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# Pharmaceutical Pricing and Reimbursement Policies in Canada

Valérie Paris, Elizabeth Docteur

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Pharmaceutical Pricing and Reimbursement Policies  
in Canada

Valérie Paris and Elizabeth Docteur

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PHARMACEUTICAL PRICING AND REIMBURSEMENT POLICIES IN CANADA

Valérie Paris and Elizabeth Docteur

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## ABSTRACT

This paper describes and assesses pharmaceutical pricing and reimbursement policies in Canada, considering them in the context of the broader policy and market environment in which they operate, and investigating their role in contributing to Canada's achievements in meeting a range of objectives relating to the pharmaceutical policy. The federal government regulates prices of patented pharmaceutical products with the objective of protecting consumers against excessive prices. Regulation has very likely been responsible for bringing Canada's prices for patented medicines roughly in line with European comparators. Prices of generic products, which are not regulated, are relatively high although high penetration of the Canadian market has been achieved. All Canadians have coverage for drugs provided in hospitals through a publicly financed scheme that furnishes hospital and physician services free of charge to patients. Drugs dispensed outside the hospital setting are not included among the insured benefits guaranteed by the Canadian Health Act. Consequently, two-thirds of the Canadian population, including most employees and their families, obtains such coverage through private health insurance, while most senior citizens, together with designated groups of vulnerable populations, are covered by provincial, territorial or federal plans. In most cases, patients share in the costs of reimbursed medicines through co-payments or co-insurance, sometimes after meeting a deductible. The lack of protection against the risk of catastrophic out-of-pocket spending for drugs remains an issue for a small part of the Canadian population, concentrated in the Atlantic Provinces. Reflecting these coverage and reimbursement arrangements, 54% of drug expenditures are financed by private insurances and households. Drug expenditures have been increasing very rapidly in recent years. Formulary management, now facilitated by a government initiative to undertake common drug reviews, and the promotion of generic substitution have been the main levers used by public plans to improve the efficiency of drug expenditures. Private plans have historically covered all medicines authorised for sale in Canada, although this is changing in light of cost pressure. Overall, new drugs are available in the Canadian market on a timely basis, but maintaining comprehensive availability and accessibility may be an emerging challenge.

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Keywords: Pharmaceutical policy; pricing and reimbursement; pharmaceutical market; Canada

## RESUME

Ce document décrit et évalue les politiques de prix et de remboursement des médicaments au Canada, en les situant dans le contexte politique et l'environnement de marché dans lesquels elles s'inscrivent ; et en observant leur rôle dans l'atteinte des objectifs relatifs à la politique pharmaceutique canadienne. Le gouvernement fédéral régule les prix des médicaments brevetés dans le but de protéger les consommateurs de prix excessifs. Cette régulation a très probablement eu pour effet d'amener les prix des médicaments brevetés canadiens au niveau des prix des pays européens auxquels le Canada se compare. Les prix des médicaments génériques, qui ne sont pas régulés, sont relativement élevés malgré une forte pénétration des génériques sur les marchés. Tous les Canadiens sont couverts pour les médicaments fournis à l'hôpital par un système public qui fournit gratuitement tous les services hospitaliers et médicaux. Les médicaments dispensés dans le secteur ambulatoire ne sont pas inclus dans le panier des services couverts au titre de la Loi Canadienne sur la santé. Par conséquent, deux tiers des Canadiens, dont la plupart des salariés et leurs familles, obtiennent une couverture médicament par les assurances privées, tandis que beaucoup de personnes âgées, ainsi que certains groupes vulnérables de la population, sont couverts par des plans publics provinciaux, territoriaux ou fédéraux. Dans la plupart des cas, les patients participent aux dépenses de médicaments remboursables selon diverses modalités (forfait, co-assurance), parfois assorties de franchises. Le manque de protection contre le risque de dépenses catastrophiques de médicament reste un problème pour une petite partie de la population canadienne, concentrée dans les provinces atlantiques. Reflétant l'ensemble de ces modalités de couverture et de remboursement, 54% des dépenses de médicaments sont financées par les assurances privées et les ménages. Les dépenses de médicaments ont augmenté rapidement au cours des dernières années. Le management des listes de médicaments remboursables, à présent facilité par une initiative gouvernementale pour entreprendre une évaluation centralisée des médicaments, et la promotion de la substitution par les génériques, ont été les principaux leviers utilisés par les plans publics pour améliorer l'efficacité des dépenses de médicament. Les plans privés couvraient, par le passé, tous les médicaments autorisés à la vente au Canada, mais ceci est en train de changer sous la pression des coûts. Dans l'ensemble, les nouveaux médicaments sont disponibles sur le marché Canadien dans des délais satisfaisants mais le maintien de bonnes conditions de disponibilité et d'accessibilité financière pourrait devenir un défi.

Codes JEL : I18, I11

Mots-clés : Politique du médicament ; prix et remboursement ; marché pharmaceutique ; Canada

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## INTRODUCTION

1. Successive legislations enacted at the federal level permitted the provision of universal coverage for hospital care (1957) and for physician services (1966) to the Canadian population through federal and provincial cost-sharing. These two federal Acts were combined and updated in the *Canada Health Act* (1984) which sets forth conditions and criteria that must be satisfied by provincial and territorial health care plans in order for them to be eligible for federal funding. In this decentralized health system, provinces and territories are responsible for the management, organisation and delivery of hospital and physician services and may offer supplemental coverage for other medical goods and services, including prescription drugs furnished outside of the hospital, for all or part of their residents. The federal government currently co-finances health expenditures of provinces and territories through earmarked cash and tax transfers. Provincial and territorial governments raise other funds through taxation and determine the appropriate allocation of resources within the health system.
2. The regulation of the pharmaceutical sector rests on several levels. Federal regulation of the pharmaceutical sector focuses on two objectives: protecting the Canadian population against safety-related risks and protecting consumers against excessive patented drug prices. Policies pertaining to drug coverage have been developed and administered mainly under the authority of provinces and territories, while responsibility for ensuring appropriate use of drugs rests mostly with health professionals.
3. This report is the first in a series of case studies aimed at describing and analysing pharmaceutical policies used in selected OECD countries. These case studies are part of a broader OECD project on the impact of pharmaceutical pricing and reimbursement policies. The main objective of this paper is to describe and analyse policies at the federal and provincial/territorial level pertaining to the prices of pharmaceuticals in Canada, and, as far as possible, to assess their effects at the national level.
4. Since these policies cannot be considered in isolation from other policies and contextual elements, this paper also takes account of the main policies pertaining to the pharmaceutical sector in Canada and the characteristics of its pharmaceutical sector before offering an assessment as to how well policy goals are being achieved and what role pharmaceutical policies have played in this respect.

## 1. THE POLICY ENVIRONMENT

5. This section describes pharmaceutical pricing and reimbursement policies in Canada, as well as some of the most important related policies and practices concerning pharmaceuticals, including marketing approvals, coverage, policies to influence pharmaceutical use and policies intended to promote innovation in the pharmaceutical and other sectors.

### 1.1. Pharmaceutical product regulatory review procedures and outcomes

6. The pharmaceutical product approval process is an important determinant of key policy outcomes, including product availability, patient safety, health outcomes and manufacturer returns on investment in research and product development.

7. In accordance with the *Food and Drugs Act* and related regulations, Health Canada is responsible for regulating the safety, efficacy and quality of drug products. The Therapeutic Products Directorate of the Health Products and Food Branch (HPFB), a branch of the Department of Health (Health Canada), is in charge of reviewing new drugs for licensing and labelling.

8. Sponsors file market licensing applications and supporting documentation for proposed new products. Drugs are reviewed by HPFB in-house experts, who collaborate with outside experts to assess their safety, efficacy and quality. At the end of the review process, Health Canada may grant a marketing authorisation or “Notice of Compliance (NOC)”, which indicates that the drug under review has met its safety, efficacy and quality requirements.

9. Sponsors may ask for priority review for promising drugs used for life-threatening or severely debilitating conditions such as cancer, AIDS, or Parkinson’s disease, for which few or no other effective therapies are available on the market. In certain circumstances, conditional approval for marketing may be granted to expedite access to potentially life-saving drugs (with the same eligibility criteria as priority review drugs) under the Notice of Compliance with Conditions (NOC/c) policy. An NOC/c authorizes the manufacturer to market a drug on condition that the manufacturer undertakes additional studies to demonstrate the drug’s clinical benefit. Conditions associated with approval allow the HPFB to monitor the safety and effectiveness of the drug through enhanced post-market surveillance<sup>1</sup>.

10. An abbreviated procedure is used to assess generic products, mainly based on comparative bioavailability studies aimed at showing that the generic product is as safe and as effective as the brand-name product.

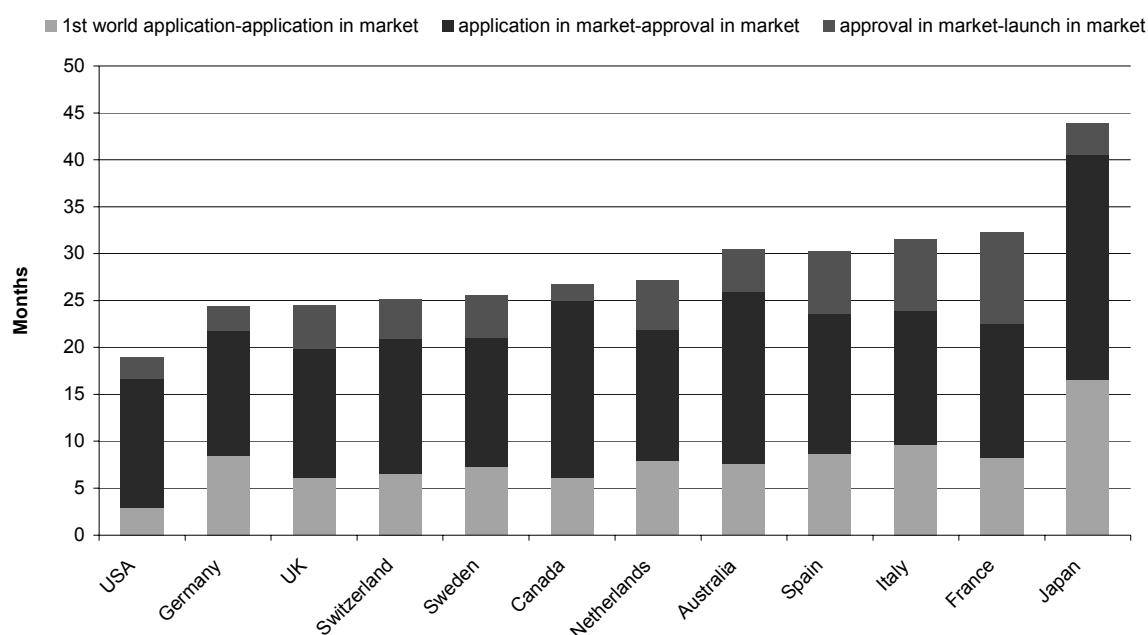
11. Canada has faced criticism for lengthy approval times. Comparative data from the pharmaceutical industry suggest that the average time from a manufacturer’s application to market

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1 Since 1999, 16 NOCs with conditions have been issued. Full NOCs have since been issued for three of these products. Obtaining further evidence of effectiveness or of side-effects can require a long period of time.

approval over the 1999-2003 period was notably longer in Canada than in 10 of 12 other OECD countries supplying data (Figure 1). Australia, at 18.2 months, was closest to Canada's 19-month average. The only country with longer average delays was Japan.

**Figure 1. Average delay between first launch in the world and launch in each country for drugs launched between 1999 and 2003**



Source: Pharmaceutical Industry Competitiveness Task Force, 2005, from Association of the British Pharmaceutical Industry calculations.

12. In 2003, Health Canada launched the Therapeutics Access Strategy, the major focus of which was improving the performance, efficiency and timeliness of the drug review process. Performance targets were set for review delays, ranging from 120 to 300 days, depending on the type of drug. As of August 2006, Health Canada eliminated the backlog in pharmaceuticals and has made progress in meeting internationally-comparable drug review targets for pharmaceuticals (Health Canada, 2006) and intends to meet them for biologics within the next year<sup>2</sup>. Consequently, average and median review times in Canada have declined significantly since 2003 (Health Canada, 2006, p. 18-19).

13. In addition to its responsibilities pertaining to drug marketing approval, Health Canada also monitors the safety, efficacy and quality of therapeutic products once they reach the market (See Box 1). Reports of suspected problems can be received from manufacturers, health care professionals and consumers, which Health Canada evaluates to determine appropriate action if a serious health risk is identified. Such actions can range from issuing warnings to the public and the health care community, to removing a product from the market.

14. Under authority of the federal *Food and Drugs Act*, decisions as to whether a drug is to be sold by prescription or over-the-counter (OTC) are based on the list of medicinal ingredients in Schedule F of the *Food and Drug Regulations*. Ingredients listed on Schedule F cannot be purchased without

2 Personal communication with Health Canada officials.

prescription. The Drug Schedule Status Committee determines the necessity for prescription status for medicinal ingredients on the basis of established and publicly available criteria. These criteria include, but are not limited to, concerns related to toxicity, pharmacological properties and therapeutic uses of the ingredients. Some prescription drugs, such as narcotics, are subject to further control pursuant to the *Controlled Drugs and Substances Act*. In 2006, about 20,750 human drugs are available in Canada, of which 6,400 are prescription-only medications<sup>3</sup>; 1,090 are “ethicals”, which do not need prescription but are generally prescribed by physicians; 8,429 are OTC drugs and 4,846 are in the category called Natural Health Products (includes vitamins, minerals, herbal products, and homeopathic medicines). Provinces may impose further restrictions on drug dispensing.

#### **Box 1. Drug safety monitoring and consumer protection**

Several databases used in drug safety monitoring are available on Health Canada's website. The Drug Product Database presents basic information on drug products (name, Drug Identification Number, prescription status). The Notice of Compliance database presents the list of drugs authorized to be marketed. The MedEffect Web site provides access to the latest advisories, warnings and recalls issued by Health Canada concerning therapeutic drugs as well as other marketed health products including natural health products and medical devices. Adverse reactions can be reported by individuals.

A new medication incident reporting and prevention system, now in the design stages, is intended to strengthen the capacity to report, analyse and manage medication incident data on a national basis, while mounting comprehensive prevention and education programs for healthcare practitioners. The system, known as the Canadian Medication Incident Reporting and Prevention System, relies on voluntary reports of incident data and is currently being phased in.

15. Health Canada also administers a Special Access Programme (SAP), which authorises the sale of drugs that have not been licensed in Canada, including drugs that are available in other countries or are still in development.<sup>4</sup> This program is reserved for patients with a serious or life-threatening disease, when alternatives have failed or are not available in the Canadian market. In 2005, the SAP received and processed approximately 30,000 requests. About 23,000 authorisations and 100-200 denials were issued. An additional 5,000-7,000 requests were returned because they were considered incomplete.

### **1.2. Pricing**

16. Prices of off-patent original products and generic products are not regulated in Canada. Since 1987, prices of patented medicines have been regulated at the federal level to ensure that they are not ‘excessive’.

#### **1.2.1. General objectives and scope of pricing regulation**

17. The Patented Medicine Prices Review Board (PMPRB) was created in 1987 through amendments to the *Patent Act*. At that time, price regulation of patented pharmaceuticals was accepted by the brand-name pharmaceutical industry in exchange for enhanced patent protection.<sup>5</sup> The PMPRB operates as an

3 Some of them are subject to further control under the Controlled Drugs and Substances Act.

4 On rare occasions, the system is used to facilitate access to drugs that have been approved for marketing in Canada, but have not been launched there by the manufacturer.

5 Brand-name manufacturers also publicly committed to increasing their Canadian R&D expenditures to 10% of the value of drug sales.

independent, quasi-judicial body empowered to enforce sanctions and impose price reductions for patented pharmaceutical products.

18. The PMPRB mandate is limited to the regulation of manufacturers' prices of all patented drugs for the duration of their patent life, whatever their status (available OTC or by prescription-only, for human or veterinary use). The Board does not regulate off-patent drugs, and does not consider determinants of the prices paid by consumers, such as wholesalers' and pharmacists' margins. The Board's authority extends to the prices of existing drugs as well as new drugs. PMPRB must report annually to Parliament on its activities, on R&D spending by drug patentees and on drug pricing trends.

19. The PMPRB has the mandate to protect Canadian consumers by ensuring that the prices of patented drugs sold in Canada are not excessive. In making this judgement the Board compares the proposed Canadian price either to prices of existing drugs in Canada, or to prices in seven markets designated in the regulations (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States<sup>6</sup>). Price increases are limited to changes in the Consumer Price Index.<sup>7</sup> In addition, the price of a patented drug may, at no time, exceed the highest price of the same drug in the seven foreign countries.

20. The 'excessive price' criterion used in assessing the price of a new drug depends on the 'degree of innovation' of the new product (PMPRB, 2003; PMPRB, 2006d), as categorised by the PMPRB using a three-tiered scale.

- Category 1 comprises drug products that are a new strength (e.g., 50 mg v. 100 mg) or a new dosage form (e.g., tablet v. capsule) of an existing medicine. The price is considered excessive if it does not bear a "reasonable relationship" to the average price of the existing medicine in comparable dosage forms.
- Category 2 comprises drug products that represent a therapeutic breakthrough or provide substantial improvement (including cost savings) over comparable existing medicines. The price is excessive if it exceeds the prices of comparable products in the therapeutic class and the international median price of the medicine.
- Category 3 comprises drug products that provide moderate, little or no therapeutic advantage over comparable medicines. For these so-called 'me-too' drugs, the price is judged excessive if it exceeds the price of comparable products in the Canadian market. PMPRB may use the international median price as a reference when it is impossible or inappropriate to identify comparable drugs in Canada.

21. Drugs are classified in these three categories by experts of the Human Drug Advisory Panel (HDAP)<sup>8</sup>, which reviews all the available information on the drug and its comparators, with reference to

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6 These comparator countries were selected as ones that had or aspired to have a strong national presence of the pharmaceutical industry.

7 To assess the compliance with this rule regarding price increases, the price of a product in year t is compared to its price three years before, adjusted by 3-year cumulative CPI. In addition, the price cannot increase by more than 1.5 times the CPI increase for a given year.

