’assurance maladie du Québec to a pharmacist, as it appears on the Quebec prescription drug insurance plan’s *List of Medications* in effect at the time the prescription is filled. The actual purchase price takes into account the supply source and package size. In most cases, the actual purchase price is the same as the guaranteed selling price.

Administrative services only plan
A plan whereby the employer pays health insurance benefits to employees but does not have an insurance plan. This type of plan can be administered by the employer or by an insurance company.

Blockbuster drug
An extremely popular patented drug.

Co-insurance
Percentage (or portion) of the prescription drug cost that insured persons must pay once they have paid the deductible. In other words, when a person’s drug cost exceeds the deductible, the person pays only a portion of the remainder. This portion is what is referred to as the co-insurance (RAMQ, 2012a).

Community pharmacy
A pharmacy in a Quebec community, owned by one or more pharmacists.

Deductible
A fixed amount that constitutes the first portion of the costs that insured persons must pay when obtaining insured drugs (RAMQ, 2012a).

Guaranteed selling price (GSP)
Price appearing on the Quebec prescription drug insurance plan’s *List of Medications*. This is the price individuals pay for their medications. The guaranteed selling price is the price a buyer must pay for a drug, less any reduction granted by the manufacturer as a rebate, discount or premium and by the value of any good or service provided free of charge to a buyer by the manufacturer, other than a benefit authorized under the *Regulation respecting the benefits authorized for pharmacists* (L.R.Q. c. A-29.01 r. 2).

Most favoured nation clause
This clause, explained in sections 1 and 2 of the *Manufacturer’s Commitment* (s. 1) in the *Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications*, stipulates that the manufacturer undertakes to submit a guaranteed selling price per package size for any drug that he wishes to have entered on the *List of medications* and that such price must not be higher than any selling price granted by the manufacturer for the same drug under other provincial drug plans.
**Pharmaceutical opinion**
The reasoned opinion of a pharmacist on the pharmacological and therapeutic history of an insured person prepared under his authority or on the therapeutic value of one or all the treatments ordered by prescription, given in writing to the prescriber. The opinion includes a recommendation specific to the insured person (change, discontinue or prevent the prescribed treatment, etc.) (MSSS, 2012).

**Pharmaceutical service covered by the Quebec public drug insurance plan**
Filling, repeating or refusing to fill a prescription, and pharmaceutical opinions.

**Pharmacist’s fees**
Quebec’s prescription drug insurance plan provides for two types of fees. The first is paid when the pharmacist renders a pharmaceutical service to a member of the Quebec public prescription drug insurance plan, and the second, to a member of a private drug plan. In the first case, the pharmacist’s fee is equal to the compensation established according to the regulated tariff applicable to the pharmaceutical service rendered. In the second, the pharmacist is free to set his fees, which are generally considered the pharmacist’s or pharmacy’s margin.

**Pharmacy’s margin**
The difference between the usual, customary price and the manufacturer’s selling price, including the wholesaler’s margin.

**Premium**
Amount paid to a public or private insurer to obtain drug insurance coverage.

**Prescription**
An individual prescription written by a physician or a health professional authorized to prescribe medication. Any prescription renewal is considered a prescription.

**Prescription price**
Includes the price of the prescribed medication, distributor’s margin and pharmacist’s fees. Also called “pharmacy’s margin” when the prescriptions are for members of private group plans.

**Private group insurance plan (private group plan)**
Private drug plans are usually available in the form of group insurance or an uninsured employee benefit plan. Persons may be eligible for a private plan through employment, through membership in a professional order or association, or through their spouse or parents. In Quebec, persons who are eligible for a private plan are required to join that plan since they are not eligible for the public drug plan. (RAMQ, 2012a).
**Professional allowance**
Reduction in the form of a discount, rebate or premium, good, service, gratuity or any other benefit granted, paid or provided, directly or indirectly, by a generic drug manufacturer to an owner-pharmacist (*Regulation respecting benefits authorized for pharmacists*, R.R.Q. c. A-29.01, r. 1). The term “discount” was used to describe these reductions before this regulation came into force in 2007.

**Quebec Prescription Drug Insurance Plan (QPDIP)**
In Quebec, everyone must be covered by drug insurance at all times. Two types of plans offer this coverage: the public plan, administered by the Régie de l’assurance maladie du Québec, and private drug plans (RAMQ, 2012a).

**Quebec Public Prescription Drug Insurance Plan (QPPDIP)**
Administered by the Régie de l’assurance maladie du Québec, the Quebec Public Prescription Drug Insurance Plan is intended for persons who are not eligible for a private drug plan, i.e. those aged 64 and under, persons aged 65 and over, recipients of last-resort financial assistance and other holders of a claim slip. Children of persons enrolled in the QPPDIP are also covered (RAMQ, 2012a).

**Subsequent entry biologic**
A drug approved by the regulatory authorities for its similarity in terms of quality, safety and efficacy to its reference biologic drug (ACMG, 2013).
Summary

To date, most industrialized countries have implemented pricing policies to somehow regulate and control the prices of generic drugs covered by their public prescription drug insurance plans. There are subtle differences in the details and context of each policy, which means that each one is unique. Pricing policies must be designed with the aim of achieving consistent government action in industrial and health policies and must be revised based on the ongoing changes in these two fields of activity.

Under the Quebec Prescription Drug Insurance Plan (QPDIP), it can sometimes be difficult to evaluate the fairness and reasonableness of the generic drug prices reimbursed by the Quebec Public Prescription Drug Insurance Plan (QPPDIP), based on available information. However, given significant government spending on reimbursed drugs and the fact that generic drug pricing is under provincial jurisdiction, it is necessary to review the effectiveness of the policies governing the prices of generic drugs on the QPDIP List of Medications.

This report focuses on generic drug pricing and sheds valuable light on generic drug pricing policies in the health systems of industrialized countries comparable to Quebec and on their potential for adaptation to the QPDIP context. Three pricing policies are analyzed: tendering, benchmarking, and descending price schedule. This last policy is the most promising for the QPPDIP. An analysis of its impacts suggests significant reductions in spending on the drugs covered by the QPPDIP and broad adaptability to Quebec’s regulatory and legislative framework.

With regard to spending, according to the estimates that have been made, application of a descending price schedule for the 10 generic drugs accounting for the biggest QPPDIP expenditures in 2011 would have reduced spending for these 10 products by nearly C$122 million in 2011, a savings of 62%. What’s more, since the rationale for this approach is comparable to that of the price control measures currently in force in Quebec, implementation of this new way of pricing generic drugs would require only small changes to the existing regulatory and legislative framework.

In light of these findings, the policy of descending price schedule seems to be a major factor in controlling generic drug expenditures covered by the QPPDIP. However, the considerable interest in this policy must be tempered by a broader reflection that includes pricing both for all reimbursed drugs and for reimbursable prescription price components.
Introduction

At a time when the health systems of many OECD (Organization for Economic Cooperation and Development) countries are focusing on controlling the cost of publicly-funded drugs and effectively allocating health resources, governments tend to favour pharmaceutical policies that call for greater use of generics in their public drug plans (OECD, 2008). Legislative and regulatory measures governing generic pricing vary widely across countries and their impact largely depends on the context in which they are applied and evolve (Seeley and Kanavos, 2008).

Between 2005 and 2011, the generic share of prescriptions grew from 43.5% to 60.1% of total prescriptions in Canada (317 million). During this same period, generic sales rose from C$2.85 billion to C$5.41 billion, accounting for, respectively, 17.3% and 24.5% of prescription sales in the country. Although the generic share of the prescription market is growing (50% in 2009 to 58.2% in 2011), Quebec still prescribes the least generics in Canada (ACMG, 2012).

To improve efficiency as regards increased use of QPPDIP-covered generics, it is relevant to examine generic drug pricing policies with a view to optimizing the allocation of health sector resources by establishing the most equitable outlay for payers, i.e. QPPDIP beneficiaries and third-party payers – the Régie de l’assurance maladie du Québec (RAMQ).

The objective of this study is to present Quebec’s generic drug pricing policy and to evaluate the impact a new pricing policy would have on expenditures associated with generics covered by the QPPDIP. This report is divided into five sections. The first discusses the regulatory framework governing generic pricing in Quebec. The second briefly describes the context in which the stakeholders in Quebec’s generic supply and distribution chain operate. The third compares the characteristics of generic prices, while the fourth describes the three main methods used to price generics – tendering, benchmarking and descending price schedule – and their applicability to Quebec’s public drug insurance plan (QPDIP). The last section presents the potential impact of a descending price schedule policy on expenditures associated with QPPDIP-covered generics.
The legislative and regulatory framework governing generic pricing in Quebec

In Canada, brand-name drug pricing is the purview of the federal government while the provinces and territories are responsible for setting the price of generics reimbursed by their provincial public plans. In the case of Quebec, the provincial government sets the prices of generic drugs reimbursed by its prescription drug insurance plan (QPDIP).

Established in 1996, the QPDIP seeks to ensure that all persons in Quebec have reasonable and fair access to the medications required by their state of health (Quebec, 1996). The QPDIP is a mixed, mandatory plan requiring eligible persons to be covered either by the QPPDIP, a private drug plan or an uninsured employee benefit plan. Reimbursed drugs must be approved by the Minister of Health and Social Services before it can be added to the QPDIP List of Medications.

The Act respecting prescription drug insurance states that as the administrator of the QPPDIP, RAMQ is responsible for providing coverage, while private group plans are responsible for providing coverage under the private component of the QPDIP (Gagné, 2010; Quebec, 1996). The Act further states that private group plans must offer at least the same level of coverage for pharmaceutical services and medications as the QPPDIP does.

In 2011, the QPPDIP spent C$3.9 billion on medications and professional pharmacy services. RAMQ assumed $3.2 billion of this amount while beneficiary contributions made up the remaining $742.1 million (RAMQ, 2011). From 2009-2010 to 2011-2012, generic expenditures rose from 21% to 22% of total QPPDIP expenditures (RAMQ, personal communication, February 2013). Two formulas regulated by the Ministère de la Santé et des Services sociaux (MSSS) are used to set the prices of generics on the QPDIP formulary:

- Prices are set according to two arbitrary ratios – For a first version of a generic (first manufacturer on the market), the guaranteed selling price

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1. For the reference period of July 1, 2010 to June 31, 2011, 41% of the population (3.3 million people) were members of the public component. Therefore, the remainder (59%) would have been covered by the private component.
2. The QPDIP List of Medications contains medications that are both fully and partially reimbursed by the QPPDIP. In October 2012, this list contained 6,880 medications and supplies (INESSS, personal communication, August 2012).
3. For ease of reading, the expression “private group plans” encompasses group insurance carriers and administrators of uninsured benefit plans.
4. The GSP of a drug is the price appearing on the QPDIP List of Medications, established as follows: 1) It must be submitted for each package size of the drug (the size is limited to two) and take into account any price granted for multiples of the package; 2) It may differ for sales to pharmacists or other wholesalers but since April 1, 2012, this difference may not exceed 6.5%; 3) It must remain in effect throughout the period of validity of the List of Medications; 4) It must not be higher than any selling price granted by the manufacturer for the same drug under other provincial drug insurance programs (Regulation respecting benefits authorized for pharmacists and Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications).
(GSP) of the drug on the List of Medications cannot exceed 60% of the equivalent brand name drug. As soon as another manufacturer producing the same medication enters the market, the GSP becomes, for all manufacturers offering this product, 54% of the price of the equivalent branded drug;

- Prices are set according to the “best price granted to provincial plans” rule5 – This rule takes precedence over the 60% and 54% formula if the generic price obtained with this formula is greater than the lowest price for this same drug covered by any other public plan in Canada. This means that the GSP of a generic must be equal to or less than the lowest price of the same drug covered by a public plan in Canada.