8 The Human Drug Advisory Panel is composed of three designated members, chosen for their scientific expertise in drug therapy, clinical research methodology, statistical analysis and the evaluation of new drugs. HDAP also relies on scientific assessments made by PMPRB staff.

documents provided by the manufacturer and to published literature<sup>9</sup>. A drug's manufacturer suggests the category that it believes is appropriate for considering the drug's price. The manufacturer also indicates the drug's primary use, its comparators and their dosage regimens and, if relevant, the comparative therapeutic class. Results of drug assessments have been published on the Internet since September 2001.<sup>10</sup>

22. Manufacturers are requested to furnish price levels for four classes of customer (hospitals, pharmacies, wholesalers and other) in all provinces of Canada, as well as prices in the seven comparator countries, when relevant. Although the PMPRB considers the national Average Transaction Price (ATP), it retains authority to act on the basis of any manufacturer's price found to be excessive for any class of customer in any market in Canada.

23. In 2000, the PMPRB checked the validity of foreign prices provided by manufacturers for a sample of 50 products. European prices observed by the PMPRB coincided in 85% of cases with European prices provided by the manufacturer. Similarly, filed prices for the United States were equal to, or below prices listed in the US Federal Supply Schedule<sup>11</sup> price in 82.5% of cases (PMPRB, 2002).

24. Upon the request of a manufacturer, the PMPRB will assess the price of a new drug prior to its launch in the market and issue an Advance Ruling Certificate (ARC). This provides the manufacturer with some assurance that the price proposed will not be found to exceed the maximum allowable price resulting from the PMPRB's price guidelines. ARCs are non-binding for PMPRB, however. PMPRB issued one ARC in 2004 and none in 2005.

### *1.2.2. Consequences of excessive price*

25. When the PMPRB considers a price to be excessive according to the criteria defined above, there are two alternatives:

- If the company agrees to cut its price and to pay to the government of Canada some compensation for the excess revenues earned, it must submit a Voluntary Compliance Undertaking (VCU);
- If the company does not agree with the PMPRB, the Board holds a public hearing to reconsider the conclusion of excessive price and, if affirmed, make a judgment regarding penalty. If the public hearing confirms that the price is excessive, the company may appeal to the Federal Court of Canada to ask that the Board decision be overruled.

26. In 2005, the PMPRB reviewed the prices of 66 new patented drugs, of which 15 appeared to be priced outside the guidelines and were subject to further investigation (PMPRB, 2006a).

27. In certain cases, the list price of the manufacturer is not altered, but the manufacturer gives some guarantee to PMPRB that no customer in Canada will pay more than the maximum non-excessive price. For instance, the Board accepted in 2004 a VCU from Sanofi Synthelabo for Fasturtec® (treatment and

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9 Guidelines for this scientific review, for the categorisation of drugs and for manufacturers' submissions are published in the Compendium of Guidelines, Policies and Procedures issued by PMPRB (PMPRB, 2003, Chap 3, pp. 22-29).

10 See <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=117&mp=68>.

11 The US Federal Supply Schedule presents prices negotiated between manufacturers and the US Department of Veterans Affairs. The listed prices do not represent average paid prices in the United States, but are among the lowest prices in the United States.



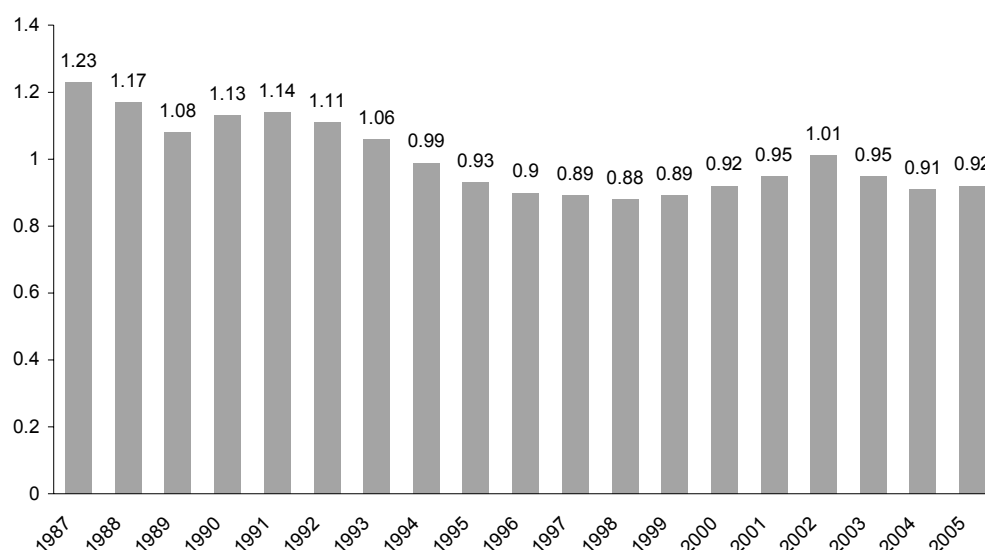
prevention of hyperuricemia in paediatric and adult cancer patients), which proposed this kind of arrangement. The company had been asked to lower its price by nearly 60%. Such a disconnection between list price and actual paid price may be desired by a manufacturer who is concerned about the implications of a relatively low Canadian list price for prices in other countries that use an external reference price scheme for benchmarking, as Canada does. This arrangement does not present any advantage for Canadian purchasers, but renders the price less attractive for potential US purchasers.

28. Investigations for excessive price increase are instigated when a price exceeds the maximum non-excessive price by at least 5%, and/or when excessive revenues exceed a defined threshold (\$50,000). In 2005, the prices of about 1,043 existing drugs were reviewed by PMPRB, leading to 37 investigations and 15 notices of hearings (PMPRB, 2006a).

### *1.2.3. Impact of pricing regulation on Canadian drug prices*

29. According to PMPRB estimates, Canadian prices have moved closer to median international prices since price regulation commenced in 1987. In 1987, Canadian prices for patented medicines exceeded the international median by more than 20%. After a fairly consistent annual decrease<sup>12</sup> until 1994, the prices have since stabilized at or up to 10% below the median in seven comparator countries. In 2005, prices of patented drugs in Canada were about 8% lower than the median prices of the seven comparator countries<sup>13</sup> (see Figure 2). These data suggest that Canadian price regulation has had a dampening effect on relative price levels in Canada, bringing them closer to the median price paid in a selected set of countries.

**Figure 2. Ratio of Canadian prices to median international prices for patented drugs, 1987-2005**



Source: PMPRB, 2006a.

12 The PMPRB amended its guidelines, effective in 1994, because of concerns that Canadian prices remained 10% above the international median in the early 1990s.

13 This figure is computed as the geometric mean of individual Canadian-to-median foreign price ratios, weighted by Canadian sales.

30. The key question is whether manufacturers would set higher list prices in Canada absent the PMPRB. One study found that Canadian drug prices in 1999 could be assessed as generally in line with what would be predicted based on the country's income level (Danzon and Furukawa, 2003). According to the authors of this study, the finding that pharmaceutical price differences in many of the countries studied roughly reflect the income differences across countries might result from the interaction of drug manufacturers' pricing strategies, using income as a proxy for demand elasticity, and regulation. Nevertheless, the question of whether income is a suitable proxy for elasticity of pharmaceutical demand is debatable, as elasticity may have other determinants (e.g., distribution of income, extent of out-of-pocket payments for the purchase of pharmaceuticals, consumers' preferences and appetite for drugs, etc.).

31. Reconciling the findings that price regulation has reduced Canada's price differential relative to certain countries with the suggestion that Canada's prices are in line with income is difficult. One hypothesis is that, prior to price regulation, Canada's prices had been relatively high due to the country's geographic proximity to the United States, which features the highest patented drug prices in the world. Price regulation has succeeded in offsetting the incentives for manufacturers to price higher in Canada to reduce risks of cross-border trade. Supporting this hypothesis is a finding that prices in the other US neighbouring country, Mexico, where price regulation is weak, are considerably higher than what would be predicted based on income (Danzon and Furukawa, 2003).

32. Certainly, it is apparent that, according to PMPRB criteria, manufacturers of drugs offering significant new therapeutic benefits have a great deal of leeway to set prices at the levels of the highest-priced countries in the world. On the other hand, Canada's policies ensure that prices of "me-too" drugs – as well as prices of other drugs that offer moderate therapeutic advantages over existing therapies – are restricted in price to the level of alternatives, where manufacturers might otherwise seek a premium.

33. Representatives of the pharmaceutical industry<sup>14</sup> claim that the PMPRB fails to fully recognize and value innovation. They also blame the PMPRB for not adequately valuing product benefits fully and for having refused price premia in cases where a new product offered enhanced patient comfort. They link these problems to the small number of categories used to classify drugs, which do not allow regulators to take into account refinements of incremental innovation.<sup>15</sup> The flip-side of this is that the PMPRB's regulatory framework works to promote value for money as well in the sense that no premium is provided for 'me too' drugs just because they are new.

34. Whether or not the PMPRB has a significant constraining effect on average pharmaceutical price levels in Canada, it is likely that the policies have other impacts. For example, the variation in price levels seen across Canada may be more limited than would otherwise exist absent price regulation. Manufacturers may sell products to some purchasers with limited market power at lower prices than those purchasers could otherwise command because of concern about the PMPRB authority to assess not only average prices paid, but to single out particular prices paid in particular geographic areas by particular purchasers.

35. Finally, the PMPRB process may in some cases provide perverse incentives, encouraging manufacturers to keep list prices artificially high, for example. Manufacturers will not be willing to lower their price, in case of increased competition for instance, if they believe that doing so will limit the amount they can charge in the future for a new variant of the same drug.

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14 Personal communication with representatives of Rx&D, the association of research-based, brand-name companies.

15 The PMPRB launched a consultation process in May 2006 in order to revise its guidelines for excessive price assessment, in which the Board raises the question of a more refined categorisation of drugs (PMPRB, 2006d).

### 1.3. Coverage of pharmaceuticals

36. Coverage in Canada is distinct from many other OECD countries with respect to the significant role of private insurance as a source of coverage for drugs prescribed for use outside the hospital setting. Another notable characteristic is the decentralisation of public drug program administration and delivery, which is distributed among the country's 13 jurisdictions (10 provinces and 3 territories), plus certain drug plans under federal jurisdiction. Finally, drug coverage in Canada has to be put in the context of free provision of all medical services guaranteed by the Canadian Health Act.

37. Given the growing cost of medicines and the unpredictability of need, drug coverage is an important determinant of the accessibility of medicines. Among the various public and private plans, formulary restrictions, reimbursement policies and cost-sharing requirements have a role to play in determining access.

#### 1.3.1. Forms of drug coverage in Canada

38. While drugs administered in hospitals are covered through the universal, publicly financed Medicare programme, other prescription drugs are not included among the insured benefits guaranteed by the *Canada Health Act*. Consequently, about two-thirds of Canadian residents are covered for prescription drugs by private insurance obtained through their employer or purchased on an individual basis. Provinces and territories administer publicly financed programmes to provide prescription drug coverage concentrated on seniors, social assistance recipients (including disabled citizens), and persons with special needs (e.g., high drug expenditures relative to income), while federal programmes exist for indigenous persons (First Nations and Inuit peoples), veterans, Canadian Forces members, Royal Canadian Mounted Police members, certain designated classes of immigrants, and inmates of federal penitentiaries, including some former inmates on parole. According to the Auditor General of Canada (2004), about one million Canadians are eligible for federal drug benefits and more than nine million people are covered by provincial plans.

39. Thanks to publicly financed drug programs offered by most provinces and territories, including catastrophic coverage programs existing in some provinces, many of those with greatest need for coverage are able to obtain it. According to estimates for 2000, 98% of the Canadian population has some form of public or private sector drug plan coverage that provides a degree of protection against severe drug expenditures (Fraser Group, Tristat Resources, 2002, page 52). The 2% of the population which is not insured against severe expenditures are concentrated in particular geographical areas, particularly in the Atlantic Provinces<sup>16</sup>, where it is estimated that 1 in 4 residents lacks pharmaceutical coverage (Fraser Group, Tristat resources, 2002).

40. Moreover, it was estimated in 1998 that 10% of the Canadian population was un-insured for routine expenditures, in the sense that they would have to pay every dollar of the first CAN\$1,000 if they had to face such expenditures (Applied Management, Fraser Group, Tristat Resources, 2000).

##### 1.3.1.1. Private insurance

41. Private insurance policies offer health benefits designed to supplement the universal, publicly financed benefits in Medicare. Drug costs are the major component of their expenditures (70%), but they also cover some services in hospitals (such as private room supplements), as well as dental, eye-care, paramedical and other professional care.

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16 Newfoundland and Labrador, Nova Scotia, New Brunswick and Prince Edward Island

42. About 1,000 private plans cover two-thirds of the Canadian population.<sup>17</sup> Private plans may be national, regional, or local in coverage, and enrolment tends to cater to those affiliated with particular employers, or through membership in a professional order or association. Individual subscriptions to private drug insurance plans are not common. In Québec, individual coverage is even prohibited. Approximately 95% of private coverage in Canada is provided through group benefits plans.

43. The level of coverage by private insurance varies from one province to another, together with employment conditions. According to Luffman (2005), high-wage and unionized workers are more likely to have access to employer-sponsored private insurance.

44. Private plans are financed by premiums from their sponsors and from beneficiaries. In 2000, 45% of employer-sponsored plans did not require enrollees to make any contribution to premiums (Fraser/Tristat, 2002). According to more recent estimates, employers normally pay about 70% of premiums. However, employers are not required to offer this benefit. If an employer offers coverage, an employee may be required to enrol (along with spouse and children).

45. Private health plans can be regulated by the provinces and territories, resulting in different policies across Canada. For instance, while risk selection<sup>18</sup> is allowed in most provinces, it is prohibited in Québec. Overall, regulation of private insurance is more stringent in Québec than in other provinces. Indeed, since 1997, prescription drug insurance coverage has been compulsory for all Quebecers, either through private plans or the public drug plan; as well, termination of coverage is regulated and insurers have the obligation to pool risks in the private system. Private plans are further required to maintain minimum coverage standards (they must be at least as generous as the provincial public plan in terms of coverage and they have no latitude to deny claims). Québec also requires private plans to undertake education and prevention activities in order to optimize drug coverage.

#### *1.3.1.2. Forms of public coverage for prescription drugs*

46. Provinces and territories offer drug coverage to social assistance recipients and persons with special needs. However, degrees of coverage vary across provinces and territories (see Box 2). Seniors are universally eligible for public coverage (irrespective of income or other tests) in Alberta and Ontario, and become eligible in Nova Scotia if they have no private drug coverage, Prince Edward Island, the Northwest Territories and the Yukon Territory. Jurisdictions often provide drug coverage for patients requiring high-cost treatments, either in the form of multiple specific plans defined for each disease (HIV, cystic fibrosis, growth hormone deficiency, organ transplant, etc.) or in the form of coverage against catastrophic drug expenditures. Some programmes cover drugs dispensed to home-care and long-term care patients.

47. Four provinces offer 'universal eligibility' for public drug coverage: Alberta, Manitoba, Saskatchewan and British Columbia. In Alberta, residents not covered by other plans may apply for coverage in the public programs<sup>19</sup> (for which they are required to pay premiums<sup>20</sup> and co-payments). In the three other provinces, all residents are entitled to enrol in the public plan but deductibles may dissuade

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17 Source: personnel communication with representatives of the Canadian Life and Health Insurance Association (CLIHA).

18 Health insurers are authorised to accept or refuse enrolment according to characteristics of the candidate and to vary the premium according to these characteristics (age, health status, gender...).

19 Note that delivery of Alberta's programs is contracted out to a private insurer, Alberta Blue Cross.

20 In Alberta, those over the age of 65 are eligible for premium-free coverage.

them from doing so, especially if they have high income and/or have access to more generous coverage through private insurance.

48. Québec has achieved universal coverage by requiring that all residents who have no access to private group insurance enrol in its public scheme, where income-dependent premiums are charged. Further, everyone under age 65 who has access to a private plan is required to obtain the prescription drug coverage provided by that plan. Persons who turn 65 and who have access to a private plan that offers basic prescription drug coverage may either retain their private plan coverage or join the public plan.

**Box 2. Drug coverage in selected provinces and in the federal Non-insured Health Benefits programme**

In **Ontario**, the Ontario Drug Benefit program (ODB) offers drug coverage to Ontario residents who are beneficiaries of the Ontario Health Insurance Plan (public coverage of medical services) and belong to one of the following categories: people 65 years and older, residents of long-term care facilities, residents of homes for special care, people receiving professional services under the Home Care programme, and recipients of social assistance programs. In addition, the Trillium Drug Program (a catastrophic coverage program, i.e., covering high prescription drug costs in relation to net household income) covers people whose drug expenditures exceed 3-4% of their income.

In 2004, the ODB covered 2.9 million people (23% of the Ontario population) and other public programs (such as federal programs) covered 246,000 people (2%). Another 7.5 million (58%) Ontario residents were covered by private insurance, while 2.2 million people (17%) were uninsured (Government of Ontario, 2006).

In **British Columbia**, PharmaCare was launched in 1974 as a social assistance program for seniors and low-income residents. PharmaCare now includes a variety of plans covering prescription drugs for eligible populations, including permanent residents of long-term care facilities, recipients of income assistance, and children who qualify for aid. Other plans provide coverage for those who meet eligibility criteria and require certain types of drugs, including psychiatric drugs, palliative care drugs, treatments for cystic fibrosis, and HIV/AIDS. On the top of these plans, Fair PharmaCare was introduced in May 2003 to improve the equity of financial assistance for purchase of prescription drugs. It functions as a safety net, providing means-tested assistance for the purchase of prescription drugs. Every British Columbia resident is eligible for this programme but people covered by private insurance have generally no incentive to enrol unless they face exceptional drug expenditures since deductibles are high (deductibles are means-tested: the annual deductible is 0 if the net family income is less than Can\$15,000, 2% of the income if income is between \$15,000 and \$30,000 and 3% beyond<sup>1</sup>).

In 2003, PharmaCare covered 899,700 people, i.e. 21.7% of the population of British Columbia, including more than three-quarters of those residents aged 65 and older.