For a few years now, Ontario, through its Ontario Drug Benefit (ODB) Program, has been applying the lowest generic reimbursement rate. By applying the “best price” rule, Quebec’s pricing policy usually mimics the one used by the ODB Program. However, this could change in the near future since some provinces are planning to set generic reimbursements (for either all or some medications, depending on the province) at 18% of the brand price (Conseil de la fédération, 2013a).

The generics supply and distribution chain as it pertains to the QPDIP

There are five stakeholders in the generics supply and distribution chain, each one with a different economic goal:

i. Generic manufacturers, who are driven by sales and profitability;
ii. Distributors6 and wholesalers, who seek to grow sales revenues;
iii. Plan beneficiaries, who try to minimize their outlays;
iv. The public third-party payer, which seeks to ensure optimal medication use (e.g. the right medication for the right patient, control of public drug expenditures, optimal allocation of financial resources);
v. Community pharmacies (pharmacy groups, independent pharmacies or supermarket pharmacies), which strive to meet customer needs while seeking to increase pharmacist fees and professional allowances.

The following sections discuss the relationships between these five stakeholders.

5. This rule, which stems from the GSP provision in the Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications of the Act respecting prescription drug insurance, refers to the most favoured nation clause, which is applied to Quebec, Manitoba and Newfoundland-Labrador. Under this clause, the price offered to a provincial drug plan by a drug manufacturer must be less than or equal to the price granted for the same drug to other provincial drug plans.

6. In Quebec, distributors and generic manufacturers are one and the same since they hold federal manufacturing licences and are responsible for entering their medications on the QPDIP formulary.
Generic manufacturers, distributors and wholesalers

To list medications on the QPDIP formulary, manufacturers must first be recognized by the Minister of Health and Social Services by meeting the conditions set out in the Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications, which include a commitment to submit a GSP.

On an outpatient basis, generic and brand name drugs covered by the QPDIP are dispensed by community pharmacies. Generic manufacturers distribute their products through three channels: 1) direct shipments from their facilities; 2) indirect shipments through intermediaries such as wholesalers (independent distributors); and 3) self-distribution (self-distributors), i.e. distribution centres that belong to pharmacy chains, banners or franchisees. Generic manufacturers are not subject to regulatory requirements as regards their choice of distribution method. Currently, pharmacies pay the same price for generics, regardless of whether they are destined for QPPDIP or private plan beneficiaries.

Like drug manufacturers, wholesalers must also be recognized by the Minister of Health and Social Services. To this end, they must adhere to the Wholesaler’s Commitment, as stipulated in Schedule II of the Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications. As intermediaries between drug manufacturers and community pharmacies, they must, among other things, distribute the medications on the QPDIP formulary and stock at least 50% of the drugs listed. Because of the services they provide, intermediaries play an important role in the supply and management of prescription pharmaceuticals intended for community pharmacies.

In their dealings with community pharmacies, intermediaries agree to respect the manufacturer’s GSP for the format purchased, to which a regulated markup of 6.5% is added. They may offer a discount not exceeding 2% of the net price for prompt payment. However, no reduction may be granted in the price of a drug for the attainment of a fixed purchase volume for a given period nor may any good be provided without consideration, and no reduction as a rebate, discount or premium may be granted. They must also provide RAMQ with an annual report on their drug sales by product and package size. While ancillary conditions such as discounts for prompt payment may vary, the price intermediaries pay for RAMQ-reimbursed medications depends entirely on the prices on the QPDIP formulary.


8. Intermediaries provide a variety of services, including daily deliveries, replenishment when the pharmacy runs out of stock, providing controlled storage and regulated temperature for certain pharmaceutical products, and inventory of high-value-low-turnover products. (BCC, 2008).
Community pharmacies

In Quebec, only pharmacists can own a pharmacy and only pharmacist-owners can buy and sell prescription drugs. A pharmacy can be owned by a pharmacist, a partnership of pharmacists or a joint-stock company. In 2011, there were 1,745 community pharmacies in Quebec, accounting for 20% of all such pharmacies in Canada and representing on average, one pharmacy per 4,531 people (Chartrand, 2012). In comparison, British Columbia had 1,068 pharmacies (1 per 4,243 people) and Ontario, 3,364 pharmacies (1 per 3,927 people).

There are three forms of community pharmacies, which in decreasing order of size are as follows: pharmacy groups (banners, franchises and chains), independent pharmacies and supermarket and mass merchandiser pharmacies (Table 1) (Chartrand, 2012; BCC, 2007). Between 2003 and 2011, the total number of community pharmacies grew by 9% (137 pharmacies). Chains, banners and franchises accounted for most of this growth, to the detriment of independent pharmacies, whose number fell by more than half (47 pharmacies closed their doors).

Table 1
Change in the number of community pharmacies, by type, Quebec, 2003 and 2011

<table>
<thead>
<tr>
<th></th>
<th>2003</th>
<th>2011</th>
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<tbody>
<tr>
<td></td>
<td>Number</td>
<td>%</td>
</tr>
<tr>
<td>Chains</td>
<td>409</td>
<td>25</td>
</tr>
<tr>
<td>Banners and franchises</td>
<td>1,008</td>
<td>64</td>
</tr>
<tr>
<td>Supermarkets and mass merchandisers</td>
<td>103</td>
<td>6</td>
</tr>
<tr>
<td>Independent pharmacies</td>
<td>88</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>1,608</td>
<td>100</td>
</tr>
</tbody>
</table>

Source: Chartrand, 2012.

9. Banners are defined as, among other things, independent pharmacies affiliated with a central office to which they pay fees for the right to use a recognized name (such as Uniprix) and to participate in centralized buying, marketing and professional services. These pharmacies are independently managed and the owners retain a high level of autonomy in the areas of local marketing and professional services (Bussières, 2012).

10. Franchises, such as Jean Coutu or Pharmaprix, are defined as a long-term business and contractual relationship between two legally independent pharmacies whereby one party (franchisor) grants the other (franchisee) the right to do business in a specific way, developed by the franchisor, in a given territory, according to uniform, pre-defined standards (management, business, professional, etc.) under a given trademark or name, for a limited time in exchange for a fee (Bussières, 2012).

11. Chains employ pharmacy managers, who are salaried employees of head office. Head office directs all marketing, merchandising, buying and professional programs. A pharmacy chain consists of at least five pharmacies (e.g. Pharma Plus) (Bussières, 2012).
In their professional activities, pharmacists must meet certain legislative and regulatory requirements. As regards conduct, the Ordre des pharmaciens [Order of Pharmacists] ensures that pharmacists comply with the Code of Ethics of Pharmacists. In their professional practice, pharmacists must encourage optimal medication use. Under the Code, which provides a framework for their professional activities, pharmacists must always preserve their independence and impartiality and avoid conflicts of interest. Owner-pharmacists must not pay, offer to pay or undertake to pay a benefit to any person in relation to the practice of their profession.

When purchasing generic drugs on the QPDIP List of Medications, a pharmacy can obtain professional allowances (discounts) of up to 15% of the value of its purchases. The purposes of such allowances are stipulated by regulation. Pharmacies must ensure that these allowances are applied only to activities permitted by the Pharmacy Act or risk prosecution by the government (Bélair-Cirino, 2011). As such, they must keep a record of all allowances and benefits received. RAMQ may demand reimbursement from any pharmacy that received professional allowances or benefits not authorized by regulation (Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications).

Accordingly, professional allowances from the sale of generic drugs on the QPDIP List of Medications allow pharmacies to offer additional services to their clienteles (e.g. diabetes, blood pressure and cholesterol management, equipment purchases to speed up the delivery of pharmaceutical services, training programs and activities, professional services aimed at optimizing medication use, for example, support with medication adherence and management). The following pharmaceutical services offered to QPPDIP beneficiaries are:

- Filling a prescription
- Refusing to fill a prescription
- Providing a pharmaceutical opinion
- Providing a hospital with the medication profile of a patient admitted through Emergency

Of these four services, only the first three are covered by the QPPDIP (Regulation respecting the basic prescription drug plan) and the rates associated with these services were set by regulation following an agreement initiated by the Minister of Health and Social Services with the Association québécoise des pharmaciens propriétaires (AQPP) (MSSS, 2012; Quebec, 1996). The compensation for pharmaceutical services rendered to QPPDIP beneficiaries consists mainly of fees for filling prescriptions. The cost of these services varies with the annual number of prescriptions filled by the pharmacy, as shown in Table 2.

---

12. The Pharmacy Act and some of its regulations as well as the Act respecting prescription drug insurance and one of its regulations (Quebec, 1996 and 1973).
13. Pharmacists’s fees for providing hospitals with medication profiles of QPPDIP beneficiaries admitted to emergency are covered by a budget other than the QPPDIP’s.
Table 2
Basic fee per pharmaceutical service covered by the QPPDIP, 2011

<table>
<thead>
<tr>
<th></th>
<th>Basic Fee</th>
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<tbody>
<tr>
<td>Filling a new prescription</td>
<td></td>
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<tr>
<td>- Up to 44,500 prescriptions/year</td>
<td>$9.00</td>
</tr>
<tr>
<td>- Over 44,500 prescriptions/year</td>
<td>$8.42</td>
</tr>
<tr>
<td>Filling a renewal</td>
<td></td>
</tr>
<tr>
<td>- Up to 44,500 prescriptions/year</td>
<td>$8.63</td>
</tr>
<tr>
<td>- Over 44,500 prescriptions/year</td>
<td>$8.07</td>
</tr>
<tr>
<td>Pharmaceutical opinion</td>
<td>$19.07</td>
</tr>
<tr>
<td>Refusing to fill a prescription</td>
<td>$8.63</td>
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Since the implementation of the QPDIP, the cost of pharmacists’ professional services has accounted for 22.3% to 27.1% of the QPPDIP’s gross costs (fees and medications). From 1996 to 2011, the cost of services kept pace with the QPDIP’s gross costs, growing at an annual rate of 10.1% and 10.7% respectively. However, from 2006 to 2011, the cost of these services rose faster (8.1%) than the QPPDIP’s gross costs (4.6%) (Table 3).
Table 3
Change in the cost of pharmacists’ professional services delivered to QPPDIP beneficiaries in relation to the QPPDIP’s gross costs,\(^a\) for 1997, 2002, 2006 and 2011, in millions of Canadian dollars and in %

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<thead>
<tr>
<th></th>
<th>Cost of Pharmacists’ Professional Services</th>
<th>Cost of Professional Services as a Percentage of QPPDIP’s Gross Costs</th>
<th>QPPDIP’s Gross Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997</td>
<td>$300.4</td>
<td>27.1%</td>
<td>$1,110.0</td>
</tr>
<tr>
<td>2002</td>
<td>$530.6</td>
<td>23.0%</td>
<td>$2,305.6</td>
</tr>
<tr>
<td>2006</td>
<td>$701.8</td>
<td>22.3%</td>
<td>$3,143.0</td>
</tr>
<tr>
<td>2011</td>
<td>$1,036.1</td>
<td>26.3%</td>
<td>$3,933.2</td>
</tr>
<tr>
<td><strong>Average annual change 1996-2011</strong></td>
<td><strong>10.1%</strong></td>
<td>-</td>
<td><strong>10.7%</strong></td>
</tr>
<tr>
<td><strong>Average annual change 2006-2011</strong></td>
<td><strong>8.1%</strong></td>
<td>-</td>
<td><strong>4.6%</strong></td>
</tr>
</tbody>
</table>

\(^a\) QPPDIP’s gross cost = total cost of medication (including the costs of medication for exception patients program) and the costs of pharmacists’ professional services.