**Québec** implemented a universal drug coverage scheme in 1997. The system requires workers to subscribe to private plans offered by their employer and provides publicly financed drug coverage for all residents who are not otherwise covered by a private group insurance plan.

The system is funded by various parties at different rates. For the public plan, the premium (paid through the contributor's income tax return), deductible and co-pays that a resident pays depends on age, net family income, and if they are recipients of certain social programs. Residents who have access to a private plan do not partake in the public plan, but must also pay premiums, though how this is paid and the amount varies by plan.

In 2005, 43% of Québec residents were covered by the public provincial scheme, either because they had no access to private coverage (24%) or because they were entitled to public coverage (19%) as seniors or as social assistance beneficiaries of the province's "Employment Assistance Program". Almost all other residents are covered by private insurance. The public regime requires the payment of a means-tested annual premium, ranging from \$0 to \$538, above a revenue threshold (for the period July 2006 to June 2007).

The **Non-insured Health Benefits** (NIHB) is a federal program administered by Health Canada. Its aim is to 'support First Nations people and Inuit in reaching an overall health status that is comparable with other Canadians' (NIHB website), by covering health goods and services not covered through other private or provincial/territorial health insurance plans. The NIHB program provides coverage for a specified range of drugs, dental care, vision care, medical supplies and equipment, short-term crisis intervention and mental health counselling. Drug coverage is its most important component, representing more than 44% of NIHB's expenditures.

The NIHB program covers about 765,000 people. The enrolled population is rather young. The average age is 29 years and only 4.5% of those are more than 65 years (Health Canada, 2004, page 10).

<sup>1</sup> <http://www.healthservices.gov.bc.ca/pharme/plani/planiinfo.html#M>, accessed on October 5, 2006.

### *1.3.2. Formularies*

49. A drug's inclusion in a formulary, or list of medicines eligible for reimbursement by a third-party payer, is an important determinant of the accessibility of that medicine to persons covered by the insurance. In Canada, where hospital care – including medicines furnished to hospital patients on an inpatient basis – is covered by Medicare, individual hospitals are responsible for developing their own formularies. Private insurers are free to draw up their own formularies.<sup>21</sup> Provinces make their own decisions regarding the formularies used by provincial drug plans.

#### *1.3.2.1. Hospital formularies*

50. Hospitals establish their own formularies through a Pharmaceuticals and Therapeutics Committee (P&T Committee) composed of physicians, pharmacists, and in many cases, nurses. The P&T Committee is usually a sub-committee of the Medical Advisory Committee to whom the P&T makes its recommendations. Formularies are adapted to the hospital's activities and patient profile. The hospital formulary may include drugs not yet approved by Health Canada but judged likely to be accessible for certain patients through the Special Access Programme.

#### *1.3.2.2. Private plans*

51. Private coverage tends to be more inclusive in terms of the number of products covered for reimbursement, as compared with the publicly financed plans. Many private plans offer open access to all drugs licensed for marketing by Health Canada, while others cover only drugs listed on a more restrictive formulary, reflecting growing concerns from employers about growth in benefit cost. Some private plans are reportedly beginning to experiment with the use of formularies which mirror those of public drug plans, while others offer employers various options in terms of formularies. Generally speaking, private plans have the option to reference public plan formularies for coverage decisions, or to maintain their own. However, in Québec all plans are required to offer coverage at least equal to the public formulary.

#### *1.3.2.3. The Common Drug Review*

52. Following the recommendations of the Commission on the Future of Health Care in Canada (2002), also known as the Romanow Commission, a Common Drug Review (CDR) was launched in 2003. The CDR is an intergovernmental<sup>22</sup> collaborative body which aims at evaluating new chemical entities (NCEs) and new combinations to inform an official recommendation as to whether a drug should be included in the formularies of participating publicly financed drug plans.

53. The CDR is part of the Canadian Agency for Drugs and Technology in Health (CADTH). This agency, until recently known as the Canadian Coordinating Office for Health Technology Assessment (CCOHTA), was created in 1989 to assess medical services and to inform decision-makers' health technology choices. CADTH is funded by Canadian federal, provincial and territorial governments.

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21 Québec is an exception to these two rules since hospitals there develop individual formularies based on drugs listed on a provincial hospital drug formulary, and the Drug Insurance Act requires private insurers to cover drugs listed on the provincial formulary.

22 All Canadian jurisdictions (provinces and territories) participate in the CDR, with the exception of Québec.

54. Recommendations regarding formulary inclusion are made by the Canadian Expert Drug Advisory Committee (CEDAC), an independent advisory body composed of individuals with expertise in drug therapy and drug evaluation. CEDAC is appointed by and accountable to the CADTH Board of Directors. In formulating recommendations, CEDAC considers clinical studies demonstrating safety and/or efficacy of the drug in appropriate patient populations; therapeutic advantages and disadvantages of the drug relative to accepted therapy, and cost-effectiveness of the drug relative to accepted therapy.

55. CEDAC may recommend a drug be listed, a drug be listed with criteria, a drug not be listed, or that a recommendation be deferred pending clarification of information. To date, the Common Drug Review is limited to new chemical entities (NCEs) and new combinations<sup>23</sup>. As of late August 2006, 51 drug reviews have been completed since the CDR's implementation, resulting in recommendations that the federal government, provinces and territories not list new products in their public drug plan formularies for half of the drugs reviewed. Some negative recommendations are based on a decision that the product is not cost-effective at the price listed, although the actual cut-off point in terms of Quality-Adjusted Life-Years (QALYs)/\$ (or other metric) is not made explicit. Another important factor is whether surrogate outcomes (such as reduced cholesterol level) are accepted in place of desired health outcomes, such as reductions in morbidity or mortality.

56. A key objective of the CDR is to gain efficiencies in the drug review process by avoiding multiple duplicative assessments by each publicly financed programme. During the first few years of the CDR, some efficiencies have been achieved – for example, a manufacturer's application to CEDAC takes the place of applications to each of the participating plans for reimbursement consideration – however, each plan continues to supplement the review with its own follow-up. Moreover, since CDR is currently limited to NCEs and new combinations, applications for formulary listing of line extensions of existing drugs or for generics are directly submitted to publicly financed drug plans.

57. Although differences in decision-making criteria across plans make some supplementary assessment unavoidable, some may be due to limitations of the current CDR process. For example, findings from a recent survey of public drug plan managers conducted by the PMPRB (2005) indicated the possible need to develop guidelines for budget impact analysis, required by most public plans for inclusion on drug formularies.

#### *1.3.2.4. Public plan formularies*

58. Processes and rules for formulary listing differ among provinces and territories, reflecting both historical development and policy objectives. Except for Québec, all other Canadian jurisdictions now consider CDR recommendations when making their own decisions. Decision criteria and methods vary (see Box 3). Generally, formulary decisions are made by the respective provincial or territorial Ministry of Health based on the recommendations of a committee.

59. Economic considerations are often taken into account, even if these considerations are not always predominant in formulary decisions or explicitly outlined in decision-making criteria. What is meant by economic considerations ranges from simple budget impact analysis to more elaborate cost-effectiveness studies provided by the manufacturer. Pharmaco-economic assessment has been formally taken into account in reimbursement decisions for several years in Ontario and British Columbia. However, no

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23 Although health ministers from all 13 participating jurisdictions have agreed to expand the CDR to include existing drugs, it is not yet known when the CDR expansion will occur. Jurisdictions participating in the National Pharmaceutical Strategy are currently working to expand the CDR mandate to new indications for old drugs.



explicit cost-effectiveness threshold has been defined by any jurisdiction. In cases where provinces decide against formulary inclusion on the grounds that the drug is not cost-effective at the proposed price, manufacturers are not constrained from presenting a new application with a lower price.

### **Box 3. Formulary listing processes used in selected drug coverage schemes**

#### **Ontario<sup>1</sup>**

The Ontario Drug Benefit (ODB) covers all drugs listed in a general formulary, although coverage may be restricted to some indications ("Limited Use"). Beyond this formulary, two specific programs exist: the Special Drug Program covers very expensive medicines, such as treatments of HIV, cystic fibrosis, growth failure, etc., and the Section 8 Program furnishes coverage for drugs which are approved for sale in Canada but which are not (yet) on the ODB formulary or which are prescribed out of the 'Limited Use' conditions required for reimbursement. This is reserved for exceptional circumstances and needs a request by the physician. The Ontario formulary contains 3,300 products and other drugs listed for limited use.

Formulary decisions are made by the Minister of Health, with the advice of the Drug Quality and Therapeutics Committee (DQTC) of Ontario. DQTC members are appointed by the Government of Ontario. In 2006, there were 12 members: 9 physicians, 2 pharmacists and 1 economist. The DQTC meets once a month to examine reviews prepared by experts. Its deliberations are confidential, as are manufacturers' applications. The Ontario Ministry of Health decided in the early 1990s that formulary decisions should be enhanced by cost-effectiveness analysis. Ontario's first pharmaco-economic guidelines were drafted in 1993 and companies seeking reimbursement of their products have been required to undertake cost-effectiveness studies since 1996.

A study of recommendations made by the DQTC from December 1997 to August 1998 (PausJenssen et al, 2003) identified factors influencing decisions of the committee. The therapeutic value of the drug was found to play a major role in decisions, over cost considerations. For the latter, budget impact was closely considered but it never overrode the cost-effectiveness analysis. However, less than 10% of the 134 manufacturers' submissions presented 'sophisticated cost-effectiveness' analysis, which played a major role in only 8 decisions. Cost-containment never led to a negative decision for a cost-effective drug. However, this study is quite old and things may have changed as officials have since had to make decisions on an increasing number of very expensive drugs.

In fiscal year 2005/2006, 98,548 patients benefited from coverage under the Individual Clinical Review (ICR/Section 8) mechanism. The numbers of both requests and beneficiaries have been increasing very rapidly (there were only 7,429 beneficiaries in 1997/1998) and the approval rate is 68%.

#### **British Columbia**

In 2003, the PharmaCare formulary contained 4,900 drugs corresponding to 750 molecules. The coverage of a drug may be limited to certain circumstances related to a patient's condition, drug intolerance, or other factors. For instance, the drug may have to be prescribed by physicians of a defined specialty or may be covered only in second-line therapy (after the failure of a first-line therapy). For these drugs to be covered, physicians have to ask for prior authorisation.

The British Columbia Ministry of Health makes formulary decisions on the recommendations of the BC PharmaCare Drug Benefit Committee, whose role is to consider if a new molecule that has been the subject of a positive recommendation from the Common Drug Review's CEDAC is both needed and affordable for British Columbia residents. This means that negative recommendations by CEDAC are not considered further. Positive recommendations are not always confirmed by the committee, which assesses the product against the following criteria: safety issues, clinical effectiveness and health outcomes, value for money compared to current treatments and budget impact of listing.

#### **Québec**

In Québec, the Ministère de la Santé et des Services sociaux (health ministry) establishes and updates a positive formulary list for public and private prescription drug coverage, but private drug plans are allowed to offer extended coverage. The formulary list includes an 'exception section' that contains drugs reimbursed only for some indications and for which prior authorisation is needed. Québec's formulary is acknowledged as the most inclusive formulary in Canada. In 2005, it contained over 5,300 drugs, of which 683 are 'exceptional drugs' whose prescription requires prior

authorisation. Québec also provides a formulary for hospital drugs.

After market approval by Health Canada, a drug's manufacturer has to file an application with the Council of Pharmaceuticals (*Conseil du médicament*), which considers whether to list the drug and provides recommendations to the Ministry. The average time taken in making a recommendation ranges between 3 to 5 months but may be accelerated under certain circumstances.

The Council is composed of medical and economic experts, as well as other experts intended to foster consideration of ethical and societal perspectives. The 1997 Act Respecting Prescription Drug Insurance defined the following criteria for inclusion in the positive list: (1) evidence-based therapeutic value and (2) fair pricing (considering the cost-efficiency ratio). Reforms introduced in 2002 (though yet to become law) added two new criteria to better take into account societal values: (3) prospective impact on population health and on other aspects of the health care system, and (4) appropriateness of listing in relation to the objectives of the general drug coverage scheme, which is to ensure reasonable and equitable access to drugs. Recommendations of the Council are published when the decision of the MSSS is announced. In 2004-2005, 100% of the recommendations issued by the Council were followed by the Québec government. Recommendations were negative in 32% of cases in 2004-2005 and in 19% of cases in 2005-2006 (Conseil du médicament, 2005 and 2006).

#### **The federal Non-Insured Health Benefits (NIHB) Program (First Nations and Inuit peoples)**

Drugs have to be listed on the NIHB Drug Benefit List (DBL) to be funded. The NIHB makes its formulary decision by considering CEDAC recommendations. Manufacturers filing a submission for listing in the NIHB formulary are required to provide a letter authorizing the NIHB to access any information in the possession of Health Canada, any province or government of Canada, the PMPRB and CADTH. Manufacturers are also required to provide information on prices and marketing, as well as a complete budget impact assessment for the NIHB program.

The review process for formulary decisions depends on the type of drug. New formulations and/or new indications for existing drugs are reviewed internally and referred to the Federal Pharmacy and Therapeutics Committee. The FP&TC, an advisory committee composed of health professionals, is in charge of providing evidence-based recommendations for all federal drug programs. Criteria for formulary listing are the following: evidence of therapeutic efficacy, safety, 'demonstrated incremental benefit in proportion of incremental cost', and consistency with NIHB program mandate and policy.

A drug may be listed for limited use when it has the potential for widespread use outside covered indication(s), it is associated with predictable severe adverse effects, it is a second or third-line choice treatment in case of intolerance, treatment failure or non-compliance with a first-line alternative, or it is very costly and there are therapeutically effective alternatives in the DBL. Limited-use benefits may require prior approval or be subject to quantity and frequency limits. For instance, beneficiaries are eligible for one 3-month supply of smoking cessation products per year. Products which are not listed may be approved in special circumstances after the request of a physician or dentist.

Products may be de-listed if they are discontinued from the Canadian market, if new toxicity data changes the benefit-risk ratio to the point where listing becomes inappropriate, if new information demonstrates that the product does not have the anticipated therapeutic benefit; when the purchase cost is disproportionate to the benefits provided; or when a drug has a high potential for misuse or abuse.

1. Current policies and practices of the Ontario Drug Benefit Program may be affected by the implementation of new drug legislation (*The Transparent Drug System for Patients Act*) passed in Ontario in June 2006. Changes will be made to the program as of October 1, 2006 and beyond.

60. In general, drugs not listed on a formulary are not included in the scope of coverage and are therefore not eligible for reimbursement. However, there are exceptions. Many plans allow physicians to apply for special-use permission for drugs not listed on a formulary, which promotes accessibility of drugs not covered or not yet covered by a patient's insurer. However, these processes are reportedly cumbersome

for the physician, acting as a disincentive to application. Efforts to address this are under way in some provinces, such as in Ontario where special-use processes have been streamlined.

61. Studies have documented wide variations in formularies across Canada. Gregoire *et al.* (2001) observed in 1999 the formulary status of 148 new prescription drugs approved and launched between 1991 and 1998 in all provinces and territories. Québec, British Columbia, Manitoba and Saskatchewan had listed more than 70% of these new drugs and had the highest rates of listing without restriction. New Brunswick, Newfoundland, Ontario and Prince Edward Island had listed less than 50% of those new products but the listing with restriction was notably low in New Brunswick and Newfoundland. Surprisingly, the authors found little consistency in provincial formularies, even among the provinces having the highest rates of listing. Only 18 drugs were listed in all formularies and 10 in none. They explain these discrepancies, also visible at the level of therapeutic classes, by differences in the population covered by provincial plans and by the concomitance of other public programmes dedicated to specific diseases (such as cancer programmes).

62. On a smaller sample<sup>24</sup>, Anis and colleagues (2001) found similar results. They also explored the factors underlying decisions regarding formulary inclusion, finding that drugs were more likely to be included where means-tested co-payments were used and when the drugs were offered at a competitive price, compared with alternative treatments. On the other hand, the integration of public and private insurance in a jurisdiction had a negative impact on inclusion decisions, and, counter-intuitively, the category of disease treated by a drug was found to have no effect.

63. Arthur *et al* (2006) show that there tends to be a common core of medications available to those with coverage, despite the existence of more than 15,000 drug products on the market and an average of 93 new drug products added per month. However, using the Anatomical Therapeutic Chemical (ATC) classification system, the analysis also suggests that there is only 55 per cent commonality at ATC level four when the listings of the products common amongst eight, nine or ten jurisdictions are combined.

64. Data from IMS allow inter-provincial comparisons of formulary listing outcomes, both in terms of formulary “generosity” and in terms of “time to listing” (See Table 1). Formulary “generosity” is measured by the ratio of the number of drugs listed to the number of listing applications by manufacturers. Québec is more inclined to include new drugs in its formulary (48% of applications in 2003) than other provinces, followed by Manitoba and Saskatchewan (39% and 38%). Other provinces are more stringent. The propensity to list new drugs declined in all provinces between 2000 and 2003.

65. “Time to listing” measures the time from the date of approval for marketing to the date of formulary listing in each province. It cannot be interpreted as an indicator of efficiency of listing procedures since it includes delays in application submissions by manufacturers. The average time to listing varied from less than one year in Saskatchewan, Newfoundland and Labrador to more than two years in the Northwest Territories. The time to listing increased in many provinces between 2000 and 2003. Since then, the Common Drug Review has been implemented and may have reduced the variation in time to listing for new chemical entities since manufacturers file a unique application for all public plans.

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24 The authors observed the status in 10 provinces of 58 products approved for sale in Canada in 1996-1997.

Table 1. Formulary listing of new products by provinces

Province	% of New Drugs Reimbursed*	Average Time to Listing (in days)**
	June 1, 2004 to May 31, 2006	June 1, 2004 to May 31, 2006
Alberta	19%	293
British Columbia	15%	371
Manitoba	25%	422
New Brunswick	8%	547
Newfoundland and Labrador	10%	298
Nova Scotia	17%	341
Ontario	13%	417
Prince Edward Island	9%	632
Quebec	31%	361
Saskatchewan	24%	381

Source: IMS Health. Provincial Reimbursement Advisor.

\* Listings for Single-Source Products Launched June 1, 2004 to May 31, 2006.

\*\* Average Time to Listing for Full and Restricted Listings June 1, 2004 to May 31, 2006.

66. Provincial and territorial formularies define the public coverage of drugs dispensed in ambulatory (outpatient) care. However, public coverage is not limited to these formularies and they should not be considered in isolation to assess the comprehensiveness of public coverage in a province or Territory. For instance, intravenous cancer drugs are not reviewed by the CDR and their coverage varies across provinces and territories. The Cancer Advocacy Coalition of Canada (2005) assessed the coverage status of 20 cancer drugs in provinces and states that there “is variable access to new drugs across the provinces, depending on a jurisdiction’s prioritisation of the treatment, timeliness of the often multi-tier vetting process, and availability of resources to support each new treatment. This results in treatments being available in some provinces but not others at any point in time” (p. 27).<sup>25</sup> The report indicates that British Columbia “has the best funded and most timely access to cancer drugs,” attributed to a consistent cancer programme coordinated by a provincial cancer agency.

67. In 2005, McMahon *et al.* (2006) compared recommendations issued by the Common Drug Review for 25 products between April 2004 and June 2005 to decisions made in 10 provinces and 3 territories in June 2005. At the time of the survey, all the drugs were still under review in Prince Edward Island, as was the case for 16 to 19 drugs in Manitoba, New Brunswick and the Yukon territories. Other provinces had made more decisions. British Columbia, Alberta, Nova Scotia, Saskatchewan and Ontario showed the highest concordance between formulary decisions and CDR recommendations.

68. Not surprisingly, formulary differences have been found to have an impact on patterns of drug use and expenditures in Canada. Prior authorisation requirements are more effective than restricting use to limited applications in constraining use of drugs, and formulary delisting is associated with lower consumption (see Box 4).

25 For instance, intravenous cancer drugs are covered through hospital global budgets in Québec, Prince Edward Island, New Brunswick and Nova Scotia while they are covered by separate cancer agencies’ drug budgets in British Columbia, Newfoundland and Saskatchewan. Provincial programs covering prescription drugs provide different levels of coverage for new oral cancer drugs. Manitoba, Ontario, Québec and Nova Scotia were found to cover only partially new oral drugs for ambulatory and home care, while Alberta, Prince Edward Island and New Brunswick do not cover them at all.

#### Box 4. Evidence of the impact of formulary listing on consumption patterns

A few studies have examined the impact of formulary changes or of differences in provincial formularies on consumption patterns.

One study evaluated the impact of a change in reimbursement policy for respiratory drugs in Nova Scotia in 2000 (Kephart *et al.*, 2005). The policy change was aimed at decreasing the use of nebulisation respiratory therapies, considered to be no more effective than less costly therapies. Several measures were adopted: criteria were developed to limit the reimbursement of nebulisers to certain conditions, a spacer device (a less costly alternative to improve the delivery of inhaled drugs) was introduced in the formulary and a fixed fee was paid to the pharmacist for patient education on the use of this device (\$10 for initial education and \$4 for subsequent refills and follow-up education). The study observed the impact of the policy on cohorts of users of nebulisation therapy before the policy. A sharp decrease in the use of nebulisation therapies was observed among former users as soon as the program was announced, partly compensated by a large increase in the use of Aerochamber<sup>1</sup>, but also by increases in other inhaled therapies. By contrast, no increase was observed in the consumption of physicians' services or in hospital admissions among these patients, suggesting that changes in consumption did not induce adverse effects. Similar results were observed in an assessment of the same kind of policy in British Columbia.

Another study assessed the impact of the exclusion of selected topical corticosteroid products from the Nova Scotia formulary in 2000, after an evidence-based drug review of this therapeutic class found certain topical corticosteroids did not meet standards for inclusion (Campbell *et al.*, 2003). Not surprisingly, use of certain topical corticosteroid products decreased after this change, as well as associated average costs.

Sketris *et al.* (2004b) studied antibiotic consumption in Manitoba, Nova Scotia and Saskatchewan among public programme beneficiaries between 1995 and 1998. Consumption of anti-infectives was higher in Nova Scotia (9,398 DDDs per 1,000 beneficiaries per year in 1997-98) and in Manitoba (9,950) than in Saskatchewan (8,590). Moreover, Saskatchewan was the only province where the consumption of antibiotics decreased over the period (by 11.5%). Saskatchewan also had a lower rate of use for broad-spectrum antibiotics, due to its more limited reimbursement policies.

Paterson *et al.* (2003) studied the impact of provincial drug policies on the use and costs to governments of Cox-2 inhibitors (a non-steroidal anti-inflammatory drug or NSAID) and atypical neuroleptics (antipsychotics with fewer side-effects than older drugs used in treatment) in two provinces. Cox-2 inhibitors are subject to limited use in the Ontario drug benefit and require prior authorisation for reimbursement in British Columbia. In Ontario, consumption of NSAID drugs rose by 70% in the year following the introduction of Cox-2 inhibitors and costs tripled. By contrast, there was no increase in use of NSAIDs in British Columbia. The authors found similar developments for atypical neuroleptics, which were included in the formulary without restriction in Ontario and covered subject to prior authorisation in British Columbia.

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1. An aerochamber is a device that facilitates inhalation of a puffer medication for patients with co-ordination problems (children, older people).

69. Recommendations for a common national formulary are a recurring item in Canadian public debates; they were mentioned in both reports of the Romanow Commission (Commission on the Future of Health Care in Canada, 2002) and of the Standing Senate Committee on Social Affairs, Science and Technology (2002) – also known as the Kirby Committee. Hollis and Law (2004) asserted that a national drug review and formulary would avoid duplicative work of formulary management; increase negotiating power of buyers, ensure an adequate investment in formulary management, impede strategic behaviours from manufacturers and provinces harming other provinces, eliminate the differences in 'available' drugs between provinces, and reduce marketing delays by increasing collaboration between Health Canada and the PMPRB. On the other hand, a single formulary could take into account neither differences in ability and willingness to pay of provinces, nor differences in the health status of the populations covered.

However, Hollis and Law note that previous studies (e.g., Grégoire *et al*, 2001) have found no link between provincial income and propensity to list new drugs quickly and without restrictions.

### ***1.3.3.Reimbursement***

70. In Canada, the main purchasers of prescription drugs are third-party payers, including publicly and privately-financed drug plans, patients and hospitals

71. Canadian hospitals operate under fixed budgets and/or payment per case, which they use to procure drugs provided free-of-charge to their patients. Hospitals typically use group purchasing programs to establish group contracts for set prices. The hospital then buys directly from the manufacturer at the contract price.

72. Private health insurance plans tend to act as passive payers, typically reimbursing plan members (who normally must pay out-of-pocket first and then seek reimbursement) for the costs of prescribed medicines used by their enrollees that are included in a given plan's formulary, less any cost-sharing amount. The reimbursement arrangements may or may not cover the dispensing fee charged by the pharmacist.

73. Provincial, territorial and federal drug plans define reimbursement prices for pharmaceutical products covered under their formularies and, in some instances, use elaborate methodologies for determining reimbursement amounts. The reimbursed prices may differ from manufacturer's list prices.<sup>26</sup> The following sections describe the various reimbursement practices and tools used by public plans in Canada.

#### *1.3.3.1. Reimbursement formulas used by publicly financed plans*

74. Public plans use different formulas to pay for prescription drug purchases and distribution services (see Table 2). When pharmacy reimbursement prices are pre-defined, this is generally the price paid to the pharmacy by the plan; in other cases the pharmacy's actual acquisition price is paid. Wholesale margins paid by the pharmacist are generally compensated according to a fixed or capped mark-up. Types and amounts of dispensing fees paid are defined by each plan.

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26 Reimbursement prices are paid to retailers, whereas wholesalers or retailers purchase drugs at the price set by the manufacturer.

**Table 2. Formulas used by public plans to reimburse drugs and related pricing policies**

	<b>Reimbursement of drugs by the public plan</b>	<b>Special pricing policies</b>
British Columbia	<b>Actual acquisition cost</b> (capped to a maximum price) + wholesaler's mark up (capped at 7%) + dispensing fee (capped to a maximum)	Reference prices for five therapeutic classes: H2-receptor antagonists (treatment of non-ulcer dyspepsia or upper gastrointestinal tract complaints), Nitrates (treatment of angina), NSAIDs (treatments of osteoarthritis and rheumatism), ACE inhibitors and Calcium Channel Blockers (both for hypertension)  Cost of the cheapest proton pump inhibitors (ulcer treatment) for first-line treatment  Low-cost alternative program: cost of the least expensive drug in generic groups
Saskatchewan	<b>Actual acquisition cost</b> + mark-up allowance (three-tiered scale markup ranging from 30% to 10%) + dispensing fee (capped to \$8.21).	Lowest cost alternative in generic groups  Standing-offer contracts for generics  Maximum allowable costs (reference price) since July 2004, only for proton pump inhibitors – to be expanded.
Alberta	<b>Actual acquisition cost</b> + Professional fee (three-tiered mark-up ranging from CAN\$10.22 to CAN\$20.94) + inventory allowance (three-tier sliding scale, ranging from CAN\$0.71 to \$5.03).	Lowest cost alternative within generic groups  Maximum allowable cost (reference price) in groups of interchangeable drugs  Generic price capped at 75% of the original product price
Manitoba	<b>Actual acquisition cost</b> + Professional fees	
Nova Scotia	<b>Actual acquisition cost</b> + Professional fees (two-tiered markup ranging from CAN\$10.42 to CAN\$15.64) + 10% for some products.	Maximum allowable cost price for interchangeable products, primarily generic drug products
New Brunswick	<b>Actual acquisition cost</b> + dispensing fee (ten-tiered, ranging from \$8.40 to \$161)	Maximum allowable price for generic groups
Prince Edward Island	<b>List price</b>	
Newfoundland	<b>List price</b>	Maximum allowable cost for 11 generic groups of over-the-counter drugs
Québec	<b>"Acquisition price"</b> , which is either the <b>price guaranteed</b> by the manufacturer for wholesalers or the price guaranteed for	Requires the best available price in Canada for listed drugs

	sales to pharmacist + the actual wholesale markup <sup>27</sup> (capped to \$20 for costly drugs).	Lowest cost alternative in generic groups after 15 years of exclusivity for the original product. If the brand-name product patent expires before the end of 15 years, generic entries are reimbursed according to the lowest cost rule, but the originator product is still reimbursed at the original rate.
Ontario	<b>List price</b> + mark up + Pharmacist fee	Price-volume agreements with manufacturers  Generic price capped at 50% of the original product price
NIHB	<b>Acquisition cost</b> + mark-up + pharmacist fee	Best price alternative in generic group and in reference price groups when applicable in the province.

Sources: Morgan et al., 2003 and provincial drug plan websites.

### *1.3.3.2. Reimbursement policies for price control and cost-containment*

75. As the most important third-party payer in their jurisdiction, provincial plans have significant purchasing power, enabling them to institute a range of reimbursement policies for price control and cost-containment. Almost all publicly financed third-party payers employ some policies aimed at containing pharmaceutical costs. Several tools are used by the plans to control reimbursement prices of drugs: direct negotiations with manufacturers, constraints imposed on manufacturers, use of reference prices or lowest cost alternatives, bids and across-the board freezes.

76. Provincial drug plans engage in very little direct negotiation with manufacturers regarding reimbursement prices. Ontario introduced in 1998 so-called “cost-sharing arrangements” linking prices to expected volumes of sales. This regulation requires written agreements between the product sponsor and the Ministry of Health for all new brand-name drugs listed in the ODB formulary. Manufacturers have to provide sales forecasts for the 3 years following listing and, if sales later exceed the forecasts, may be asked to demonstrate that no inappropriate use occurred (for instance, if new uses have been approved). An audit conducted in 2001 revealed that, in most cases, actual expenditures were at least 10% below the forecast provided by the manufacturer. Moreover, auditors were unable to determine how forecasts had been made since they were often significantly higher than amounts predicted on the basis of the ministry’s documentation. Finally, the auditor noted that no penalties have ever been applied in cases of unjustified excess (Auditor General of Ontario, 2001). Morgan, Barer and Agnew (2003) concluded that the most important benefit of these negotiations is to offer a better predictability to the program rather than to share risk<sup>28</sup>.

27 The price guaranteed by the manufacturer may be higher for direct sales to pharmacists than for wholesalers, but the difference between the two prices cannot exceed 9%. If this difference is greater than 5%, the price paid by the public plan is the price guaranteed for pharmacists and includes payment for the wholesaler. If this difference is lower than 5%, the price paid is the price guaranteed for wholesalers + the actual wholesale markup.

28 However, things may change in Ontario since new drug legislation will enable the newly created office of the Executive Officer, responsible for formulary management, to more actively negotiate formulary prices with manufacturers as of October 1, 2006 (Legislative Assembly of Ontario, 2006).



77. Some plans impose constraints that manufacturers must accept for a given drug to be listed on the public plan formulary. For a number of years, Québec has required that manufacturers offer their drug at the best price available in the rest of Canada. Non-compliance with this rule may lead to the delisting of all of the manufacturer's products. For instance, Québec withdrew 37 generic drugs of the manufacturer Nu-Pharm from its formulary when it was found to have offered a lower price in Saskatchewan (University of Calgary, 2004). However this de-listing was contested in court by the manufacturer, who argued that Québec should not benefit from the lower price offered in Saskatchewan, since Québec does not offer the 6-month period of market exclusivity provided by Saskatchewan (see below). After several judgments and appeals, the case is now before the Supreme Court. Incidentally, Québec's listing requirements are suspected to have created a price floor for smaller provinces. According to a report by the Federal, Provincial and Territorial Taskforce on Pharmaceutical Prices (published in 1999 and quoted by University of Calgary, 2004), Saskatchewan's generic drug prices jumped by around 10% at the time of the introduction of Québec's lowest price policy.

78. Since 1998, Ontario has required that the price of the first generic listed on the formulary not exceed 70% of the brand-name product price and that prices of subsequent generic entrants not exceed 90% of the price of the first generic product. As of October 2006, generics will have to be priced 50% lower than the comparator product to be listed in the Ontario drug benefit formulary. Alberta also limits the price of generic entrants to 75% of the brand-name price. As a consequence of its own regulation requiring the "best available price", Québec benefits from the regulation adopted in Ontario. In a policy paper issued by the Québec Ministry of Health in December 2004, the government proposed to further regulate the price of generics by limiting the price of the first entrant to 60% of the originator's brand-name price and the price of following entrants to 54% of that price.

79. British Columbia is the only province using so-called internal or therapeutic price referencing. This system, established in 1995, sets reimbursement caps below the level established by PMPRB price guidelines. The reimbursement price is defined as the price of the most cost-effective drug of the therapeutic class. Reference prices exist for five therapeutic classes (see Table 2). Similarly, in 2003, British Columbia limited the reimbursement for proton pump inhibitors (PPIs) to the cost of the least expensive PPI product for first-line treatment.

80. British Columbia's reference price system was highly contested by the pharmaceutical industry. Its impact has been assessed by several independent researchers. They concluded that the public drug plan realised net savings by implementing this policy, even if the reform seems to have had a one-time effect in some drug classes with cost growth resuming at the former rate. (Grootendorst *et al.*, 2001; Marshall *et al.*, 2002, Schneeweiss *et al.*, 2002a; 2002b; 2003; Grootendorst *et al.*, 2005). Conclusions on its impact on health care utilisation and health outcomes were more nuanced. A temporary increase in physician visits was observed among people switching to the reference drug in a class of cardiovascular drugs (Grootendorst *et al.*, 2001; Schneeweiss *et al.*, 2002a; 2002b; Schneeweiss *et al.*, 2003), as well as higher hospitalisation rates for some cardiovascular procedures (Grootendorst *et al.*, 2001). These studies also showed increases in out-of-pocket payments for enrollees. A recent study raises questions about the methodology used in previous studies and concludes that, in the case of anti-hypertensive drugs, actual savings have been only about one half of the amount found previously (Grootendorst and Stewart, 2006).

81. Several plans set reimbursement prices at the level of the least costly alternative in generic groups (See Table 2). Quebec adopted such a policy with a particular feature: the rule applies only 15 years after the listing of the brand-name product in the positive list. In the interval between patent expiry and this deadline, generics are authorised and reimbursed but originator drugs are still reimbursed at their initial price.

82. Although they are based on a similar concept, lowest cost alternatives are generally better accepted by the industry than reference prices, since they only apply to generic groups after patent expiry. On the contrary, reference prices may apply to larger therapeutic groups – this is the case in British Columbia – where several brand names and, possibly, generics – are placed in price competition by the reimbursement policy. Manufacturers allege that drugs grouped in these “therapeutic groups” cannot be considered as perfect substitutes and that price constraints may lead to non-optimal choices for patients. Proponents note that it introduces price competition in markets where competition is traditionally based on differentiation of products.

83. Saskatchewan employs an original system of ‘standing offer’ for generics by which the manufacturer offering the best price for a given market obtains listing exclusivity for a given period, as well as guaranteed payment within 30 days (University of Calgary, 2005). As seen before, this policy created some tension with other provincial policies. In reaction, generic manufacturers have created affiliates to serve Saskatchewan so as to avoid demands to receive the same price elsewhere. No complete assessment of this policy was found, but the PMPRB mentions that a sharp decrease in generic prices in 1999-2001 seems to have been compensated by exceptional growth between 2001 and 2004 (PMPRB, 2006b, p. 30).

84. Reimbursement price freezes have been used in at least two provinces. Since 1994, Ontario has frozen the retail price it will pay for drugs listed on its formulary.<sup>29</sup> In Québec, prices of drugs included in the positive list are not allowed to increase, except in exceptional circumstances (such as an increase in the cost of an input).

85. In spite of these policies pertaining to reimbursement prices, it is fair to say that, at present, Canadian purchasers are not very active in pursuing low prices for pharmaceuticals. With some exceptions, Canada’s publicly financed drug plans have largely refrained from applying their significant purchasing power in price negotiations and from using their regulatory authority to obtain concessions on prices. Indeed, the development of pricing and purchasing strategies was identified as a priority work area by the federal/provincial/territorial National Pharmaceuticals Strategy (NPS).