Source: RAMQ, 2012b.

Amendments made to the *Pharmacy Act* in 2002 made some changes to the activities pharmacists can exercise and introduced the notions of determining and ensuring proper medication use. While pharmacists must fill prescriptions according to doctors’ instructions, they can substitute generics unless instructed to the contrary by the prescriber (Quebec, 1973). Under the legislative provision on substituting a generic for a prescribed medication, the practice is not obligatory but rather a right that pharmacists enjoy, provided they fulfill certain conditions (Gagné, 2010).

Because of this right, community pharmacies play a pivotal role in the competition between generic drug manufacturers. When pharmacists fill prescriptions, they have the right to replace brand name drugs with their generic equivalents, so long as they are considered interchangeable. This means they get to choose which generic version to give the patient. To keep inventory costs down, it is in the pharmacist’s interest to stock as few generic versions of a brand name drug as possible, perhaps even just one. Since bioequivalent generics are interchangeable, the goal of drug manufacturers is to sell as many of their versions as possible or to make sure their generics are stocked by as many community pharmacies as possible.

The generic industry’s business model is very much shaped by generic substitution. Generic manufacturers and suppliers compete fiercely for the community pharmacy market, on which they focus most of their marketing efforts (BCC, 2007). Until 2007, when they became professional allowances regulated and capped by the MSSS, the discounts offered by generic manufacturers provided a major source of funding for
community pharmacies (CBC, 2007), some reaching as much as 80% of the price of the generic. These sizeable discounts on the invoiced price helped pharmacies boost their bottom line, which in turn encouraged them to offer generics.

However, these discounts were not reflected in the price paid by QPPDIP beneficiaries or in the amount reimbursed by the third-party payer (RAMQ) since the generic medications were not being sold for less than the amounts appearing on the QPDIP List of Medications. Since the MSSS is a major third-party payer of generic drugs, it became concerned about these business practices in which generic manufacturers were charging community pharmacies net prices well below the amounts reimbursed by the public third-party payer and by QPPDIP beneficiaries. These discounts, which made the pharmacies a captive market for drug manufacturers, were not reducing the price of generics in Quebec and furthermore, were penalizing third-party payers and drug plan beneficiaries.

Since 2007, generic manufacturers have had to comply with standards and regulations applicable to their marketing activities (Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications). As such, professional allowances must not exceed 15%\(^{14}\) of total sales of the generic drugs on the QPDIP List of Medications to a community pharmacy in Quebec over a given period. Manufacturers must also agree to send RAMQ an annual report detailing the cost reductions in the form of discounts, rebates, premiums, gratuities, goods, services or any other benefit, other than the 2% discount for prompt invoice payment, paid directly or indirectly to each community pharmacy in Quebec. The report must also state the value of all the sales of generic drugs on the List of Medications sold to banners or pharmacy chains. This pertains to direct sales to community pharmacies as well as indirect sales by way of wholesalers or distributors, under the QPDIP.

\(^{14}\) Rate in effect since April 1, 2012.
Generic Drug Pricing Policy in Quebec

Generic drug prices

Expenditures associated with generic drugs covered by drug plans are essentially determined by the price of the generic medication and the quantities used. Many studies in the last decade have shown that greater use of generics could reduce the total cost of prescription drugs. These studies clearly show that increasing generic drug use could help better control prescription drug expenditures. In this context, the price of generics plays a key, complementary and essential role.

Thus, many drug plans would like to see increased use of fairly and reasonably priced generics. This section compares the prices of generic drugs in Canada from two perspectives. First, they are compared with those of other industrialized countries. Then, the generic prices in Canada’s provinces are weighted based on the average generic price in various industrialized countries.

An international comparison\(^\text{15}\) of generic drug prices\(^\text{16}\) reveals that with the exception of Switzerland, Canadian prices are much higher than their comparable foreign counterparts. It also reveals significant variations among countries in the average foreign-to-Canadian price ratios. The countries with the greatest difference in price vis-à-vis Canada are Sweden and the U.K., where generic prices are estimated, respectively, at 42% and 54% of Canadian prices. Excluding Switzerland, the country whose pricing structure most resembles Canada’s, is France, at 73% of Canadian prices. Lastly, the ratio for Canadian and U.S. drug prices shows the latter at 57% of Canadian prices (Table 4).

Table 4
Average foreign-to-Canadian generic price ratios\(^a\), by bilateral comparator, 2008

<table>
<thead>
<tr>
<th></th>
<th>France</th>
<th>Germany</th>
<th>Italy</th>
<th>Sweden</th>
<th>Switzerland</th>
<th>United Kingdom</th>
<th>United States</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average price ratio</td>
<td>0.73</td>
<td>0.62</td>
<td>0.7</td>
<td>0.42</td>
<td>1.12</td>
<td>0.54</td>
<td>0.57</td>
</tr>
<tr>
<td>Number of drugs(^b)</td>
<td>82</td>
<td>101</td>
<td>75</td>
<td>67</td>
<td>67</td>
<td>94</td>
<td>96</td>
</tr>
</tbody>
</table>

a. A ratio below 1 means that Canadian prices are higher than those in the comparator country. For example, the average price in France is 73% of the Canadian price.
b. Number of drugs concerned when each ratio was calculated.

Source: CEPMB, 2011.

At the provincial level, with the exception of Quebec and Newfoundland-Labrador,\(^\text{17}\) the two provinces excluded from the study, the figures compiled for each of the other eight provinces clearly show that generic prices in their respective public drug plans are much higher than those in the comparator countries (Table 5). For example, in 2008, their

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15. Bilateral comparisons of prices in seven comparable foreign countries (Germany, United States, France, Italy, United Kingdom, Sweden and Switzerland) in relation to Canadian prices (CEPMB, 2011).
16. Price data derived from direct sales to pharmacies and indirect sales through wholesalers. Discounts and other forms of price reductions were not taken into account in the selling price (CEPMB, 2011).
17. The PMPRB’s estimates also exclude data from the territories.
foreign mean and median prices were 32% and 40% less than the reimbursed prices of the eight Canadian provinces. The mean and median prices of the comparator countries were 25% and 34% less than these of the Ontario public plan.

Given that Quebec typically models its generic pricing policy after Ontario’s, the same general observation can be made about generic drug prices reimbursed by the QPPDIP.

Table 5
Average foreign[^a]-to-Canadian price ratio[^b], mean and median foreign prices, by provincial public drug plan, 2008

<table>
<thead>
<tr>
<th></th>
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<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>0.75</td>
<td>0.69</td>
<td>0.63</td>
<td>0.56</td>
<td>0.6</td>
<td>0.63</td>
<td>0.65</td>
<td>0.52</td>
<td>0.68</td>
</tr>
<tr>
<td>Median</td>
<td>0.66</td>
<td>0.59</td>
<td>0.55</td>
<td>0.51</td>
<td>0.52</td>
<td>0.54</td>
<td>0.57</td>
<td>0.44</td>
<td>0.60</td>
</tr>
</tbody>
</table>

[^a]: Germany, United States, France, Italy, United Kingdom, Sweden and Switzerland.
[^b]: A ratio below 1 means that foreign prices are lower than those in the comparator province. For example, an average foreign-to-Ontario price ratio of .75 means that average foreign prices are, on average, 75% of the Ontario prices.
[^c]: National data represent the total results for the eight provinces analyzed.

Source: CEPMB, 2011.

Despite provincial policies framing the prices of generics reimbursed by public drug plans, provincial plan prices are still higher than those in comparable countries (CEPMB 2011 and 2010). The higher prices paid by both provincial plan beneficiaries and third-party payers suggest a suboptimal allocation of resources.

In Quebec, changes made to the province’s drug policies since 2007 (decrease in generic prices, capped professional allowances, a framework for pharmacists’ fees, etc.) have created a situation with important implications for payers of reimbursed medications, i.e. drug plan beneficiaries and third-party payers (private group plans and RAMQ). These changes have, over time, altered the competitive environment of the generic industry and caused pharmacies to change their business models.

The resulting market dynamics have led to complex and inefficient distribution and supply channels in that the benefits do not flow to those who assume the costs, i.e. beneficiaries and third-party payers. This is a highly problematic situation that raises questions on several fronts, including pricing methods for generics, transparency in the prescription price components, pharmacists’ professional autonomy, and equal, fair access to reimbursed drugs. However, of all these, the most fundamental for the QPDIP is the question of setting fair and reasonable prices for generics. This could prompt a reflection that could lead to new pricing policies for generics and potential adaptation to Quebec’s legislative and regulatory framework.
Generic pricing methods

What is the best mechanism for setting generic drug prices? Different countries take very different approaches, and achieve very different outcomes.

Canada’s “arbitrary ratio” system of setting generic drug prices

In Canada, generic prices are normally set at some percentage of the brand price. This is economically incoherent, since the percentage is chosen arbitrarily and is clearly not related to the cost of producing a generic drug. For many drugs, the regulated price is far above the cost of production and distribution. For other drugs, the regulated price is too low, and so the manufacturers have sought special exemptions, based on manufacturing cost, to allow them to price higher. In effect, for those products, provinces are using a kind of cost-of-service regulation, of the sort typically reserved for public utilities.

Recently, dissatisfaction with the prices achieved by this arbitrary approach led most of the provinces to propose reforms to obtain lower prices. Initially, the Council of the Federation proposed a “national competitive bidding process” (tendering) (Conseil de la fédération, 2012). However, after consultation, the Council decided only to drop the reimbursement rate for six generic drugs to 18% of the brand price. This new price would be in effect by April 1, 2013 (Conseil de la fédération, 2013b). Alberta announced in its last budget that it would reduce the price of all generics to 18% of the brand price as of May 1, 2013.