#### ***1.3.4. Cost-sharing arrangements***

86. Both public and private plans usually require patients to contribute to the cost of medicines through some form of cost-sharing.

87. Private drug plans generally impose deductibles and copayments. Employer-sponsored drug plans have lower levels of cost sharing than do individual plans, typically setting annual deductibles at about CAN\$ 25 for individuals or CAN\$ 50 per family and copayments at 20% of the cost (however, copayments vary from 0 to 30%). In 2000, about 29% of private plans did not require any co-payment (Fraser/Tristat, 2002). Out-of-pocket payments are regularly capped at \$2,000 per year.<sup>30</sup> Enrolees may have to pay pharmacists’ fees.

88. Co-payment is the most common form of patient cost-sharing in public drug plans (see Box 5). Total out-of-pocket spending amounts are sometimes capped. Deductibles are also frequently used.

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29 However, this policy may be affected by Ontario’s new drug legislation will enable the newly created office of the Executive Officer, responsible for formulary management, to more actively negotiate formulary prices with manufacturers as of October 1, 2006 (Legislative Assembly of Ontario, 2006).

30 Personal communication from CLIHA representatives.

Enrolees sometimes have to pay pharmacists' fees. Cost-sharing requirements tend to be set at higher levels, as compared to private employer-sponsored plans.

**Box 5. Cost-sharing arrangements in selected provincial drug plans**

The cost-sharing arrangements employed in the provincial drug plans of Ontario, British Columbia, and Québec illustrate the diversity of arrangements used.

Beneficiaries of the ODB may be required to pay a part of the cost of prescription drugs. Single seniors (people aged 65 or older) who have an annual income of \$16,018 or more and seniors in couples with a combined annual income of \$24,175 or more pay a \$100 deductible per senior before they are eligible for drug coverage. After these seniors pay the deductible, they then pay up to \$6.11 towards the dispensing fee each time they fill a prescription for a covered drug product in Ontario in the benefit year (ODB website, consulted in May 2006). All other ODB eligible people, including Trillium Drug Program (a catastrophic coverage program) recipients, may be asked to pay up to \$2 each time they fill a prescription.

In the British Columbia Fair Pharmacare plan, an annual income-related deductible determines when reimbursement will begin. Once the deductible is met, the cost of prescription drugs is covered by the plan up to 70 or 75% of cost, and co-payments are capped by an annual maximum. Both the deductible and the maximum depend on the beneficiary's family income. The deductible ranges from 0 to 3% of family net income while the annual maximum ranges from 1.25 to 4% of income.

In Québec, users of the public scheme in 2006 contributed to the costs of drugs via a deductible of \$145 and a co-payment of 29% beyond this deductible. Québec residents' co-payments are limited to \$881 per year, in public as well as in private insurance. The public regime requires the payment of a means-tested annual premium, ranging from \$0 to \$538, above a revenue threshold.

Sources: websites of public plans and CIHI (2006).

89. There is some evidence of a negative impact of cost-sharing arrangements on drug use and adverse events in the Canadian context (see Box 6). Particularly important is evidence suggesting that use of essential medicines has been affected, in addition to the use of medicines judged less essential.

**Box 6. Canadian evidence on the impact of cost-sharing on drug use**

The impact of co-payments on the use of drugs has been assessed among elderly patients using rheumatoid arthritis drugs in British Columbia (Anis *et al.*, 2005). When the study was undertaken, the ingredient cost of drugs was totally covered by BC Pharmacare for people over 65 but they had to pay pharmacist fees up to a deductible of \$200. A cohort of users of rheumatoid arthritis drugs was observed between 1997 and 2000. Patterns of health care consumption were compared between “cost-sharing periods” and “free periods”, i.e. between years in which patients did not reach the deductible for co-payments and periods in which they reached it. Prescriptions filled per month were significantly higher in “free” periods than in cost-sharing periods. On the other hand, physician visits and hospital admissions per month were significantly higher in the cost-sharing periods. This suggests that the existence of co-payments on pharmaceuticals may induce substitution with other (free) medical services.

Tamblyn *et al.* (2001) studied the impact of the introduction of cost-sharing among poor and elderly persons at the time of implementation of Québec reforms. Before these reforms, beneficiaries of social assistance/welfare through Québec’s Employment Assistance Program were fully covered for drug purchases and the non-poor elderly had to pay \$2 per prescription up to an annual \$100 ceiling. Commencing in August 1996, both groups had to pay coinsurance of 25% up to an annual means-tested maximum, ranging from \$200 to \$750. A deductible, added to the 25% coinsurance fee, was introduced in 1997. As a result of these policy changes, consumption of drugs judged as essential decreased by 9% among the elderly and by 14% among welfare recipients, while the consumption of “less essential drugs” decreased by 15% and 22% respectively in the two populations. Moreover, increases in cost-sharing were associated with substantial increases in rates of adverse events (first occurrence of acute-care hospitalisation, long term care admission or death) and in emergency department visits for those who reduced their drug utilisation.

**1.3.5. Adequacy of drug coverage and financial protection against drug expenditures in Canada**

90. Adequacy of drug coverage can be assessed by the extent to which medicines are affordable and otherwise accessible to Canadians. The extent and comprehensiveness of insurance coverage are key determinants.

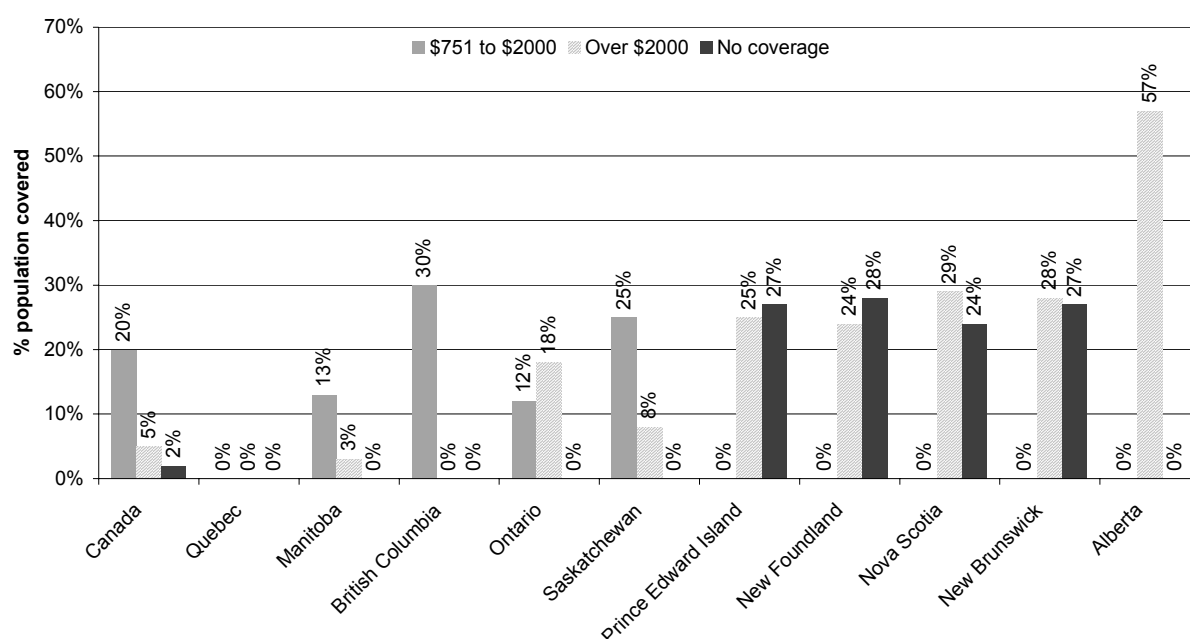
91. A report commissioned by Health Canada in 2000 provided an in-depth description of the range and extent of drug coverage in 1998 (Applied Management, 2002). The first conclusion was that the comprehensiveness of drug coverage provided by both private and public plans is very different from one province to another. Seniors receiving guaranteed income supplements and beneficiaries of social assistance are often covered by public plans and benefit from good coverage for drugs expenditures. Full-time employees also benefit from good coverage through private insurance. The report identified overlaps in eligibility to federal, provincial and private drug plans, as well as gaps, notably in the case of relocation or change of employer since many private and public drug plans impose a waiting period before enrolment (generally 3 months). In addition, the authors reported that drug coverage was not satisfactory for low-income families (above thresholds for social assistance) and “special needs groups”, i.e. young adults suffering from certain debilitating and chronic diseases (such as multiple sclerosis and schizophrenia, see pp. 67-68).

92. The report also used simulations to analyse patients’ co-payments, according to three indicators: the coverage for routine expenses (share of the first CAN\$1,000 of annual drug expense covered by the drug plan), the coverage for catastrophic expenses (proportion of the “last CAN\$1,000” covered by the drug plan for an annual expense of CAN\$50,000), and the share of family income which would be absorbed by out-of-pocket payments of CAN\$1,000. It concluded that 90% of the Canadian population has some coverage for routine expenditures and the remainder would pay every dollar if they had to face expenditures up to CAN\$1,000. People who are uninsured against routine expenditures are most often under 65 years and working. It also concluded that full coverage of the last CAN\$1000 of catastrophic

expenditures would be provided to 93% of the Canadian population. Another 4% would be required to co-pay 20% of these expenditures and another 3% (concentrated in the Atlantic Provinces and in Alberta) have no coverage against such expenditures. Finally, people for whom out-of-pocket payments of CAN\$1,000 would represent more than 4.5% of family income accounted for 2% of the Canadian population, concentrated in the same provinces and British Colombia (Applied Management, 2000).

93. A more recent report (Fraser Group, Tristat Resources, 2002) assessed the protection of Canadians against “severe expenditures” (defined as annual expenditures for pharmaceuticals ranging from CAN\$5,000 to CAN\$80,000). It concluded that “98% of the Canadian population has some form of public or private coverage that provides a degree of protection against severe drug expenses”. The report shows also that some people would face non-negligible out-of-pocket payments in case of exposure to severe drug expenditures (CAN\$20,000, see Figure 3). Almost all residents of Québec, Manitoba, Ontario, British Columbia and Saskatchewan would be protected against out-of-pocket payments exceeding CAN\$2,000 per year, while only one half of residents of Alberta and the Atlantic provinces would be. Altogether, it estimated that 89% of Canadian citizens were protected against exposure to severe drug expenses (as defined above), 9% of Canadian citizens were only partially protected and 2% were unprotected.

**Figure 3. Share of population that would have to pay more than CAN\$750 out-of-pocket in case of exposure to annual drug expenses of CAN\$20,000**



Source: Fraser Group/Tristat Resources, 2002

94. The fact that 10% of the Canadian population has to pay every dollar for routine drug expenditures and that 2% of the population is not even covered against severe expenditures undoubtedly creates some financial barriers to access, particularly as those without coverage tend to be poorer. However, such financial barriers arise in the context of a health system which otherwise offers universal coverage of all needed medical services at no charge (zero cost-sharing) to the patient.

95. Somewhat surprisingly, there are few studies of the impact of lack of insurance in Canada on prescription drug use and implications for health or other outcomes. The accessibility problems caused by lack of drug coverage are ameliorated, in part, by the existence of catastrophic coverage programs in several jurisdictions and the availability of publicly-financed programs covering drugs for particular

diseases and populations, including those on social assistance. Because of such programmes, many of those with greatest need for coverage should be able to obtain it.

96. Underinsurance, variously defined, also leaves some Canadians at risk of reduced access to medicines and/or spending a significant proportion of income on pharmaceuticals. Since the mid-1990s, increased premiums, deductibles, or co-payments have greatly reduced the generosity of benefits furnished in Canadian provincial drug plans (Grootendorst, 2002 as cited in Morgan, Barer and Agnew, 2003). Although some stakeholders and experts are concerned about the ramifications of underinsurance, as well as inequities across groups in the levels of coverage, there is little information available about the impact of underinsurance on the health or financial situation of Canadians.

97. There is some evidence of financial barriers to access in Canada, indicating problems with the levels of insurance coverage. In a survey of patients conducted by the Commonwealth Fund, 20% of Canadian sicker adults<sup>31</sup> did not fill a prescription because of cost in the past 2 years. This is comparable to the percentages recorded in Australia (22%) and New Zealand (19%), and far better than that observed in the United States, where this percentage reaches 40%. However, financial access to drugs seems to be better in the UK (8%) and in Germany (14%) (Schoen *et al.*, 2005).

#### *1.3.5.1. Canadian proposals for improving drug coverage*

98. The need for catastrophic coverage was limited when most of the public drug plans were designed, but it is more important today, given the increase in drug costs per individual. This need has been acknowledged recently in two prominent policy reports produced by the Romanow Commission and the Kirby Committee (Commission on the Future of Health Care in Canada, 2002; Standing Senate Committee on Social Affairs, Science and Technology, 2002).

99. The Romanow report advocated the integration of prescription drugs into the insured benefits guaranteed by the *Canada Health Act*. It argued for a gradual integration in order not to threaten the sustainability of the system and recommended first the introduction of a new federal financial transfer aimed at high-expense individuals to help provinces and territories to better cover the costs of prescription drug plans. It defined the threshold for catastrophic expenses as being \$1,500 out-of-pocket per individual, and proposed catastrophic coverage in the form of a federal contribution of 50% of costs per individual exceeding \$1,500.

100. The Kirby Committee report proposed to cap out-of-pocket payments (at 3% of income for enrollees in public provincial drug plans and at \$1,500 for those enrolled in private drug plans) and to establish federal funding for 90% of any payment per patient exceeding \$5,000 a year (including payment by the plan). This solution would both protect citizens against catastrophic expenditures and limit the financial responsibility for provincial payers and private insurers. However, national catastrophic drug coverage has not yet been implemented.

101. Another approach to addressing perceived problems in the current system of coverage that has been discussed in Canada is to create a comprehensive national system of coverage. The creation of a federal Pharmacare program<sup>32</sup>, originally evoked by the National Forum on Health in 1997, was proposed again during the meeting of Canada's Premiers and Territorial Leaders (the First Ministers from each

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31 "Sicker adults" are adults who rated their health as fair or poor, who had a serious illness, injury or disability that required intensive medical care in the past two years.

32 Québec would maintain its own program and would receive compensation comparable to the costs of the program put in place in other provinces and territories.

province or territory) in July 2004, but was not kept on the agenda of the new National Pharmaceuticals Strategy (NPS) defined for Canada in September 2004 (see Box 7).

#### **Box 7. Developing a new national strategy for pharmaceuticals in Canada**

In September 2004, First Ministers agreed to a National Pharmaceuticals Strategy. They agreed that no Canadian should suffer undue financial hardship in accessing needed drug therapies, and that affordable access to drugs is fundamental to equitable health outcomes for all Canadians. They established a Ministerial task force to develop this strategy and charged it with the following responsibilities: develop, assess and cost options for catastrophic drug coverage; establish a common national drug formulary for participating jurisdictions based on safety and cost-effectiveness; accelerate access to breakthrough drugs for unmet health needs through improvements to the drug approval process; strengthen the evaluation of 'real world' (i.e., post-market) drug safety and effectiveness; pursue purchasing strategies to obtain best prices for drugs and vaccines; enhance action to influence the prescribing behaviour of health care professionals so that drugs are used only when needed and the right drug is used for the right problem; broaden the practice of e-prescribing; accelerate access to non-patented drugs and achieve international parity on prices of non-patented drugs; and enhance analysis of cost-drivers and cost-effectiveness, including best practices in drug plan policies.

A public report on NPS progress was issued on September 21, 2006. See [http://www.hc-sc.gc.ca/hcs-sss/pubs/care-soins/2006-nps-snpp/index\\_e.html](http://www.hc-sc.gc.ca/hcs-sss/pubs/care-soins/2006-nps-snpp/index_e.html)

102. In a recent paper, Marchildon (2005) advocates the creation of a 'Federal Pharmacare' programme in order to concentrate all relevant regulatory power and administrative, delivery and funding functions at the federal level and thus clarify respective roles of the different levels of government and address corresponding funding issues. According to the author, expected costs of such a program could range from \$8 billion (if the federal program just replaces existing provincial and territorial programs) to \$19 billion (if the program provides universal first-dollar coverage). Under a scenario of universal coverage with co-payments set at the level of the most generous provincial plans, and the inclusion of hospital drugs in the federal program (to avoid cost-shifting between out-patient and in-patient sectors), the estimated cost is \$12 billion.

#### **1.4. Policies and other initiatives intended to influence pharmaceutical consumption**

103. Canada uses a range of policies to influence physicians' prescribing practices, dispensing by pharmacists, and use of medicines by patients. As is true in the United States, these policies are more geared towards educational measures than towards binding constraints: physicians' and pharmacists' professional autonomy is emphasized.

##### ***1.4.1. Publicly financed assessment of health technologies and prescribing practices***

104. The Canadian Agency for Drugs and Technology in Health (CADTH)<sup>33</sup> is responsible for furnishing Canada's federal, provincial and territorial health care decision makers<sup>34</sup> (with the exception of

33 Until April 2006, the CADTH was known as the Canadian Coordinating Office for Health Technology Assessment (CCOHTA). The name change was intended to better reflect the organisation's mandate and activities.

34 Specific target audiences for the work include drug plan managers, regional health authorities, federal and provincial government policy makers, hospital administrators and healthcare professionals.

Québec) with assessments of the evidence and advice about the effectiveness and efficiency of drugs and other health technologies. In addition to responsibility for the Common Drug Review (discussed above), the agency has two other main areas of work in the field of pharmaceuticals: health technology assessment and promotion of best practices in drug prescribing and use.

105. Under CADTH's Health Technology Assessment Program, multidisciplinary teams of researchers are convened to review and interpret evidence regarding the clinical effectiveness, cost-effectiveness and other impacts of drugs and medical technologies for patients and health systems. Proposals for assessment subjects are solicited from decision makers and the public at large. The program's products include full reports, overviews and updates. It also produces reports describing issues relating to emerging health technologies and maintains a list of emerging drugs to aid planning efforts.

106. The Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) is a relatively new programme administered by CADTH to identify and promote best practices in drug prescribing and use. Priorities for work by COMPUS are identified by a committee – using criteria such as evidence of over- or under-use, size of patient population, and ability to measure outcomes – and approved by federal, provincial and territorial deputy ministers of health. The first three priorities were identified as proton pump inhibitors (drugs for gastrointestinal problems), diabetes management, and anti-hypertensives. A report on proton pump inhibitors was released in 2006. Key products of COMPUS are reports that rate the quality of evidence supporting practice guidelines developed by others. COMPUS itself does not create guidelines for drug prescribing and use. Future plans include tool kits to help provinces and territories wishing to implement guidelines.