No explanation was provided for why these six drugs were chosen, or why 18% was the appropriate price. In effect, the policy of arbitrary price settings is now arbitrary and capricious, with political decisions differentially determining prices for competitively provided goods. Operating in this manner can lead to a multitude of exceptions, particularly if the manufacturer claims that its production costs are higher than the maximum authorized price. The provinces must implement a mechanism to resolve this issue, where it arises.

When the reimbursement price is above the costs of production and distribution, the difference, or “margin,” accrues to pharmacies and generic manufacturers. (The portion accruing to pharmacies is called the “rebate” or “professional allowance.”) The size of rebates is determined by the degree of competition between different generic manufacturers for the pharmacy’s business. If the competition between different generics for the pharmacy’s business is particularly fierce, then the pharmacy captures most of the margin.

A sensible policy must have prices related to costs. In a typical competitive market, prices will be related to costs as firms compete against each other for business. However, in pharmaceuticals, even if manufacturers compete, retailers do not, since consumers are
so well covered by insurance. This means that retail prices are inflated and not responsive to costs.

Quebec’s current system of generic reimbursement setting has two components. Prices are set at the lower of either 1) 60% or 54% of the brand price, or 2) the lowest price afforded to any other public plan in Canada. Typically, the QPPDIP price is determined by Ontario’s rules, under which prices are equal to 25% of the brand price for most generic drugs and equal to 20% for a small selection of generics. Regardless of whether the QPPDIP pays the Ontario price, or the price determined by its 60-54 rule, generic prices are set at some fixed fraction of the price of the branded drug.

An important feature of Quebec’s system is that rebates paid by generic drug companies to pharmacies are limited to 15% of the invoiced amount for all sales of generics listed in the QPDIP. The professional allowances don’t change the price paid by the drug plan; it only moves margins between the pharmacies and manufacturers. Presumably, restrictions on professional allowances are intended to ensure that any benefits from competition between manufacturers are passed on to the payer. However, in practice, prices have not fallen because of this restriction, so there seems little point in it. If the goal is to control the amount paid by the payer, it is clear that the only reasonable approach is to directly control the reimbursable price, rather than proxies such as rebates and professional allowances. The mechanisms described below are all targeted at the final price, and as such do not require that the drug plan regulate transactions between manufacturers and pharmacies.

Approaches used in other countries

The arbitrary ratio system is but one of the mechanisms that could be used. Other countries use variants of the “descending price,” “benchmarking” and “tendering” approaches. With benchmarking, the drug plan computes the average cost per reimbursable drug based on the pharmacy’s acquisition cost. With tendering, the purchaser (public or private plans) buys its medications, for a set period of time, from the drug manufacturer that offers the best price. With the descending price method, prices are set as a percentage of the brand price, which varies depending on the number of manufacturers on the market.

These approaches lead to different outcomes. This can be illustrated by comparing the reimbursement price for a commonly prescribed drug, simvastatin, in jurisdictions that use different methods to set generic drug prices. The data, arranged in Table 6, indicates that prices in Quebec and Ontario are relatively high, but much less than the price paid in Australia, a jurisdiction that uses the benchmarking approach. Evidently, the manner in which generic drugs are procured is but one of the factors affecting prices since prices paid in England (or more precisely the UK National Health Service) are much lower than

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18 Benchmarking is also sometimes called “yardstick regulation” and the early theory was developed by Andrei Schleifer (Schleifer, 1985).
prices paid in Australia, yet both use benchmarking. Prices are lowest with the tendering system used in New Zealand and some insurers in the Netherlands. The descending price approach generates prices that also vary across countries, with prices being much lower in Austria than in Estonia.

Table 6
Prices paid for 40mg simvastatin tablets, by public drug plans operating in a variety of different jurisdictions.

<table>
<thead>
<tr>
<th>System</th>
<th>Jurisdiction</th>
<th>Price (C$) per pill of simvastatin 40mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arbitrary ratio</td>
<td>Quebec and Ontario</td>
<td>0.62</td>
</tr>
<tr>
<td>Descending price</td>
<td>Austria</td>
<td>0.28</td>
</tr>
<tr>
<td></td>
<td>Estonia</td>
<td>0.72</td>
</tr>
<tr>
<td></td>
<td>Portugal</td>
<td>Not available generically</td>
</tr>
<tr>
<td>Benchmarking</td>
<td>Australia</td>
<td>0.80</td>
</tr>
<tr>
<td></td>
<td>England</td>
<td>0.07</td>
</tr>
<tr>
<td>Tendering</td>
<td>Netherlands</td>
<td>0.04</td>
</tr>
<tr>
<td></td>
<td>New Zealand</td>
<td>0.03</td>
</tr>
</tbody>
</table>


Goals

The choice of generic drug procurement policy should be guided by the following objectives.

*Low prices*

A chief goal for generic drug pricing policy is obtaining low prices for the payer. Low price, however, is not the only objective, given that there are considerable price differences between jurisdictions for the same drugs. Evidently, some jurisdictions are willing to pay higher prices to achieve other goals.

*Reliability of Supply*

Most drugs need to be available to patients in a timely manner. This is true of drugs taken over a long time for a chronic condition, and of acute care drugs used temporarily. This implies that for most drugs, security of supply is a high priority.

*Quality of products*

It is important that generic drugs, like other drugs, be of the expected quality.

*Limiting Discretion*

It is highly desirable to create a pricing system that limits discretion, or decision-making, by regulatory authorities. There are many reasons for this. Discretion creates
opportunities for lobbying by firms, and in extreme cases, even abuse by regulators. Even without abuse, discretion is costly because decisions must be made, often in a controversial environment. Such decisions need to be rationalized and documented in order to show the absence of abuse. Decisions that are based on unclear reasoning are also vulnerable to litigation by firms that feel disappointed by the outcome. Litigation is already extremely common in the drug industry. Since regulators have limited time and resources, there are real costs from having to make and justify such decisions; there are also likely to be delays. Discretion also creates uncertainty for industry, which may have difficulty in predicting the outcome of the decision-making process. Uncertainty of this sort increases financial risks, and in turn causes investors to demand higher returns in recognition of the regulatory risk.

In summary, discretion creates many types of costs: lobbying, decision-making effort, regulatory delay, and uncertainty and related costs. Discretion can also create political costs, since the politicians that are lobbied by industry may then provide politically motivated direction to bureaucrats. This has the effect of undermining the entire structure of government.

Despite the many undesirable features of discretion in regulatory decision-making, there are many situations in which it is unavoidable, because no simple rule can be implemented. However, when a simple rule that can be implemented and enforced is available, it is highly desirable to use it. Simplicity and transparency are, however, critical features of a good rule: a lack of either will tend to create the opportunity for discretion and its associated problems.

**Earliest legal competition**

It is easy, when focusing on the outcome of generic competition in drug markets, to lose sight of the fact that the time of generic entry is not typically fixed, and this in turn means that a good system should encourage the earliest legal generic competition, since generic entry creates large savings, even if the generic entrants do not price at the lowest possible levels. While provinces do not directly control entry timing, they can, as we describe below, create incentives that encourage or discourage generic entry.

Generic manufacturers can go to court to challenge any patent, arguing that it has expired or that there is no infringement. Legal challenges by generic drug companies to brand drug patents confer a spillover benefit to drug plans and consumers. That is, if the generic drug manufacturer is successful in litigation, lower priced generic drugs are available sooner than they would otherwise be. Generic firms incur the costs and risks of patent challenges, not as a public service, but in the pursuit of profits: Getting into the market before other firms normally results in a permanent increase in market share.

**High generic penetration**

Given fixed costs of entry, it is important for generic firms to be able to earn some profits on their investments. (In the language of economics, these profits are known as “quasi-rents.”). In general, to achieve a given level of profitability, there is a trade-off between
volume and margin: firms are willing to enter for small volumes only if there is a high margin, and are willing to enter large volume markets even if the margin is thin. This in turn suggests that one way to achieve thin generic margins is to have a high generic share of the total sales of a drug, since higher volumes enable thinner margins.

A high generic penetration rate is particularly desirable for payers if generic drugs are reimbursed at a price far below that of the brand.

**Supporting pharmacy services**

Pharmacy services are valuable and need to be remunerated, and the system under which retail prices for generic drugs is high, but wholesale prices are low, offers substantial support to pharmacies. Reimbursement for pharmacy services should be transparent and clearly based on the service delivered, since pharmacists are health professionals and should be paid as such. The system of professional allowances paid by generic firms to pharmacies is not transparent, since the insurer pays a higher price than in the absence of the allowance, whether or not any professional service is delivered.\(^{19}\) While this enables pharmacies to earn profits or to support the delivery of services not otherwise funded, the lack of transparency is troubling.

**Supporting Manufacturing**

Some jurisdictions have industrial policy considerations that affect their pricing policy. It is apparent that using pricing policy to support generic manufacturing employment is a sub-optimal way of increasing employment. Nevertheless, we acknowledge that industrial policy may be a factor considered by policy makers.

**Consumer Choice**

There are two aspects of consumer choice: pharmacy and manufacturer. Typically since generic drugs are bioequivalent, choice between manufacturers is likely to be of little importance. However, it could be relevant in rare cases where a consumer cannot tolerate the binding material or other inert substances used by a particular generic manufacturer. More important, consumers value pharmacy choice, since the location and characteristics of a given pharmacy may be better or worse than others. It is desirable to enable such choice between pharmacies, not least because service quality is likely to suffer if pharmacies do not have to be responsive to consumer preferences.

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\(^{19}\) Quebec has strict limits on professional allowances. While we are not claiming that any companies are explicitly violating the regulations, we believe that there are many ways of paying allowances, some of which may be technically legal. For example, Jean Coutu pharmacy chain has purchased a generic manufacturer Pro Doc: any transactions between the companies are not at arm’s length. Similarly, the Pharmaprix drug chain has a manufacturer in-house (Sanis). Another way of evading limits on allowances is to use extra-territorial opportunities. For example, since Pharmaprix is part of the Shoppers Drug Mart chain, it can effectively escape Quebec restrictions on allowances by making allowances tied only to sales made in unrestricted provinces, such as Alberta.
Mechanisms for determining the generic price

In this section, we describe the different mechanisms used to set generic prices in different countries. We begin with tendering, followed by benchmarking and ending with the descending price schedule, which is similar to the price-setting method currently used in Quebec.

**Tendering**

*Tendering* is a mechanism whereby a drug plan (or other purchaser) buys medicines exclusively, for a set period of time, from the *pharmaceutical* drug manufacturer that offers the best bid. Drug plan beneficiaries who wish to use an alternative product are normally required to cover the entire cost out of pocket. Because relatively few beneficiaries are willing to pay extra, pharmacies have no choice but to stock the product of the winning bidder. The prospect of selling a large volume of medicines, without the need to offer rebates to pharmacies, acts as an incentive for firms to bid aggressively for the contract.