107. It is too early for the accumulation of adequate evidence through which to assess the influence of COMPUS in improving drug prescribing and use. While the decision not to issue specific practice guidelines may help avoid criticisms of government-dictated medical practice or promotion of “cookbook medicine” – problems which caused a US agency with similar responsibilities to cease production of guidelines under pressure – COMPUS' findings may be more difficult to communicate clearly and, ultimately limit the ability to influence prescribing patterns and use. On the other hand, perceived success in accomplishing its current mission may well lead to enhanced trust and authority in future, as was apparently the case for the evolution of health-technology assessment from reports to support for reimbursement recommendations by CEDAC.

#### ***1.4.2. Efforts by third-party payers to influence drug prescribing and dispensing behaviour***

108. At present, Canada's private health insurance plans do not have many policies in place that are intended to influence how pharmaceuticals are prescribed or dispensed. While so-called pharmaceutical benefits management firms (PBMs) are employed by some insurers, their actions at present are restricted to prescription claims and data management. In the United States, by contrast, PBMs take a more active role in managing drug dispensing.

109. Canada's public plans provide efforts to encourage appropriate prescribing behaviours. For the most part, these efforts concentrate on formulary management (prior authorisation, restricted listing). However, public drug plans increasingly produce prescription guidelines<sup>35</sup> and some of them provide feedback to doctors on their prescribing patterns<sup>36</sup>. By contrast with third-party payers in some OECD

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35 For example, the Ontario government has, in the past, subsidized the production of a series of guidelines covering different systems (e.g., gastrointestinal), and it continues to produce guidelines for antibiotics.

36 e.g., In Nova Scotia physicians have been providing feedback on their prescribing patterns (Sketris et al. 2004c; Sketris et al., 2005).



countries<sup>37</sup>, public plans do not set prescription spending targets or budgets for physicians and do not use any kind of financial incentives to influence doctors' prescribing.

110. Public drug plans are more active in promoting and ensuring appropriate dispensing. A first set of rules pertain to maximum "supply per prescription" policies. Most drug plans limit drug supply per prescription to a given period. For instance, British Columbia Pharmacare is limited to a 30-day supply for the first prescription fill of a given drug and to 100-day supply for subsequent refills (Anis *et al.*, 2005).

111. Some drug plans introduced incentive fees for pharmacists. For instance, both Québec and British Columbia compensate the pharmacist fee when the pharmacist refuses to deliver a drug because of potential interactions with other treatments. Nova Scotia introduced a special fee for educating patients in the use of metered dose inhalers for respiratory drugs when it decided to restrict the prescription of respiratory nebulisers to some categories of patients (Murphy *et al.*, 2005).

112. More recently, several public drug plans implemented drug utilisation reviews (DURs). For instance, the NIHB implemented a DUR at the point of service in order to monitor potential drug interactions and avoid duplicate therapies (NIHB Drug benefit list, April 2006). Drug utilisation reviews also allow retrospective analysis of the frequency of potential dangerous interactions. However, in 2004, the Auditor General of Canada wrote that these utilisation reviews were under-used by public drug plans.

#### *1.4.2.1. Policies relating to prescribing and dispensing of generic products*

113. In addition to patent policy and policies pertaining to the approval process, a number of other policies affect the prescribing and dispensing decisions that determine the share of prescriptions that are filled with generic formulations of pharmaceutical products.

114. Provinces usually establish lists of interchangeable products after generic market approval by Health Canada. These lists generally apply only to public drug plans but some provinces (British Columbia, Manitoba, New Brunswick and Nova Scotia) extended inter-changeability rules to the whole market (see Skinner, 2004). This means that provincial scientific committees re-assess the equivalence of generic drugs imposing further delays for substitution and introducing discrepancies in substitution possibilities across provinces (Public Policy Forum, 2006). Generic manufacturers claim for immediate inter-changeability after Health Canada approval. This rule already applies in British Columbia where, since mid-2003, pharmacists have been allowed to rely on data published by Health Canada or on information from their professional association to make judgements on drug interchangeability (BC College of Pharmacists, 2004).

115. Financial incentives for generic utilisation differ from one province to another but are generally directed to patients rather than to pharmacists. They consist of reimbursement policies that require patients to pay out-of-pocket the difference between the retail price and the reimbursement level for a drug included in a reference group of interchangeable drugs.

116. As a result of discrepancies among provincial policies, there is significant variation across Canada in the extent to which generic alternatives are dispensed in place of brand-name products, providing an indication of the impact of policies relating to prescribing and dispensing of generics. For instance, generic products were dispensed for only 38% of prescriptions filled in Québec during 2005, compared with 49% in British Columbia (IMS Health, 2006).

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37 For example, prescription spending targets are used in Germany whereas fixed budgets are allocated to UK primary care trusts to treat their patients (Walley and Mossialos, 2004).

117. In hospitals, payment schemes provide strong incentives for cost-containment. Once a generic version of a medicine is approved by Health Canada, hospital purchases concentrate on the generics and avoid using the original brand-name product.

## 1.5. Innovation policies

118. Policies providing incentives to innovate are important in shaping pharmaceutical markets. Such policies include direct or indirect subsidies for R&D investments, and protection of intellectual property rights allowing manufacturers to recoup R&D expenditures through pricing based on market exclusivity. This section provides a brief overview of innovation policies in the Canadian context.

### 1.5.1. Intellectual property rights

119. Overall, Canada's drug patent policy aims to achieve a balance between adequate patent protection and timely introduction of generic drugs. Adequate patent protection is needed to encourage the development of better drug therapies, while timely introduction of generic drugs, coupled with patented medicine price regulation, helps to contain drug costs.

120. The *Patent Act* of 1923 and its subsequent amendments define patent rights in Canada. Before 1987, intellectual property rights protection for patented drugs was not among the highest: patents pertaining to drug and food were for shorter terms than in some other developed countries, and were subject to compulsory license<sup>38</sup> to manufacture (since 1923) and to import (since 1969).

121. In 1987, amendments to the *Patent Act* were introduced (Bill C-22) to enhance patent protection of pharmaceuticals<sup>39</sup>. These amendments guaranteed an increase in protection against compulsory licensing after market approval: 10 years against compulsory licensing to import and 7 years against compulsory licensing to manufacture. They also introduced the ability to issue product patents to complete the protection offered by process patents. As well, the patent protection period was extended to 20 years from date of filing instead of the previous system granting 17 years from date of patent's issue.

122. In 1993, following negotiations related to the General Agreement on Tariffs and Trade (GATT) and the North American Free Trade Agreement (NAFTA), the government passed Bill C-91, which substantially amended Canada's drug patent policy. Most notably, C-91 repealed Canada's longstanding compulsory licensing regime for patented drugs<sup>40</sup> and introduced in its stead what is commonly called the "early-working" exception, as well as a provision to ensure that generic drugs will not be marketed before patent expiry.

123. The "early-working exception" allows generic manufacturers to use the patented invention without the patentee's authorisation for the purpose of obtaining approval of a generic product before the patent expiration date. Originally, Bill C-91 authorised generic manufacturers to create stocks of their

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38 A regime of compulsory licensing allows generic manufacturers to make and sell generic versions of patented drugs before patent expiry, in exchange for royalty payments to patent holders,

39 These amendments also introduced the prices regulatory body, which later became the PMPRB.

40 As of May 2005, Canada permits compulsory licenses to be issued to manufacturers to produce certain drugs for export to a developing country for treatment of designated public health problems (e.g., HIV/AIDS, tuberculosis, malaria and other epidemics), providing the ability for Canada to export generic versions of patent-protected drugs to eligible importing countries unable to manufacture their own. [See <http://www.ictsd.org/weekly/03-10-15/story5.htm>].

products up to six months before patent expiry, but Canada repealed this provision to comply with a World Trade Organisation ruling against it.

124. However, to prevent generic manufacturers from selling their approved drugs before patent expiry, Bill C-91 introduced the *Patented Medicines (Notice of compliance) Regulations*. This provision requires patentees to provide Health Canada with the list of valid patents linked to any product when seeking approval. Generic manufacturers have to check dates of patent expiry of listed patents before marketing their drugs or to make an attestation explaining why their product is not infringing on current patents. If the patentee disagrees, litigation ensues and an automatic stay is triggered that bars Health Canada from issuing the generic product a marketing authorisation for 24 months, until the litigation is resolved or the patent expires, whichever comes first.

125. In recent years, provisions aiming at protecting patent rights have been used by manufacturers of some top-selling patented drugs to delay generic entry through what is commonly called “ever-greening” strategies. In particular, brand-name companies were suspected of routinely protecting old products by new patents in order to trigger multiple 24-month stay periods against generic market entry (Government of Canada, 2004a and 2004b).

126. In light of the above, the Departments of Industry and Health developed a joint package of regulatory amendments designed to bring a greater degree of stability and predictability to the pharmaceutical marketplace by establishing a firmer upper and lower boundary to the period during which brand-name drugs enjoy market exclusivity. These amendments were conceived in response to specific concerns expressed by stakeholders following pre-publication of the proposed amendments in *Part I* of the *Canada Gazette* on December 11, 2004. Following extensive consultations with industry stakeholders, a revised set of amendments came into force on October 5, 2006 and was published on October 18, 2006 in the *Canada Gazette*, Part II<sup>41</sup>.

127. Amendments to the *PM(NOC) Regulations* will facilitate the market entry of a generic version of the original form of a brand-name drug immediately following expiry of the relevant patents, as was originally intended, while at the same time allowing brand-name companies to duly protect improvements to the original form of the drug that are innovative and therapeutic (so-called “incremental innovation”). There are two primary means by which the market entry of generic drugs would be facilitated: (1) through the so-called “freezing” of Health Canada’s patent register; and, (2) by reaffirming the rules for listing patents on the register. The freezing of the register would prevent any patent arising after the date the generic files its regulatory submission with Health Canada from triggering additional 24-month stays against that company.<sup>42</sup> In terms of reaffirming the rules for listing patents on the register, the proposed amendments entrench the concept of product specificity as the key consideration required of the Minister of Health in applying the listing requirements under section 4 of the *PM(NOC) Regulations*. They do so through more precise language respecting the intended link between the subject matter of a patent on a patent list and the content of the underlying submission for a marketing authorisation in relation to which it is submitted. In addition, under the amendments, only certain clearly defined submission types would provide an opportunity to submit a new patent list.

128. Health Canada’s amendments to the Food and Drug Regulations address the issue of data protection for pharmaceuticals and bio-pharmaceuticals. Both the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the North American

41 See <http://canadagazette.gc.ca/partII/2006/20061018/html/sor241-e.html>.

42 This approach is inspired by recent amendments in the United States in response to similar strategic behaviour on the part of brand-name companies there.

Free Trade Agreement (NAFTA) require that test data be protected from unfair commercial use. NAFTA defines a minimum period of time for the protection as “not less than five years”. The amended regulations provide 8 years of data protection for new and innovative drugs from the date on which marketing authority is granted. A subsequent manufacturer is prohibited from filing its submission for the first six years of this period. A further 6 months of protection is provided for drugs that have been subject to paediatric clinical trials. This is longer than in the United States, which provides 5 years during which a generic submission cannot be filed, and an additional three-year period for improvements to the drugs as well as an additional 6 months for drugs that have been tested in paediatric populations. Recently passed EU legislation grants 8 years of data exclusivity and an overall 10-year period of market exclusivity, which can be extended by one year in case of the approval of a new indication with significant therapeutic value in the first 8 years of marketing, and by one year for OTC switch (in addition to the 6 months granted for paediatric products). According to officials, under the former Canadian regulations, data exclusivity was less than 8 years only in 22% of cases, which means that the new regulation would affect only a part of the market.

129. Unlike in the US and in Europe, there is no ‘complementary protection’ after patent expiry (commonly called “patent-term restoration”) to compensate for long regulatory delays of patented products. The effective length of market exclusivity in Canada is not easy to assess since two regimes are still in force for marketed drugs (drugs patented before 1989 were granted shorter patent protection). The actual market exclusivity (the time between launch and first generic entry) was estimated for a sample of 73 molecules by Health Canada (document provided by I respectively ndustry Canada for 2003): average and median market exclusivity were 12.9 and 11.4 years, respectively. However, a few products experienced much shorter periods of market exclusivity (3 to 5 years)<sup>43</sup>.

130. Unlike a number of other OECD countries, Canada does not have any specific IPR policy aimed at encouraging R&D for orphan drugs, such as extended patent protection. In a policy paper issued in the 1990s, Canadian authorities concluded that Canadian patients were able to benefit from new drugs discovered in foreign countries and that there was no need to foster national innovation in this sector (Health Canada report of 1997 quoted by the Canadian coalition for rare disorders, 2005). However, BioteCanada (2004)<sup>44</sup> calls for the implementation of such a policy in order to take advantage of the good development of the biotech industry in Canada to develop biotech orphan drugs.

### ***1.5.2. Other policies intended to promote innovation***

131. In 2002, Canada launched an innovation strategy,<sup>45</sup> aimed at improving public and private investments in R&D, further developing labour force skills, improving the business environment and fostering community-based innovation. Each strategic goal was assigned more specific targets, such as “rank in 2010 among the Top 5 countries in terms of R&D performance” or “develop at least 10 internationally recognized technology clusters”. According to an assessment produced by the Conference Board of Canada, results of this policy are mixed in the sense that very ambitious targets have not always been met (OECD, 2006). However, some measures are likely to be beneficial to the pharmaceutical sector.

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43 Other products experienced very long periods of market exclusivity (24 to 36 years), but in these cases, the relative roles of regulation and attractiveness of the market for generics cannot be easily distinguished.

44 BioteCanada is a not-for-profit association representing the interests of biotech companies. However, BioteCanada (2004)<sup>44</sup> calls for the implementation of such a policy in order to take advantage of the good development of the biotech industry in Canada to develop biotech orphan drugs.

45 This overview relies on a summary presented in the forthcoming OECD Economic Survey of Canada 2006.

132. One of the first goals of this policy was to increase public and private expenditures on R&D with the target of ranking among the top five countries in the world in terms of R&D performance by 2010. In the health field, R&D expenditures have increased faster than in other sectors since the 1990s and now represent a larger share of total gross domestic expenditures on R&D (23% in 2005 versus 15% in 1990). In 2005, gross domestic expenditures on R&D in the health field were estimated at almost \$6 billion, of which 33% was funded by business enterprises and 52% by the public sector (federal, provincial and higher education). The higher education sector – including teaching hospitals – plays a major role in conducting health-related R&D (62%) while business enterprises conduct about 27% of it (Statistics Canada, 2006). However, these figures relate to total health-related R&D and the share of business funding is higher when the pharmaceutical sector is considered alone.

133. Tax credits for R&D expenditures constitute another form of incentive. The Canadian Scientific Research and Development (SR&D) tax credit applies to current and capital expenditures on eligible R&D activities and is designed to favour small companies. The tax credit amounts to 35% of refundable expenditures under a threshold, defined at different levels according to the size of the company. (100% of current expenditures and 40% of capital expenditures under this threshold are refundable). Small companies benefit from an additional 20% tax credit for 40% of total expenditures (current and capital) beyond a defined threshold (generally \$2 million). Provinces provide additional tax subsidies for R&D, with wide variations, Québec being the most generous (McKenzie and Kenneth, 2005).

134. The regulation of patented medicine prices by the PMPRB may also, to some extent, be considered as an innovation-related policy geared towards the pharmaceutical sector. The seven comparator countries used for the assessment of the median international price were chosen among the greatest investors in pharmaceutical innovation. Moreover, price regulation was accepted by the patented medicines industry as part of an arrangement in which the industry committed to increasing R&D investment in Canada in exchange for extended patent protection.

## 2. PHARMACEUTICAL MARKET CHARACTERISTICS

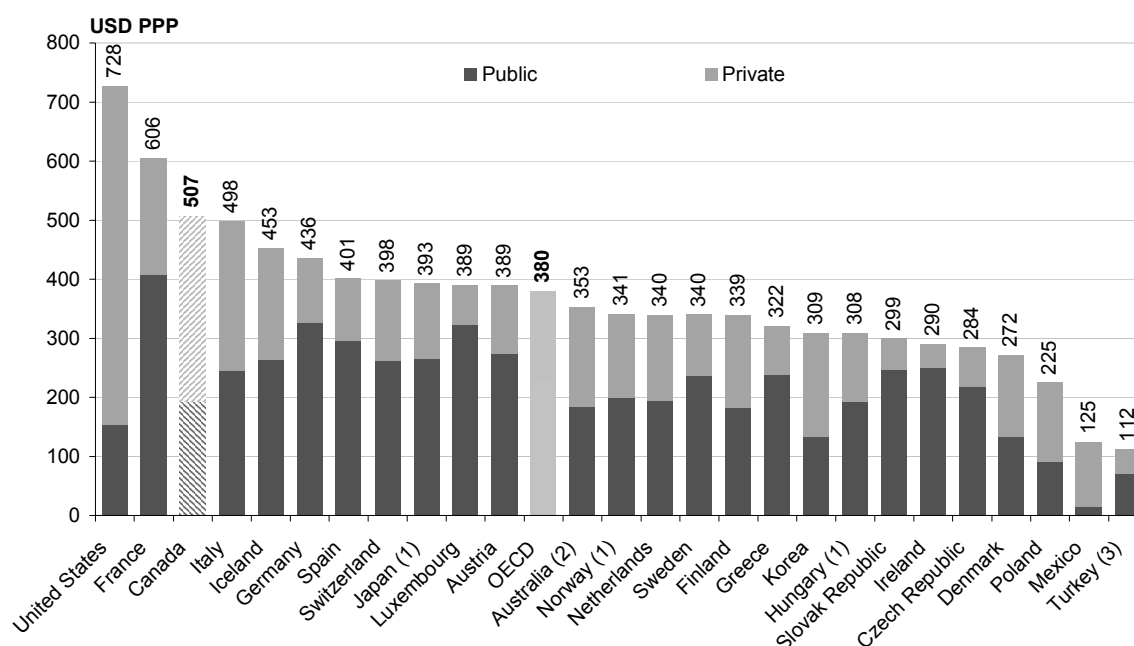
135. This section reviews various components of the pharmaceutical market in Canada, including expenditure trends and components of spending, pharmaceutical production, supply and trade.