Tendering has long been used to procure vaccines and drugs for hospital use; it is increasingly being used to procure generic drugs that are dispensed in community pharmacies. In the last decade, healthcare insurers in the Netherlands and sickness funds in Germany have initiated large-scale tenders to supply generic drugs for use outside of hospital. New Zealand has used tenders for its national public drug plan since 1996. The available evidence suggests that tendering has markedly reduced generic drug prices in these countries. Tendering has attracted considerable attention in Canada recently owing to the announcement by the provincial premiers to collaborate on tendering for several generic drugs.

Tendering for outpatient generic drugs has been used on a limited basis in Canada, but without much success. Since the 1970s, the Saskatchewan government has issued tenders to supply medicines for the entire province, but few generic firms have participated. One reason may be that firms that offer a low price in Saskatchewan are required to offer the same low price to the Quebec drug plan. Evidently, generic firms earn more by abandoning the relatively small Saskatchewan market, and selling at a relatively high price in the large Quebec market, than they do by selling at a low price in both markets (Hollis, 2010a, 2010b). As a result, relatively few manufacturers compete in the Saskatchewan tenders. Currently, the number of products being tendered has fallen to only three: two of the three are priced higher in Saskatchewan than in Quebec, as we

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20 Boonen and colleagues report that the use of tendering by a consortium of health insurers in the Netherlands reduced generic medicine prices by 76–93%. Kanavos (Kanavos, 2009) do not provide savings estimates, but suggest that the policy has lowered prices. New Zealand issued its first tender in 1996 for the product paracetamol, resulting in a 44 percent price reduction. In 1999, tenders were expanded to cover more products. The 2002-03 tender calls for bids for over 1000 items, and produced savings of about $23 million. Source: http://www.pharmac.govt.nz/patients/AboutPHARMAC/history. For evidence on the very low prices that New Zealand currently obtains for its drugs (Law, 2012).
show in Section 4. It appears that Saskatchewan has more or less abandoned its tendering system.

The Ontario Drug Benefit Program (ODB) also attempted, in 2008, to use tenders to procure four drugs (enalapril tablets, gabapentin, metformin and ranitidine tablets). The attempt was unsuccessful, however, as generic firms did not participate. This non-participation appears to be due to two factors. First, the ODB did not offer exclusive contracts to winning bidders. Instead, up to three firms – one brand and two generics – could potentially win. Generic firms would therefore be required to pay rebates to pharmacies in order to gain market share. Second, even had the ODB awarded a sole source contract, so that no rebates would have been required, generic firms may have been reluctant to participate given potential retaliation by pharmacy chains. The ODB market for these four drugs, while large, is only a small fraction of the total Canadian generic market for all drugs. Generic firms may have feared that the national pharmacy chains and banner operations (and other similar organizations with a national scope) would punish the firm that won the ODB contract by refusing to stock its product in the rest of Canada.

Several lessons can be drawn from the Canadian experience of tendering drugs for outpatient use. Generic drug companies are less likely to participate in a tender, the larger the penalties they face in generic markets not subject to the tender. There are two kinds of penalties from winning a tender: 1) a requirement that they sell at the same low price in other markets and 2) loss of sales in other markets, owing to retaliation from pharmacy chains. The size of the penalty depends on the size of the national generic market that is not procured via tendering.

The New Zealand, Netherlands and German experience with tendering multi-sourced drugs provides corroborating evidence. In these countries, a substantial share of the national generics market is procured via tender. Hence generic firms that participate in tenders in these countries do not face the same kind of penalties faced by the firms participating in the Saskatchewan and Ontario tenders. The EU experience also speaks to the importance of having a sufficient number of independent generic drug companies bidding, so that firms bid aggressively for the contract. According to Dylist and colleagues (Dylist, 2011), the German tender is open to generic companies from across the EU (it is unclear if this was also the case in the Dutch tenders). There also appears to be a large number of generic firms bidding on the tenders in New Zealand. Inspection of the identities of the sole source suppliers, listed on the formulary of Pharmac, the national drug plan, reveals that there are at least 8 independent firms participating in the tender.

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21 At the time of the tenders, the ODPD set generic drug reimbursement at 50% of the price of the reference brand drug. At this price, generic firms likely still offered rebates to compete for pharmacies.

22 Multi-sourced drugs is another way of identifying generics drugs.

23 Another possible reason is that pharmacies in these countries are not organized in ways that allow them to exert pressure on generic drug manufacturers that participate in these tenders. It is possible, for instance, that chain and banner pharmacies have a smaller share of the market in these countries than they do in Canada. Similarly, these manufacturers might not face constraints on their ability to price discriminate as manufacturers in Canada face given Quebec’s “most favored nation” rule.
Several of these are large international generic firms, including Apotex, Mylan and Dr. Reddy’s.

Tendering achieves low prices by creating a potentially lucrative reward – a sole source contract – to the firm that offers the lowest prices. Sole source contracts, however, can lead to shortages should the contractor face supply disruptions. An advantage of a system with several suppliers is that if one firm faces a manufacturing or distribution problem, others can fill the gap. A related issue is that once the term of the contract comes to an end, other suppliers may have ceased to produce the drug, or indeed may have ceased operations entirely, so that there are fewer firms bidding on the next tender. (Of course, if many firms exit the market, then tendering may result in relatively high prices and this may result in the re-entry of firms in the next bidding cycle. There may thus be some oscillation in prices.)

There is yet another supply issue. It might be difficult to tender the entire range of generic drugs in use. A relatively small number of generic drugs are routinely prescribed; these drugs include atorvastatin and amlodipine. At present, in Canada many generic firms supply these drugs. There are many generic drugs, however, that are not routinely prescribed and that have commensurately fewer suppliers. Three generic firms in Canada specialize in the full range of products – Apotex, Teva and Pharmascience. The firms with the next biggest product catalogs, which include Mylan and Pro-Doc, offer only about 2/3 the number of products compared to the “big three.” Many firms focus solely on the high volume drugs. The big three invest in large product catalogs as a means to compete for pharmacy business. The low volume drugs are not particularly profitable, but being able to offer pharmacies a full range of products (and provide “one stop shopping”) is. Tendering a contract to supply the full suite of generic products would leave only the big three in the running. Prices for the high volume drugs would be lower if the tender were restricted to these high volume drugs, as more firms could bid. But then the big three would be left to bid on contracts for the low volume drugs. It seems possible that should these drugs go to a competitive tender, one or two of these firms would drop out (unless they have other reasons to produce, such as for export markets). Then security of supply becomes an issue.

A common response to security of supply concerns is that even if there is only one manufacturer in Canada, other manufacturers globally could step in to fill the gap if needed. Unfortunately, other manufacturers may not be in a position to fill the gap in a timely manner. First, foreign manufacturers who are not selling in Canada are likely not to have a Notice of Compliance from Health Canada, and the process of obtaining a Notice of Compliance could take months. Second, Canadian standards for pharmaceuticals are that generic drugs use the same size, shape, and colour as the branded drug. This is not typical in other countries, so there is a requirement to have a special production run for Canada.

A remaining concern with sole source tendering is that having only one generic drug available on a drug plan formulary may be problematic for those drug plan beneficiaries who cannot tolerate that particular generic version because of its composition.
There is some evidence on the security of supply of tendered drugs. The recent disruption in the supply of dozens of parenteral drugs commonly used in hospital settings has focused attention on the procurement drugs for inpatient use. It appears that there was only one manufacturer (Sandoz) producing these drugs for the Canadian market. One possible reason that there was only one manufacturer is that hospitals acquire their drugs through group purchasing organizations (GPOs). GPOs are known to negotiate aggressively. Given this, and the relatively small size of the market, other firms may not have found it profitable to set up productive capacity for these specialized pharmaceuticals (Comité de travail sur les ruptures d'approvisionnement en médicaments, 2012; Born, Petch et Dhalla, 2012).

What is the evidence on the effect of tendering on the supply of conventional oral solid drugs? There have not been any reports of serious supply disruptions in the EU countries that use tendering. This could be due to the fact that tendering has been practiced there for only a few years, so that the longer-term effects have yet to be realized. Another possible reason that supply appears to be stable is that the tenders in Germany and the Netherlands do not encompass the entire national generics market so that there are likely alternative suppliers able to fill in any gaps. There are probably a large number of alternative suppliers owing to the EU’s mutual recognition system. All EU member states recognize the safety and efficacy review of the European Medicines Agency (EMEA). Once the EMEA approves a generic drug, it grants marketing authorisation for all markets within the European Union (European Generic Medicines Association, 2012).

The New Zealand tendering system has been in operation for longer – since 1996 – and there have been frequent supply disruptions in this jurisdiction. For the most part, shortages have been resolved through buying the branded product at a higher price.

Probably the most important problem created by tendering is that it is likely to undermine incentives for generic firms to challenge patents that would be found invalid or not infringed if challenged. Since it is costly for generic firms to launch such court cases, and for important drugs the costs are many millions of dollars with no guarantee of success, generic firms are unlikely to invest in such challenges without corresponding rewards. Tendering is problematic because it does not reward early entrants. Thus, the firm that invests in a successful court challenge may find that it is entirely excluded from the market that it enabled (Hollis, 2012). These problems could be addressed by setting a separate reward mechanism for successful generic patent challenges, similar to the 180-day exclusivity period that is used in the United States, but this mechanism has created substantial problems of its own, and leads to a temporary period of high prices.

Another defect of tendering is that it isn’t a comprehensive solution. Almost certainly, some drugs, at some times, would not be suitable for tendering. For example, tendering will not work if there is only one generic on the market. If there are only a few generics, one might expect relatively weak competition and resulting high prices.
For biosimilars, tendering also fails to offer a solution, since bioequivalence is not present for these products. In this circumstance, tendering creates a problem because it limits the choices of available products.

**Application to the QPPDIP**

Would tendering result in low prices in the Quebec public drug plan? While it is difficult to say definitively, we suspect that it would. We note that the factors that have limited participation by generic drug firms in the Saskatchewan and Ontario tenders are not as acute here. First, the other drug plans that apply most favored nation (MFN) rules, namely the provincial government plans in Manitoba and Newfoundland, are rather small so that the firm winning a Quebec tender would probably gain more from the tender than it would lose by offering the same low price to Manitoba and Newfoundland. Second, the size of rebates paid to pharmacy chains has been declining as each provincial drug plan, and private plans in Ontario, reduce generic drug reimbursement rates and/or make the payment of rebates illegal. Since the chains earn less rebates on the sale of generic drugs, one might expect their resistance to tendering to wane. We also note that the national pharmacy chains have a smaller share of the Quebec generic drug market than they do in the rest of Canada.

Tendering for the QPPDIP would be unlikely to create problems with reliability of supply, assuming that the tender was used only for appropriate drugs. The reason is that the QPPDIP comprises a small share of total sales volume in Canada, approximately 10%. Therefore, there would likely be multiple suppliers with NOCs operating in Canada for major drugs, even if the QPPDIP was using a tender mechanism. A suitable tender contract would require the winning firm to guarantee availability at the tendered price, and would make the winner responsible for any costs of the QPPDIP in buying product from other suppliers in case the winner failed to meet its supply obligations.

Not every product would be suitable for tendering. Tendering is not suitable in the following situations:

- Tendering a drug within 3-5 years following generic entry would inhibit generic entry into other drug markets
- Tendering products with fewer than 6 active suppliers in the Quebec market would typically lead to less competitive bids
- Tendering products with total QPPDIP sales of less than $10 million per annum would generate relatively small totals savings; these savings are likely less than the cost of administering the tender.

Another issue to consider is whether Quebec could face similar problems as those faced by Saskatchewan’s Standing Offer Contract (SOC) system, in which the savings have been very limited. The first observation is that since Quebec’s price matching laws have

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24 Manitoba and Newfoundland and Labrador have not enforced their most-favoured nation regulations.
been the primary barrier to the success of the Saskatchewan system, there is no obvious barrier to Quebec’s success. Second, one should consider whether other provinces would likely impose any kind of formal or informal price matching rules in response to a tender in Quebec. Indeed, both Manitoba and Newfoundland & Labrador do require price matching, but appear unable to enforce it. Other larger provinces such as BC should be able to enforce price-matching, but the history of BC prices compared to Ontario prices suggests that they would not do so. In general, the fact that there are large and persistent price differences between prices paid by the public plans must imply that price matching is not in effect across the Canadian provinces, with the exception of Quebec effectively matching Ontario prices.

**Benchmarking**

The general approach to benchmarking generic drugs is as follows: pharmacies report their drug acquisition cost to the drug plan, the drug plan computes the average of these costs and reimburses all pharmacies this average amount. Pharmacies that procure their drugs at a price higher than the average lose money on each prescription and thus have strong incentives to find less expensive sources of supply. Pharmacies that procure their drugs at a price less than the average get to keep the profit. The net result is that the reported drug acquisition costs should, over time, decline to the lowest possible level. Thus, even though the drug plan does not restrict reimbursement prices, this system gives pharmacies incentives to try to find low prices, which leads to low prices in the long run. This scheme, like the descending price schedule, is designed to replicate the prices of a competitive market, in a market that is otherwise non-competitive.

Benchmarking was for many years used by the BC provincial drug plan to set the dispensing fees paid to pharmacies for prescriptions dispensed to its beneficiaries. Pharmacies were free to set their own dispensing fees and reported these to the drug plan. The average of these reported fees became the amount paid by the BC drug plan. A unique feature of the BC scheme was the use of beneficiary cost sharing to stimulate additional price competition. At the time, BC covered 75% of the dispensing fee; the patient was responsible for the 25%. Patients therefore had some incentive to search out pharmacies with low dispensing fees. Some pharmacies (particularly those located in grocery stores) used low dispensing fees to attract patients. This had the effect of reducing the average dispensing fee and thus the dispensing fee paid by the BC drug plan.

For benchmarking to achieve low prices, pharmacies must truthfully report their costs to the drug plan. While most pharmacies will truthfully report, not all will. Drug plan monitoring and verification is therefore required. In the case of dispensing fees, monitoring is easy since dispensing fees are normally conspicuously displayed within the pharmacy. Moreover many chain pharmacies charge the same price. The same is not true for drug acquisition costs. The drug plan would need to inspect purchase records, and even then it is possible that the pharmacy would conceal discounts and rebates.


**Australia**

For many years, the national drug plan, the Pharmaceutical Benefits Scheme (PBS) priced most generic drugs at 87.5% of the brand price (Australian Government, 2010). Many brands would match the price, since the reduction was so small, and so generic volumes would also be quite small. Generics, competing against each other for the limited volume, would provide substantial rebates to pharmacies. The PBS did not benefit from these rebates.

The PBS has now put in place a system of benchmarking to set prices. Prices in each period are set based on the average reported net price at which pharmacies purchased drugs in the previous period. The average discounted selling price of a drug is monitored over the course of a 12 month period (typically October 1 – September 30) and then this price becomes the new “approved ex-manufacturer price” starting the following April 1 (National Authority of Medicines and Health Products, 2008). The system requires comprehensive reporting of all kinds of incentives, with the incentives to be fully valued, and includes a mechanism for apportioning the discounted amount when the incentives offered to pharmacies are global rather than product-specific (Australian Government, 2010).

Australia seems to have relatively slow uptake of generic drugs because there is no consumer financial incentive to consume generic drugs. This makes the generic volumes small and reduces competition. Australia also seems to have late generic entry typically.

The most likely reason for the high generic prices in Australia, however, is due to the nature of the benchmarking system. In the standard benchmarking system, the reimbursed price can increase or decrease, based on the reported costs. In the Australian system, price increases are restricted. This makes pharmacies less willing to report low prices, given that once the reimbursement price is reduced, it cannot subsequently increase.

The 18-month cycle of pricing means that following generic entry, there is a long delay before prices fall meaningfully. (Initially there is a 16% price reduction.) While in principle this creates an incentive for generic challenges, pharmacies will capture most of the benefits. However, the flow of rebates to the pharmacies depends largely on the rate of new generic drugs: this is clearly an unreliable stream of revenues, so it can’t finance a steady provision of services.

**England and Wales**

The National Health Service (NHS) has a highly regulated system in which average net prices are measured quarterly (Department of Health, 2010). Prices are reported to the NHS within 30 days of the end of the quarter, and NHS reimbursement prices adjust in the following quarter. The system operates within a “voluntary” agreement negotiated between the government and industry, under which the companies open their books to scrutiny by the Department of Health. This leads to a very lean industry, and one with relatively little manufacturing in England. The British Generic Manufacturing
Association claims that “Generic prices in the UK are the lowest in the developed world.” (BGMA, site Internet).

**Application to the QPPDIP**

In the UK, the benchmarking appears to generate very low prices in part because of more rapid price adjustment and because the price adjustment is not unidirectional. The slow price adjustment mechanism with a one-way ratchet in Australia appears to create substantial risks for manufacturers and pharmacies, leading to slower price reductions.

Benchmarking requires honest reporting. An integrated manufacturer/pharmacy with a substantial market share has no interest in honest reporting since the lower the price it reports, the lower the price it gets in the next period. Honesty cannot be enforced for integrated firms since there is no transaction price to report. This implies that integrated firms should not be included in the price determination mechanism, even if, as in Quebec, they constitute a large share of total sales. However, a similar problem arises even when considering large pharmacy chains generally: their incentives would be misrepresent prices upwards. The authority would also require an attribution mechanism such as is used in Australia to ensure that rebates paid were attributed to products appropriately.

How would such a system operate in conjunction with the fixed price systems in other provinces? Since individual firm prices would be confidential, manufacturers could continue to offer low prices to pharmacies, as they do now, in order to capture business. There would inevitably be some effects downstream. This system would effectively harness the market power of pharmacies in price reduction.

Since manufacturers can capture business by offering lower net prices than their competitors, this mechanism appears to preserve incentives for entry by efficient firms.

One of the undesirable aspects of this system is that it requires the government to obtain confidential commercial information (on net prices and allowances) in order to be implemented. In principle, this seems to be no worse than is required in terms of the current reporting requirements in Quebec. However, the accuracy of the information obtained would become much more important, and there would be incentives for firms to overstate prices. Auditing of data could be an issue and a substantial burden. Although this system requires extensive reporting of transaction prices and auditing, it is improbable that it would enhance transparency: the problem is that the transaction prices between pharmacies, wholesalers, and manufacturers is confidential and must remain so in order to induce honest reporting.

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25 Our assumption is that it is impossible to enforce « honest » reporting of prices by integrated firms.
Descending Price Schedule

The descending price schedule is an attempt to recreate the outcomes of competition, in an otherwise non-competitive retail pharmacy system. A descending price system has fixed price points, typically percentages of the brand price, which are lower the larger the number of generic entrants. The merit of this approach is that firms will enter as long as the price is greater than their expected average production costs; and entry will cease once the price with the next entrant falls below this level. This mimics the outcome that one would expect in a perfectly competitive market, which is characterized by prices equal to the marginal cost of production.

Aside from its effect on pricing, this system has many attractions. First, this system is universal in the sense that it can be applied to all drugs. Some systems, such as tendering, cannot be applied in every situation: for example, tendering cannot be used when the number of firms is too small, or immediately following generic entry. This means that the QPDIP would need another mechanism to determine pricing in situations where tendering was not applicable. The descending price mechanism can operate in situations with few generic producers (indeed, even if there is only one generic producer) or with many; immediately following generic entry and later too. No decisions are required to implement it.

Second, the descending price mechanism operates automatically. It does not require that the QPDIP exercise discretion over its operation. The pricing simply depends on the price established by the entry of the last producer. Non-universal systems such as tendering require decisions to be made about which drugs should be tendered and when and for how long.

Third, the descending price mechanism provides some rewards to early entrants. This is extremely important since it allows an automatic reward to the litigating generic, which is most likely to be an early entrant. In the absence of generic litigation, it is likely that many weak patents will not be challenged (Hollis, 2012). Entry order matters in generic drug markets, with early entrants establishing a market share advantage even if their pricing is identical to other firms. Thus, even if many firms enter the market, it is likely that the first entrant or entrants will have a market share advantage that will effectively create a reward for their early entry. Systems such as tendering create a perfectly level playing field for generics, so that there is no advantage based on entry order.

Fourth, like other alternative systems, the descending price schedule mechanism would not require the QPDIP to police the private transactions between manufacturers, wholesalers, and pharmacies. With a mechanism to reduce the final price effectively, there is no need to restrict or to monitor rebates and professional allowances.

We examine below the use of the descending price schedule in the public insurance systems of other jurisdictions.
**Estonia**
Estonia uses a system in which the first generic product must be priced at least 30% below the original. The next pharmaceutical to join the list must offer a price reduced by another 10%; and the next two pharmaceuticals must offer a price at least 5% lower. Each subsequent generic entrant must be priced lower than the prevailing generic price (Pudersell et autres, 2007).

**Austria**
Austria does not allow generic substitution at the pharmacy, so generic volumes are small. Spending on generics constitutes only 11% of the total pharmaceuticals market. Austria does, however, have a complex scheme of mandated price reductions following generic entry. The sequence of price reductions is roughly designed so that the first generic is priced at 52% of the brand. The second generic must offer a price no higher than 44%, and the third follower must offer a price no higher than 40% of the brand. Additional price reductions are very small for subsequent entrants. While the system works, the prices remain stubbornly high, in part because of the high permitted price ratios, even in cases of multiple entrants, and in part because the market volumes are too small to attract really robust competition (Gesundheit Österreich GmbH, Austria, 2010).