### 2.1. Expenditures

#### 2.1.1. Drug spending levels and time trends

136. Canada spent CAN\$24.8<sup>46</sup> billion for drugs in 2005, i.e., CAN\$ 770 per capita (CIHI, 2006). These expenditures represent 17.5% of total health expenditures and 1.9% of Canada's GDP.

**Figure 4. Drug expenditure per capita, public and private spending, 2003**



Converted to USD using purchasing power parities (PPPs)

1) 2002; 2) 2001; 3) 2000.

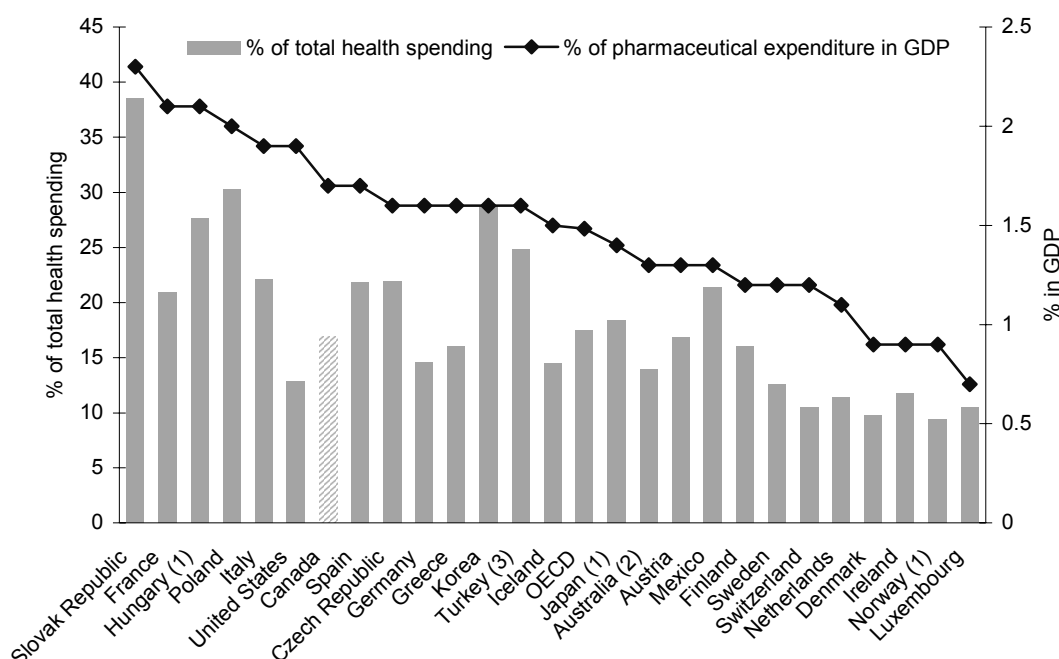
Source: OECD HEALTH DATA 2005, June 05.

137. In 2003, Canada ranked third among OECD countries in expenditure per capita on pharmaceuticals, far behind the United States and France but 65% above the OECD average (Figure 4).

46 This estimated total represents the final cost to consumers, including dispensing fees, mark-ups, and appropriate taxes. Total drug expenditure includes expenditure on prescribed drugs and non-prescribed drugs (over-the-counter drugs and personal health supplies). The figure does not reflect expenditure on drugs dispensed to hospital inpatients.

Canadian drug expenditures represent a relatively high share of the country's GDP in comparison with most OECD countries, except for the United States, France, Italy and those Eastern European countries that have experienced very rapid recent growth in drug expenditures (see Figure 5). By contrast, the share of total health expenditure devoted to drugs is slightly lower in Canada than the OECD average and similar to Austria, Finland and Greece. However, Canada's high per capita expenditure on health care may be an explanatory factor.

**Figure 5. Share of pharmaceutical expenditure in GDP, and share in total health spending, 2003 or latest available year**



1) 2002; 2) 2001; 3) 2000

4) The OECD average excludes Belgium, New Zealand, Portugal and the United Kingdom.

Source: OECD HEALTH DATA 2005, October 05.

138. Expenditures vary widely across Canadian jurisdictions, ranging from CAN\$ 481 per capita in Nunavut to CAN\$ 836 per capita in Ontario and New Brunswick (See Table 3).

139. Cross-provincial differences have been analysed using IMS data on sales of prescription medicines<sup>47</sup>, which differ somewhat from expenditure estimates. Variations across the provinces in the value of drug sales per person<sup>48</sup> were primarily the result of differences in the volume of drugs consumed, a part of which could be explained by difference in the age structure of the population (Morgan *et al.*).

47 These estimates are based on sales (at ex-manufacturer prices) of oral solid prescription drugs (which account for about 80% of the total drug market), collected by IMS. Accordingly, average amounts by province presented in this study do not correspond to average expenditures presented in CIHI estimates, which include OTC drugs, mark-ups of distributors and administrative costs of public drug plans. Moreover, deviations from the national average are significantly different in these two estimates, probably reflecting differences in usages of OTC drugs, hospital drugs and injectibles.

48 In 2004, prescription drug sales revenue in Canadian provinces ranged from \$312 per capita in Saskatchewan to \$486 per capita in New Brunswick, a differential of 56%.

2005). Some differences across provinces were also found in the mix of drug classes and types of drugs purchased within particular classes used, but these differences did not play a major role in explaining spending differences. Prices were not an important explanatory factor, as only relatively minor cross-provincial differences in prices were found.<sup>49</sup>

**Table 3. Drug expenditure by province/ territory and Canada, 2005**

	Total drug expenditure			Public drug expenditure	Private drug expenditure	Prescribed drug expenditure		Public coverage of prescribed expenditure
	\$ million	% THE	\$ Per capita	\$ million	\$ million	\$ Per capita	% TDE	% Rx exp.
New Labrador	380.4	16.8	737.3	243	494	630.5	85.5	38.6
Prince Edward Island	95.8	16.7	691.7	194	498	545.5	78.9	35.5
Nova Scotia	728.4	17.2	775.8	242	534	627.7	80.9	38.5
New Brunswick	628.3	19.2	836.0	227	609	701.6	83.9	32.3
Québec	5,860.5	20.0	775.6	341	435	674.4	86.9	50.5
Ontario	10,485.6	18.2	836.8	313	524	693.2	82.8	45.1
Manitoba	804.7	14.3	686.3	291	396	571.0	83.2	50.9
Saskatchewan	674.8	15.4	677.9	265	412	554.2	81.8	47.9
Alberta	2,285.0	14.7	707.3	269	438	566.1	80.0	47.6
British Columbia	2,771.3	15.1	651.5	219	432	521.1	80.0	42.1
Yukon Territory	20.9	11.0	667.8	370	298	540.1	80.9	68.5
Northwest Territories	24.6	8.3	569.6	340	230	485.6	85.3	70.0
Nunavut	14.5	4.5	481.7	259	223	398.4	82.7	65.0
<b>Canada</b>	<b>24,774.8</b>	<b>17.5</b>	<b>769.68</b>	<b>295</b>	<b>475</b>	<b>640.5</b>	<b>83.2</b>	<b>46.0</b>

Source: CIHI report 2006, 13

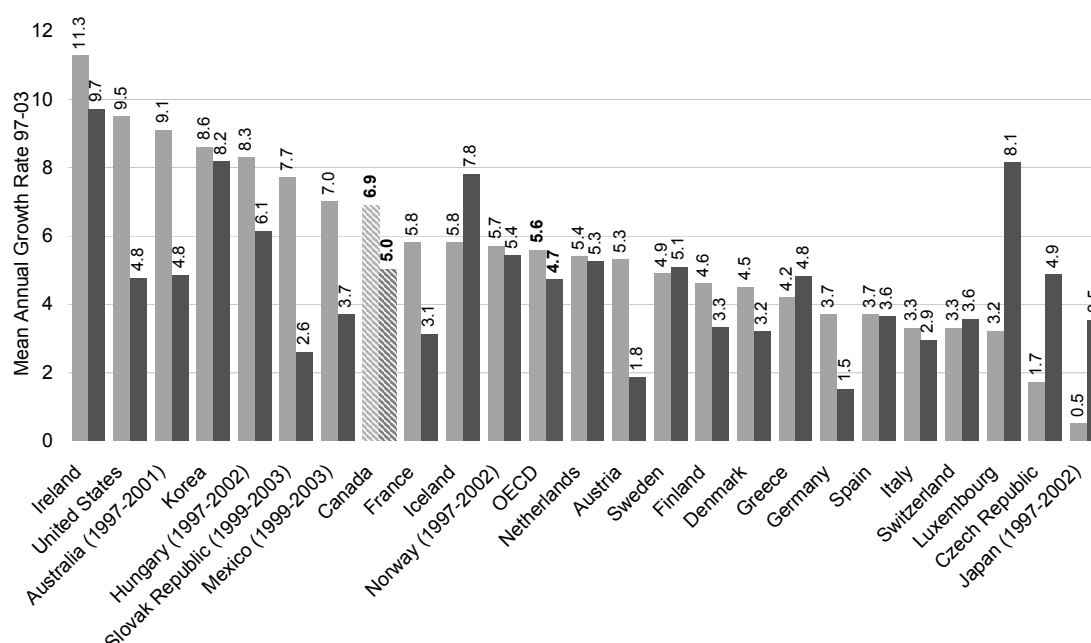
140. As in most OECD countries, Canadian drug expenditures have been increasing more rapidly than other major components of health expenditure (see Figure 6). Between 1999 and 2003, Canada

<sup>49</sup> The small price differentials seen were considered to be primarily a result of different levels of dispensing fees, which could not be adjusted for in the price data provided for the study by IMS Health.



experienced a 6.9% real annual growth of pharmaceutical expenditures, above the OECD average growth rate of 5.6%.

**Figure 6. Real annual growth in pharmaceutical spending and total health expenditure (net of pharmaceutical expenditure), 1997-2003**



Source: OECD Health Data 2005.

141. Price trends (described below) suggest that annual growth in drug expenditures has been essentially due to increases in volumes and changes in therapeutic mix. A study conducted by Morgan *et al.* (2005) on growth in sales revenues for oral solid prescription drugs between 1998 and 2004 supports this hypothesis. The annual average growth rate was 11.9%, of which 8.4% was due to volume increases, 2.9% to changes in the therapeutic mix and -0.3% to price effects (the offset essentially reflecting generic substitution).

### **2.1.2. Drug expenditure disaggregated by pharmaceutical types**

142. Prescribed drugs accounted for 83.2% of total drug expenditures in 2005, and this share has been increasing over time. In 1985, they were responsible for only 67.5% of total drug expenditures (CIHI, 2006). Expenditures for non-prescribed drugs include both over-the-counter drugs (CAN\$ 2.23 billion or 9.0% of total drug expenditures in 2005) and personal health supplies such as dental floss and disposable diabetic syringes (CAN\$ 1.93 billion, 7.8% of drug expenditures). Compared with other OECD countries for which data are available, Canada's level of OTC consumption seems rather low<sup>50</sup>.

143. Expenditures for hospital drugs accounted for CAN\$ 1.5 billion in 2003, representing 7% of prescription drug expenditures in Canada. Again, there are wide variations across provinces, with

50 Data are available only for Canada, Denmark, Finland, France, Germany, Japan, Korea, Slovak Republic, Spain, and Switzerland in 2003. For these countries, the average per capita expenditures for OTC drugs is 62 US(PPP)\$ -versus 49 in Canada and the average share in total expenditures for drugs is 16% -versus 9.6% in Canada.

expenditures for hospital drugs ranging from CAN\$ 37 per capita in Prince Edward Island to CAN\$ 58 in New Brunswick. Hospital drug expenditures range from an average of CAN\$ 44.8 per inpatient day in Nova Scotia to \$76 in British Columbia<sup>51</sup>. According to IMS data on manufacturers' sales in Canada<sup>52</sup>, hospital drugs accounted for 11.6% of total prescription drug sales in Canada in 2005 and the market is growing at twice the rate of the ambulatory market (IMS Health, 2006).

144. Canada is one of relatively few OECD countries – along with the United States, Germany, and the United Kingdom – in which generic products account for a relatively large share of drug consumption (Danzon and Furukawa, 2003). Generic drugs represent 16.8% of Canadian pharmaceutical sales and 42.7% of prescriptions in the 12 months ending June 2005, with significant variations across provinces, ranging from 37.5% in Québec to 49.5% in British Columbia (Canadian Generic Pharmaceutical Association (CGPA) website consulted on March 21st, 2006). In addition, generic prescription is increasing faster than prescription of brand-name medicines. According to IMS Health, generic drugs accounted for 50% of the growth in the number of prescriptions in 2003. Generics represented the majority of prescriptions for antibiotics and analgesics, and about 90% of diuretics in 2003.

### ***2.1.3. Volume of pharmaceutical consumption***

145. The number of prescriptions filled in Canadian retail pharmacies has increased significantly over the past 10 years, from 228.2 million in 1995 to 395.8 million in 2005, according to IMS Health calculations, an increase of 73%. Considered in per capita terms, this equates to an increase in the number of prescriptions filled from an average of 7.8 to approximately 12 per year.

146. The number of annual prescriptions per person also varies widely across Canadian provinces, from a low of 9 in British Columbia to a high of 20 in Québec in 2005 (IMS Health, 2006). Among the factors explaining this variation are differences in the period of time for which a drug is normally prescribed. Prescriptions in Québec are normally smaller in terms of the quantity of dosages than are those of other provinces; therefore, a greater number of prescriptions are issued for the treatment of chronic conditions or extended spells of illness. Differences in the age composition of the population,<sup>53</sup> as well as differences in policies or practices that influence prescribing behaviour, may also explain some of the variation.

147. Both in terms of the average number of prescriptions filled and the range of variation across jurisdictions, Canada appears roughly similar to the United States, where the average number of prescriptions per capita in 2004 was 10.6, with variation across states ranging from 6.5 (in Alaska) to 15.4 (in Kentucky) (Kaiser Family Foundation, 2006).

148. Although prescription data are interesting, they provide a less-than-ideal measure of the change in the volume of drug consumption over time. No information is publicly available by which to assess the volume of pharmaceuticals consumed in Canada in terms of the so-called “defined daily dose (DDD)” standard or other comparable metric (Sketris *et al.*, 2004a). This makes it difficult to assess how the

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51. These figures need to be interpreted cautiously since categories of drugs dispensed in hospitals and covered in ambulatory care may vary from one province to another. For instance, cancer or HIV drugs are dispensed in ambulatory care in some provinces but only by hospitals in some provinces.

52. Market shares are measured at ex-factory prices whereas expenditures are measured at public prices. Differences in distribution costs in ambulatory and hospital care explain differences in the share of hospitals in market sales and in pharmaceutical expenditures.

53. Canadians aged 80 and over fill an average of 73 prescriptions per person in retail pharmacies, compared with less than 6 per person for those under age 39 (IMS, 2006).

increase in consumption of prescription medicines over time compares with trends outside Canada, although significant consumption growth in several important therapeutic classes of medicines tracked across OECD countries is evident among those countries reporting such data (*OECD Health Data*, 2005).

149. Cooke *et al.* (2005) compared the consumption of statins among elderly patients covered by public drug plans in Nova Scotia and in Queensland, Australia between 1997 and 2001. Patterns of consumption were found to be very similar. The use of statins increased sharply over the period in both jurisdictions, from 50 DDDs/1,000 beneficiaries per day in 1997 to 205 in 2001, reflecting worldwide evolutions in recommendations for the use of cholesterol-lowering drugs and in statins use. Prescription costs per 1,000 beneficiaries increased during the period although average unit costs per DDD actually decreased in both countries (Prices in Nova Scotia have historically been higher than in Queensland (CAN\$ 1.14 per DDD versus CAN\$ 0.88)).

150. A recent survey, conducted by the Commonwealth Fund, of patients in several OECD countries sheds light on some differences in drug use. Among ‘sicker’ adults with at least one chronic condition, 84% of Canadians take prescription medications regularly, which is higher than in Australia (79%) and in Germany (81%), but lower than in the United Kingdom (88%) or in the United States (88%). The proportion of Canadian interview subjects taking “4 or more medications” regularly was 41%, which is higher than in Australia (34%) and Germany (40%) but lower than in the United States (53%) (Schoen *et al.*, 2005).

#### **2.1.4. Pharmaceutical prices**

151. Variation in pharmaceutical prices across Canada is minimal, with price differentials across jurisdictions estimated to be no more than 10%. Price growth of existing products is rather weak and Canadian patented drug prices are comparable to the medicine prices in the seven comparator countries used by the PMPRB in conducting price reviews. However, generic drug prices in Canada are higher than in other countries.

##### *2.1.4.1. Variation in prices sub-nationally*

152. There is some variation in manufacturers’ list prices in different geographic regions of the country and actual prices paid by purchasers (hospital, retailer, wholesaler, public plans) can differ according to the purchaser as well. We did not find any recent public information on the difference in prices paid by hospitals and by other purchasers. Reliable price comparisons between provinces were available only for 1999/2000.

153. A report by PMPRB (2001) compares the price of an average Canadian basket of drugs (composed of products available in all jurisdictions, weighted to reflect utilisation in all jurisdictions) in six provinces (British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Nova Scotia) for the 1999-2000 fiscal year. Ex-manufacturer prices were found to be more or less equivalent in the six provinces ( $\pm 1\%$ ), although discrepancies were higher for the reimbursement prices paid by drug plans, which include wholesale and pharmacist mark-ups. Deviations from the average price range from -1.9% in Ontario to +5% in British Columbia. In a more recent work, prices of 101 top-selling drugs were found to vary between -3% to +9% from the national average (Morgan, Barer and Agnew, 2003). When the market is segmented according to drug status related to patent, it appears that price differentials are higher for generic drugs than for patented drugs: for generics, Saskatchewan pays 7.3% less than the average while British Columbia pays 4.7% more.