**Portugal**
Portugal has been experimenting with a descending price schedule for several years. Initially, the scheme required the first generic to offer a price no greater than 65% of the brand, with each subsequent generic to provide a further discount of 3% of the price of the lowest priced generic (National Authority of Medicines and Health Products, 2008). Thus should ten generic competitors enter, generic prices would be 50% of the brand price. With thirty generics, price would still be at about 27% of the brand. Evidently, this price schedule was too “flat” to deliver significant price reductions. More recently, the system has been modified so that the first generic is priced at no more than 50% of the brand; then each subsequent entering generic has to offer a price at least 5% below the price charged by the previous generic entrant.

**Norway: stepped pricing system**
Norway has a complicated system of fixed price reductions that depends on the time since the first generic entry and on the volume of sales (National Authority of Medicines and Health Products, 2008). In the first six months, the reimbursable price for the drug falls to 70%. Following 6 months, the price falls to either 45% or 25%, depending on the volume of generic sales. Then after one year, there are further price reductions for drugs with sufficiently large sales volume: for the largest volume drugs, reimbursement levels fall to 15%. There is no restriction on rebating or discounting, so pharmacists have an incentive to dispense the product with the lowest wholesale price.

In the Norwegian system, the generic reimbursement price depends not on the entry decisions of generic firms but instead on arbitrarily chosen function of time since first generic entry and generic sales volumes. As such it does not benefit from the primary attraction of the descending price approach, namely that firms will continue to enter as long as the reimbursement price exceeds marginal costs.
One of the features evident in the descending price systems observed in other countries is the lack of aggressiveness in the pricing schedule. Indeed, this resembles the implementation of the descending price mechanism in Quebec, in which the price falls from 60% of the brand price to 54% with two or more generics. To achieve larger price reductions, it would be necessary to force more rapid reductions in price upon entry by additional generic firms.

Application to the QPPDIP

The descending price schedule already operates in Quebec in a limited way, since the maximum price that may be charged for a generic drug is 60% if there is only one generic producer, and 54% if there are two or more generic producers of the product. For most products, the price-match with Ontario leads to yet lower prices, and so the 60/54% prices are not relevant. However, a more complete implementation of the descending price schedule is evidently feasible and would require little effort to implement. A reasonable descending price scheme would be one that uses a price scale that varies with the number of entrants. The descending price scale would “self-adjust” in that it would set generic prices as a proportion of the brand price, which would range from 50% to 2%. In so doing, the regulator could adapt it based on its objective. The price scale proposed in Table 7 provides an example of how the sliding scale method would apply to brand prices.

Table 7
Proposed descending price schedule

<table>
<thead>
<tr>
<th>Number of generic firms</th>
<th>Price ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>50%</td>
</tr>
<tr>
<td>2</td>
<td>25%</td>
</tr>
<tr>
<td>3</td>
<td>20%</td>
</tr>
<tr>
<td>4</td>
<td>15%</td>
</tr>
<tr>
<td>5</td>
<td>12%</td>
</tr>
<tr>
<td>6</td>
<td>10%</td>
</tr>
<tr>
<td>7</td>
<td>8%</td>
</tr>
<tr>
<td>8</td>
<td>6%</td>
</tr>
<tr>
<td>9</td>
<td>4%</td>
</tr>
<tr>
<td>10</td>
<td>2%</td>
</tr>
</tbody>
</table>

Would it generate low prices? The success of the descending price schedule would fundamentally depend on two things: getting the schedule approximately right, and getting enough firms to enter. We think that to get enough firms to enter, it would be
important to offer generics the ability to gain market share without restraints. In particular, generic firms should be allowed to pay rebates. This would even the playing field with the integrated pharmacies, such as Pharmaprix, which have their own generic drug lines. It would also enable firms that wanted to enter the opportunity to grant discounts large enough to attract customers.

Second, we believe that implementation of this system would require a time lag between entry and price reduction. Thus, the price drop from entry might occur only two months following entry of the firm. This would enable a new entrant to enter the market on the same terms as all existing players.

Third, when each firm enters, it should agree to be prepared to supply all the needs of the QPDIP at the predetermined prices. Firms that are not prepared to supply the market indefinitely should not be allowed to affect prices. For instance the reimbursement price should not be affected by the entry of the firm that intends to sell off some unwanted inventory and then exit the market. Firms that commit to supplying the QPDIP market but that are subsequently unable to would need to be penalized; moreover, the reimbursement price would need to be restored to a higher amount.

As an example, consider the following timeline. The first generic enters on January 1. The second generic enters on February 10. The third generic enters on April 15, and the fourth generic enters on May 20. The fourth generic announces that it cannot supply at the given price on November 1. Then price would follow a timeline according to the following table.

Table 8
Generic entry timeline

<table>
<thead>
<tr>
<th>Generic firm</th>
<th>Date of Entry or Exit</th>
<th>Date of price change</th>
<th>Price change to</th>
</tr>
</thead>
<tbody>
<tr>
<td>A enters</td>
<td>January 1</td>
<td>January 1</td>
<td>50%</td>
</tr>
<tr>
<td>B enters</td>
<td>February 10</td>
<td>April 10</td>
<td>25%</td>
</tr>
<tr>
<td>C enters</td>
<td>April 15</td>
<td>June 15</td>
<td>20%</td>
</tr>
<tr>
<td>D enters</td>
<td>May 20</td>
<td>July 20</td>
<td>15%</td>
</tr>
<tr>
<td>D exits</td>
<td>Nov 1</td>
<td>Nov 1</td>
<td>20%</td>
</tr>
</tbody>
</table>

One interesting issue is how the integrated pharmacies would work with this descending price mechanism. The integrated pharmacies are currently advantaged in that they, in effect, do not face a restriction on professional allowances. This works well for them in the current fixed price context. But with the descending price schedule there would be little appeal in introducing an in-house brand, since it would result in a lower price, and hence lower earnings. In particular, given no restrictions on rebates or professional allowances, there would be no incentive for the pharmacies to buy from their in-house brand.
An important question is whether pharmacies would boycott later entrants given that their entry depressed the reimbursement price and thus reduced the amount of rebate that could be paid. For instance, suppose that the price was set at 20% of the brand, with the pharmacies earning a rebate equal to half the price. When another generic enters, it reduces the price to 15% of the brand, and also reduces the rebates, perhaps by half. Pharmacies collectively might find it in their interest not to buy from a new generic, in order to deter excessive entry. However, the new player needs only commit to entry and then offer larger rebates than other firms in order to enter successfully, since individually each pharmacy will benefit from accepting larger rebates. Pharmacies also have a reason collectively to value additional entry: it increases competition and hence the size of potential allowances. In addition, if allowances continue to be strictly capped, pharmacies will be motivated to buy from new entrants.

Another important issue is how Quebec could implement the descending price schedule for existing drugs. In our view, the best approach would be to simply apply the mechanism with price reductions every three months, for all drugs that qualify. Thus, for all drugs with three or more generic versions, the QPDIP would solicit information from all participants on whether they were willing to reduce their selling price to 20% of the brand. If at least one firm were willing to do so, the reimbursement price would be reduced to 20%. Firms that had indicated that they were unwilling to reduce their price would be excluded from the market for at least the next six months. After another 3 months, a similar offer would be made to the remaining firms in the market, only if there were at least four firms in the market. If at least one firm was willing to accept a price reduction to 15%, the price would be reduced, with only the firms willing to accept the lower price eligible to participate in the market for the next six months. The same procedure would be followed for all drugs, repeatedly, until there was no additional willingness for existing firms to accept a lower price, or if the number of firms in the market was too low to justify further price reductions. At that point, the price would only fall when a new firm entered with the new lower price, following the standard price reduction schedule. One useful benefit of this approach is that it can be applied to all drugs, older or newer, regardless of the number of firms currently in the market.

Empirical evidence

Having described the advantages and disadvantages of the different approaches, we next assess how well they work in practice. In Table 9, we present reimbursement prices for the most important generic drugs paid by a number of different jurisdictions. We also estimate the likely prices achievable within the descending price schedule following the proposed descending price schedule in Table 7. We have chosen the top 10 generic drugs, ranked according to total spending by the QPPDIP in 2011.
Table 9
Prices paid for commonly prescribed generic drugs, for the QPPDIP and for other public drug plans, expressed as a percentage of the QPPDIP reimbursement price.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage form</th>
<th>Dosage strength (that is most frequently prescribed)</th>
<th>Prices paid for generic versions of the drug; international prices include $0.03/tablet cost.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>QPPDIP formulary</td>
</tr>
<tr>
<td>Amlodipine</td>
<td>immediate release</td>
<td>5</td>
<td>100%</td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>immediate release</td>
<td>10</td>
<td>100%</td>
</tr>
<tr>
<td>Citalopram</td>
<td>immediate release</td>
<td>20</td>
<td>100%</td>
</tr>
<tr>
<td>Metformin</td>
<td>immediate release</td>
<td>500</td>
<td>100%</td>
</tr>
<tr>
<td>Nifedipine</td>
<td>sustained release</td>
<td>60</td>
<td>100%</td>
</tr>
<tr>
<td>Olanzapine</td>
<td>immediate release</td>
<td>10</td>
<td>100%</td>
</tr>
<tr>
<td>Pantoprazole</td>
<td>enteric coated</td>
<td>40</td>
<td>100%</td>
</tr>
<tr>
<td>Risedronate</td>
<td>immediate release</td>
<td>35</td>
<td>100%</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>immediate release</td>
<td>20</td>
<td>100%</td>
</tr>
<tr>
<td>Venlafaxine</td>
<td>sustained release</td>
<td>75</td>
<td>100%</td>
</tr>
</tbody>
</table>

Notes:
- Spending data was obtained from the IMS Brogan Pharmastat Database.
- Except for the price of venlafaxine, the prices reimbursed in New Zealand include, under local regulations, $0.03 per tablet.
- Prices for most drugs were obtained during the month of October 2012. The prices for amlodipine, atorvastatin, venlafaxine were set at 18% of the price of the branded price.
- Missing values indicate that the drug was not paid for by the public drug plan.
- Spot exchange rates as of October 26, 2012 were used to convert foreign currency into Canadian dollars.
- Prices are expressed as a percentage of the price paid by the QPPDIP. For example, the Saskatchewan Formulary price for amlodipine is 37% more than the price paid by the QPPDIP.

Sources: Government of Saskatchewan, 2013; RAMQ, 2012b; NHS, 2012; Australian Government, site Internet; Pharmac, site Internet; Hauptverband, site Internet.
There are a number of observations to draw from a comparison of the prices in different jurisdictions. These largely mirror the observations drawn from the comparison of prices paid for simvastatin in Table 6.

First, with respect to tendering, New Zealand obtains the lowest prices, but Saskatchewan, which also uses tendering, has prices for tendered drugs that are higher than Quebec’s. Saskatchewan appears to be phasing out its Standing Offer Contract (tendering) program. Half of the drugs examined were never tendered under the program. Some of the drugs that were tendered are now procured by the standard approach, i.e., all generic drug versions of the drug are reimbursed at some fixed fraction of the branded drug price. Second, with respect to benchmarking, the UK has relatively low generic prices, and Australia has relatively high generic prices. Third, with respect to the descending price schedule, Austrian prices tend to be higher than those in Quebec, which is not surprising because the schedule prices in that country are relatively high and do not generally drive prices below 25% of the branded price.

What would it mean for Quebec if prices there were the same as those obtained by these other jurisdictions? We calculated savings that are achievable for the QPPDIP for each of the top ten drugs if Quebec achieved the same prices as other jurisdictions. These savings estimates are presented in Table 10. We also estimated the savings achievable under a descending price schedule. The details regarding calculations for the descending price schedule are provided in Appendix 1.
Table 10
Savings to the QPPDIP achievable at different generic drug reimbursement prices

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage form</th>
<th>QPPDIP spending on generics in 2011</th>
<th>Savings achievable at:</th>
<th>Descending price schedule</th>
</tr>
</thead>
<tbody>
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<td></td>
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<td>UK prices</td>
<td>Austrian prices</td>
</tr>
<tr>
<td>Amlodipine</td>
<td>immediate release</td>
<td>$36,000,000</td>
<td>$28,035,412</td>
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<td>Atorvastatin</td>
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<td>immediate release</td>
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<td>$11,778,372</td>
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<td>$(3,739,353)</td>
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<tr>
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<td>immediate release</td>
<td>$6,700,000</td>
<td>$5,404,981</td>
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<td>Simvastatin</td>
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<td>$15,000,000</td>
<td>$13,853,592</td>
<td>$13,272,600</td>
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<tr>
<td>Venlafaxine</td>
<td>sustained release</td>
<td>$17,000,000</td>
<td>$(15,992,769)</td>
<td>$(56,116,102)</td>
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<tr>
<td>Total cost to QPPDIP</td>
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<td>$195,500,000</td>
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Savings to QPPDIP ($):

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<th>UK prices</th>
<th>Austrian prices</th>
<th>Descending price schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>$115,488,224</td>
<td>$52,284,190</td>
<td>$(132,602,133)</td>
<td>$121,810,511</td>
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<tr>
<td>59%</td>
<td>27%</td>
<td>-68%</td>
<td>62%</td>
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a. Totals were rounded. Reductions in savings are indicated in parentheses.
Conclusion

The data in Table 10 shows the increase or decrease in drug expenditures based on the application of different generic pricing policies to the 10 medications reimbursed by the QPPDIP. As the table indicates, a descending price schedule based on the sliding price scale described in Table 7 would have generated the greatest savings, estimated at C$122 million or 62% of the QPPDIP’s annual expenditures on these medications. The generic prices obtained through New Zealand’s tendering process would have generated less savings, estimated at C$115 million, while benchmarking, as used in the UK, would have resulted in the least savings (C$52 million). Three of these four approaches would have saved the QPPDIP money in relation to the current approach.

Which approach should Quebec adopt?

We think that benchmarking requires too large an administrative oversight and is excessively intrusive. Furthermore, it is not clear that it is possible to obtain “honest” reporting of costs relevant only to Quebec in the framework of national pharmacy chains buying from national manufacturers. In these circumstances, it is too easy for firms to transfer rebates and allowances to other provinces. This leaves tendering and the descending price schedule.

Tendering would result in the largest potential savings, but it also has the largest risks. Savings potential is large because tendering delivers strong incentives for generic firms to reduce prices. First, the firm that wins the tender captures the entire QPDIP market. The large volumes and certainty of demand during the period of the tender allow it to benefit from economies of scale and efficient production planning. This results in lower costs of production and distribution. Second, tendering generates tougher competition: firms are competing for the entire market or nothing, and this helps them to sharpen their pencils and reduce their margin. Thus, tendering leads to lower costs and lower mark-ups. This makes it very potent for achieving the lowest possible cost.

But tendering does have risks. Forcing very tough competition can have the effect of weakening the industry and can, in the long run, result in weak competitors. Even more critically, tendering weakens the incentives of generic companies to challenge invalid patents, which could lead to substantial delays in the arrival of generic competition, leading to much higher costs. The risk in terms of competition and timing of generic competition largely depends on whether other provinces would themselves use tendering if Quebec used tendering. If Quebec were the only province to use tendering, then the incentives for litigation would be weakened but not eliminated. If all provinces tender, these incentives would be greatly reduced.

In terms of supply security, there are clear benefits from the redundancy of having multiple generic manufacturers supplying a market. This seems to imply that tendering could compromise supply security. However, if Quebec uses tendering while other provinces do not, or if other provinces engage in a separate tendering process, there could
still be multiple suppliers operating in Canada. The security of supply could be compromised, particularly for pharmacies in remote, sparsely populated areas.

Service quality in pharmacies could be somewhat reduced by tendering, relative to the alternatives. The reason is that with tendering, there is a single supplier who enjoys a monopoly position with respect to the pharmacies. Such a supplier need not offer superior convenience to pharmacies, and may in fact offer quite poor service. This could result in delays in supply to pharmacies and generally poor service to pharmacies, resulting in higher costs for pharmacies and potentially temporary unavailability of some drugs at some pharmacies. At the same time, tendering would result in zero professional allowances to pharmacies, which would reduce the profits of pharmacies. This would likely result in a reduction in the number of pharmacies and a reduction in consumer convenience and service quality to patients. It is not clear how large this effect would be.

Tendering is also not a universal solution: it will not work at all for some products where there is inadequate competition, and it will undermine the generic sector if applied too quickly following generic entry. Manufacturing employment is an important goal of governments, but we will not address it here except to indicate that the generic industry employs over 4,000 people in Quebec. Tendering would likely result in a loss of jobs with generic companies in Quebec, as outlined in (Hollis, 2012).

The descending price mechanism, while not achieving the same savings as tendering, avoids most of the latter’s risks and is relatively straightforward to implement. The descending price mechanism is a natural extension of the 60-54 pricing rule. This mechanism can be implemented without any confidential information, so all players can see exactly what the prices will be, given the number of firms in the market. This mechanism is universal: it can be applied immediately following generic entry and can be applied regardless of the number of generic manufacturers in the market. Thus, unlike tendering, there is no need to wait for some predetermined level of competition or for some predetermined time period for it to be applied.

The descending price schedule does not offer the same level of reward to firms that successfully litigate branded drug patents, but unlike tendering, it does offer some rewards. This approach would also preserve incentives for drug manufacturers to offer adequate levels of service to pharmacies.

Savings to the QPPDIP from the application of the descending price mechanism to the most commonly prescribed generic drugs would likely be substantial. Currently, there are around 20 different generic firms supplying these drugs. With the descending price mechanism, there would likely be fewer. However, even if there were just four producers, the price would drop to 15% of the brand price; this is lower than the 25% price currently being paid.

---

In summary, the QPDIP should adopt a descending price schedule approach for its generic drug pricing policy, which would be used in tandem with the “best price” rule applied by the provincial plans. This method of setting prices would generate substantial savings for the QPPDIP while shielding the government, industry stakeholders and QPPDIP beneficiaries from the downsides associated with tendering.
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## Appendix 1: Descending price schedule

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage form</th>
<th>Dosage strength that is most frequently prescribed</th>
<th>Number of generic producers</th>
<th>QPDIP formulary price</th>
<th>Ratio QPDIP formulary generic to brand price</th>
<th>Lowest possible price (reservation price)</th>
<th>Ratio reservation to QPDIP formulary brand price</th>
<th>Lowest feasible schedule price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amlodipine</td>
<td>immediate release</td>
<td>5</td>
<td>20</td>
<td>1.2990</td>
<td>0.2338</td>
<td>18%</td>
<td>0.05</td>
<td>4%</td>
</tr>
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<td></td>
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<td></td>
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<td>4%</td>
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<td></td>
<td></td>
<td>4%</td>
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<td>0.05</td>
<td>3%</td>
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<td></td>
<td>4%</td>
</tr>
<tr>
<td>Nifedipine</td>
<td>sustained release</td>
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<td>1</td>
<td>1.7100</td>
<td>0.9374</td>
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<td>0.37</td>
<td>21%</td>
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<td>7.0000</td>
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<td>3%</td>
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<td></td>
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<tr>
<td>Simvastatin</td>
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<td>20</td>
<td>20</td>
<td>2.4182</td>
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<td>2%</td>
</tr>
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<td>Venlafaxine</td>
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</table>
Notes:

- The descending price schedule considered here pays the following generic reimbursement prices (expressed as a fraction of the reference brand price): one generic on the market: 50%, two generics: 25%, three generics: 20%, four generics: 15%, five generics: 12%, six generics: 10%, seven generics: 8%, eight generics: 6%, nine generics: 4%, ten+ generics: 2%.

- With one exception, the prices paid in New Zealand (which include an additional three cents per unit to meet local regulatory requirements) were used as the lowest feasible prices that could be paid in Canada. The exception was the drug venlafaxine: the QPDIP formulary price was lower than the price paid in New Zealand. For this drug, the QPPDIP reimbursement price was used as the lowest feasible price.

- We assumed that generic firms would enter the market as long as 1) the QPDIP reimbursement price exceeded the lowest feasible price and 2) the number of firms expected to enter was less than the number of firms actually supplying the Quebec market. For most of the drugs examined here, the number of firms predicted to supply the market is less than the number of firms actually supplying the market. The exception was the drug nifedipine: there was only one generic on the market. As per the price schedule, the QPPDIP reimbursement price of this drug would be 50% of the branded drug price. (The nifedipine brand reimbursement price was obtained from the 2008 QPDIP formulary.)

- The key column in the table of Appendix1 is entitled “Ratio reservation to brand price.” This is the lowest feasible price, expressed as a share of the branded drug price. The lowest feasible price is generally the price paid by the New Zealand public plan. The lowest feasible schedule price is the price that the QPDIP would obtain under the descending price schedule. As an example, the lowest feasible price for atorvastatin is 3% of the brand price. Firms are assumed to enter the market until the reimbursement price is equal to or immediately above the lowest feasible price. The atorvastatin reimbursement price at which no additional generic firms would enter is 4%. This reimbursement price is the one in which nine firms enter the market. We ensured that there were in fact at least nine firms supplying the market. In the case of atorvastatin, 20 generic firms supply the market.

- Nifedipine is the one case in which the number of firms presently supplying the Quebec market acts as a binding constraint. The lowest feasible price is 21% of the brand price. This implies that two firms would enter the market, dropping the reimbursement price to 25% of the brand price. However, there is only one firm presently supplying the market, so that the QPPDIP would pay 50% of the brand price for this drug under this descending price schedule.

- The calculation of the savings estimate for the drug venlafaxine requires some explanation. We assume that the QPPDIP price is the lowest feasible price (since the international prices are all higher). Since we did not have a reasonable estimate for the firm reservation price, the savings estimate was removed.