154. Differences in prices paid by private and public insurers have also been computed for the 101 top selling drugs. Public drug plans paid lower prices than private ones in most provinces: sometimes 10% less

(Québec, Nova Scotia) and sometimes only 1% less (Alberta and Manitoba). In two provinces, public plans paid higher prices than private plans (+7% in Ontario and +9% in Newfoundland) (Morgan, Barer and Agnew, 2003).

155. Prices of generics were found to be on average 39.2% cheaper than brand-name drugs in the Ontario drug formulary in 2005, with some generics being 63% cheaper than their branded counterparts (CGPA data). Closely similar results were observed for Québec's drug formulary, with generics being on average 37.3% cheaper than brand-name drugs. However, prices of generics have been found to be not significantly lower than the price of the original drug, in some cases. For instance, in 2003, prices of generics of some hypertensive molecules were almost identical to prices of originators in all provinces (Morgan *et al.*, 2003).

156. Relatively high prices of generics are explained by a lack of competition in the Canadian market, due to a high concentration of the market. Using results derived by PMPRB from federal/provincial/territorial drug plan data, Skinner (2004) observes that one company accounted for 50% of all public spending in generic drugs in 6 provinces in 1999/2000, while the three largest competitors accounted for 82% of these spending. According to more recent data, this concentration has been slightly decreasing (PMPRB, 2006c, p. 4).

#### 2.1.4.2. Price trends

157. In line with the price regulation scheme, price increases of patented drugs<sup>54</sup> were parallel to those of the general CPI, however with lower annual growth rates (PMPRB, 2006a, page 24). Growth rates were even negative from 1993 to 1997 and between 2002 and 2003.

158. Even if patented drugs represent a growing fraction of pharmaceuticals sales, from 43.2% in 1990 to 71.4% in 2005 (PMPRB, 2006), one might assume that the Patented Medicines Price Index is not necessarily representative of price increases in the whole market. However, recent analysis by the PMPRB on price trends in seven public drug plans shows that price trends in the last four years were very similar for patented and non-patented-drugs<sup>55</sup>.

#### 2.1.4.3. Prices in international comparisons

159. To assess the international position of Canadian prices, the OECD used several studies chosen according to the following criteria: they are quite recent (1999 and after), of high quality and as

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54 The best available index to assess pharmaceutical price changes is the one computed by the PMPRB for patented drugs. Actually, several indexes exist to measure price changes in the pharmaceutical sector in Canada. Statistics Canada provides two types of indexes for pharmaceuticals: the industrial product price index (IPPI, for manufacturer prices) and two separate consumer price indexes for prescribed drugs and for non-prescribed drugs (consumer prices, including distributors' mark-ups and taxes). The latter serve as a basis for the composite index for pharmaceuticals and other non-durable goods published in OECD Health Data. All these indexes show higher price increases than the PMPRB index for the 1987-2005 period (see CIHI, 2006, page 47 for instance). These indexes, computed with a small number of pharmaceutical products (from 8 to 30 according to Statistics Canada's methodology), may not be representative of the pharmaceutical market. Moreover, the more rapid increase in consumer prices reported in the non-PMPRB indexes may be in part due to increases in distributors' margins. The PMPRB's PMPI (Patented Medicines Price Index) is a Laspeyres index, computed as a weighted-by-sales average of year-over-year changes in ex-manufacturers' prices. It is based on all patented drugs and not only on a sample.

55 With the notable exception of Saskatchewan, which experienced high growth in generic prices in the 2001 to 2004 period, after a sharp decline between 1999 and 2001.

representative as possible of the Canadian market. Some studies deal with the whole market, while others focus on one segment (e.g., patented drugs/generics). A review of the studies is presented in an Annex.

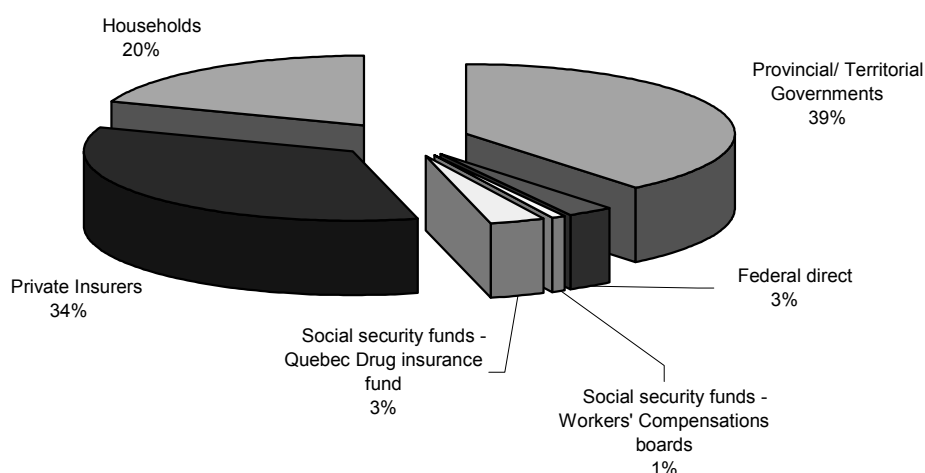
160. Although reconciliation of the results of these studies is challenging given the sensitivity of results to variations in methodology, it is possible to draw some conclusions about relative price levels in Canada. Prices of patented drugs seem to be close to average European price levels, lower than in the more expensive European countries (the United Kingdom, Switzerland) and higher than in the European countries with the lowest price levels (France, Italy). On average, patented drug prices are between 35% and 45% lower in Canada than in the United States, the country with the highest prices for patented medicines. By contrast, such differentials with US prices are not observed for generic products. In fact, Canada's generics appear to be priced higher than they are in other countries (including the US).

161. According to PMPRB calculations, Canadian prices of patented drugs tend now to be more in line with prices in the seven countries chosen as comparators than before the enforcement of the excessive price regulation in the late 1980s. The achievement of such parity for non-patented drug prices is regarded as one of the objectives of the National Pharmaceuticals Strategy (PMPRB, 2006c).

## **2.2. Financing**

162. Considering total expenditures devoted to pharmaceuticals, including both prescription and over-the-counter medicines, public funding in Canada is relatively low compared to most other OECD countries. In 2003, it reached 38% of total drug expenditures, while the OECD average was about 60% (see Figure 4). Only Mexico (11%) and the United States (21%) had lower shares for public funding of drugs. This low share of public funding results from the prevalence of private coverage of prescription drugs for a large part of the population. This situation further reflects policy choices implicit in Canada's health system, in which medical and hospital services are publicly and 100% covered, as well as drugs used in inpatient care.

163. In spite of increasing public funding of prescription drugs, from 43.4% in 1985 to 46% in 2005, private expenditure (through private insurance and households' expenditures) continues to be an important means of financing in Canada. Provincial and territorial governments are the largest payers for prescription drugs: they finance 39% of total prescription drug expenditures. Federal direct contributions and social security funds (including the Québec drug insurance fund) add to public funding with respectively 3% and 4% of total prescription drug expenditures. Private insurers covered another 34% of these expenditures and households are responsible for the remaining 20% (see Figure 7).

**Figure 7. Expenditure on prescribed drugs by source of finance in Canada, 2005**

Source: CIHI, 2006.

164. As a consequence of discrepancies in the scope of provincial and territorial drug plans, public financing of prescribed drug expenditures varies widely across provinces, from 32% in New Brunswick to 70% in the Northwest Territories (Table 2).

165. Households' expenditures on drugs averaged \$218 per family<sup>56</sup> in 2002, an increase of 71% (in 2002 dollars) since 1992 (Luffman, 2005). Drug spending represented 25% of households' expenditures on health, of which 16% were out-of-pocket payments for partly subsidised drugs and 9% payments for other drugs. Premiums paid by households for private health insurance represented another 34% of households' health expenditures. Again, the situation differed across Canada. In Saskatchewan, families spent 27% of their health care dollar on prescription drugs (CAN\$ 386), while families in Ontario and Alberta spent the least (13%, CAN\$ 188).

166. These variations can also be seen when drug expenditures are considered as a share of household income. In Canada, 6.5% of families spend more than 3% of their after-tax income on pharmaceuticals. This proportion reaches 15.9% in Saskatchewan, 11.7% in Prince Edward Island, about 10% in New Brunswick and Manitoba, and 9% in Québec and Nova Scotia (Luffman, 2005).

### **2.3. Pharmaceutical industry presence and activities**

167. According to Statistics Canada, 262 companies are operating in the pharmaceutical manufacturing industry and employing about 30,000 people in Canada in 2005. R&D-based companies provide two-thirds of employment, with about 49 generic companies accounting for the balance (Industry Canada, 2006 and Industry Canada website).

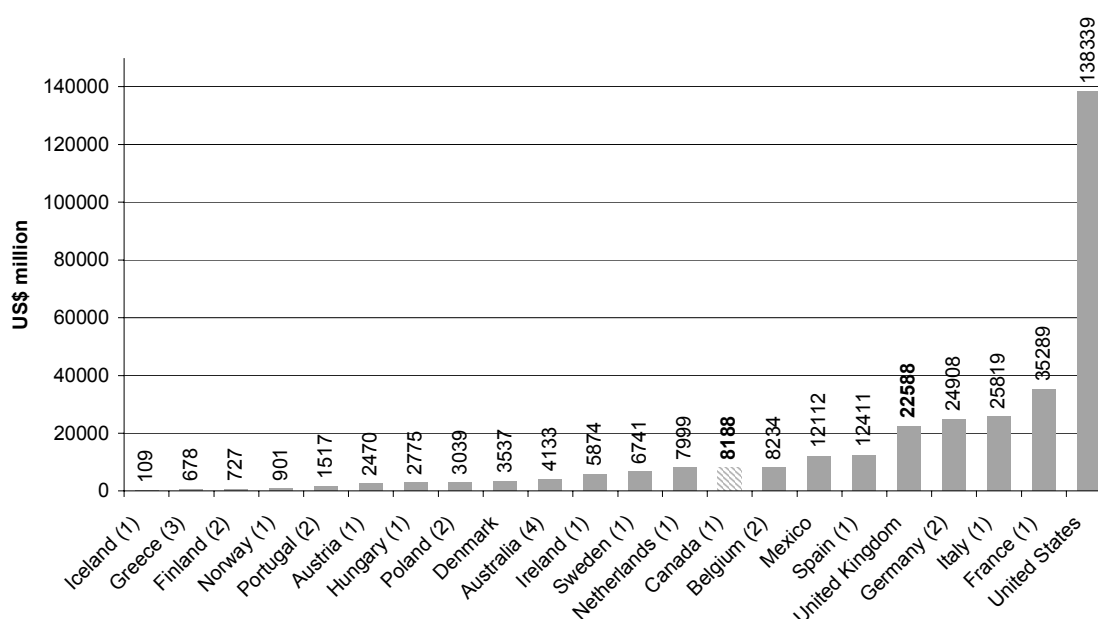
<sup>56</sup> When only consumers are considered, this average expenditure amounted to \$378. 35% of respondents to this households' expenditures survey did not report drug expenditures.

### 2.3.1. Production

168. In 2003, Canada ranked 9<sup>th</sup> among OECD countries for the production of pharmaceuticals (Figure 8). Related to its population, however, this represents a rather low level of production (\$261 per person, i.e. 2/3 of the OECD average).

169. Generic manufacturers have a notable presence in Canada, with a production oriented both towards the internal market and exports. The sector is highly concentrated, with 60% of market volumes being sold by two companies and 90% by twelve companies (data from PMPRB and CGPA at different dates, quoted in Skinner, 2004). However, concentration has declined considerably since 1996, when 90% of the market was shared by two firms (personal communication with Health Canada officials).

**Figure 8. Pharmaceutical production in OECD countries, 2003 or latest available year**

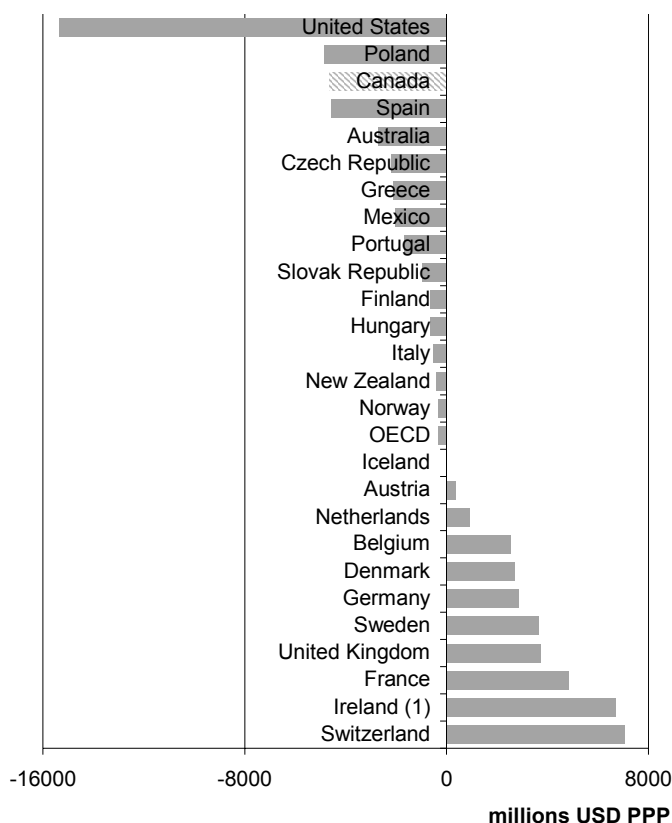


(1) 2002; (2) 2001; (3) 2000; (4) 1999.

Source: OECD Health Data, 2005.

### 2.3.2. Trade

170. Canada imports 45% of its domestic supply of pharmaceuticals and exports more than 80% of its production. Relative to many other OECD countries, Canada is not a particularly significant exporter of pharmaceuticals, but has notably greater relative importance as an importer. It shows a trade deficit for pharmaceuticals, as do more than half of OECD countries (Figure 9).

**Figure 9. Trade balance for pharmaceuticals in OECD countries, 2003**

(1) 2001.

Source: OECD Health Data, 2005.

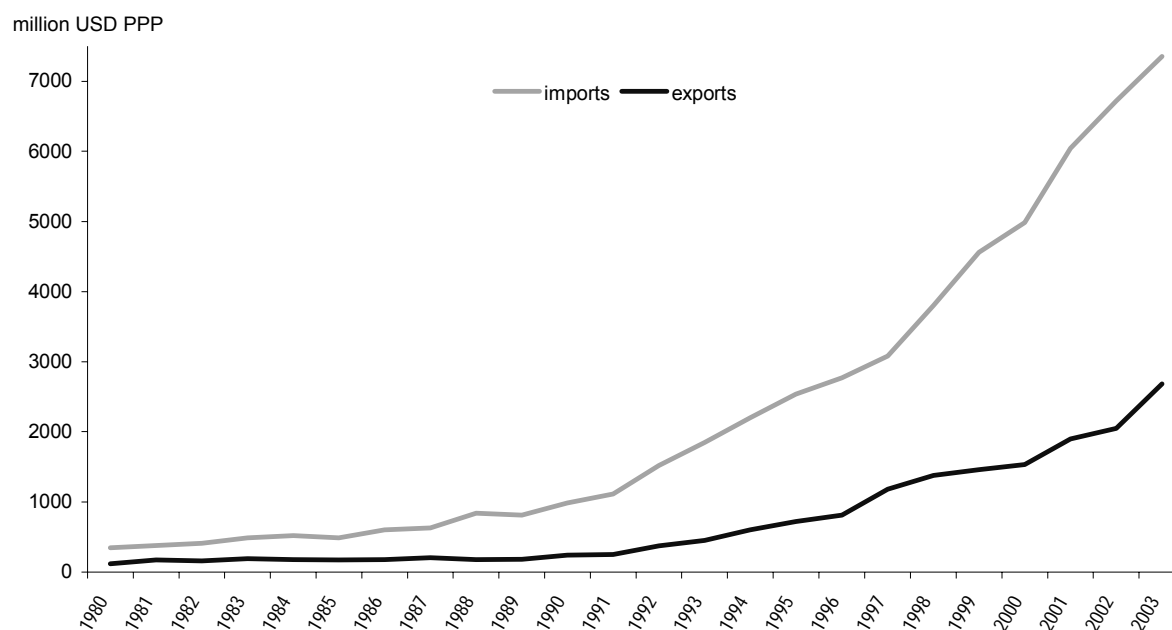
171. The United States is Canada's most important partner in pharmaceutical trade. Nearly half of Canada's pharmaceutical imports in 2002 came from the United States.<sup>57</sup> In the same year, 81% of Canada's pharmaceutical exports went to the United States (US Department of Commerce, 2004).

172. The North American Free Trade Agreement (NAFTA) had a significant impact on the Canadian pharmaceutical market by eliminating tariffs and facilitating imports and exports of pharmaceutical products. From the perspective of US pharmaceutical manufacturers who export medicines to Canada, benefits of NAFTA include greater transparency in Canadian government rule-making and stronger intellectual property rights and enforcement (US Department of Commerce, 2004). NAFTA also benefited Canadian manufacturers that export pharmaceutical products to the United States. From 1992 to 2002, Canada's exports to the United States increased 487%, while its imports from the United States increased by 125%.

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57 Canada accounts for 13% of total US pharmaceutical exports.



**Figure 10. Trends in pharmaceutical imports and exports in Canada 1980-2003**

Source: OECD Health Data, 2005.

#### Box 8. Cross-border trade

Given relatively high US drug prices, proximity to Canada, and gaps in US insurance coverage, there is a long history of some degree of sales by Canadian pharmacies to US consumers.<sup>58</sup> The development and expansion of Internet pharmacies provided a boost to this activity. Between 2002 and 2003, the value of pharmaceutical purchases made by Canadian Internet pharmacies (primarily for cross-border sales) doubled (IMS, 2006). Sales peaked in 2004 at a level representing 8% of total Canadian prescription drug sales.

Since then, manufacturers (most of which are Canadian subsidiaries of multinational firms with headquarters in the United States or Europe) began to tighten up the supplies to wholesalers suspected of providing drugs to Internet pharmacies, though they committed to ensuring there would be an adequate supply of medicine for the Canadian market. Physician and pharmacy regulatory associations also increased enforcement of professional standards, issuing fines and suspending the licenses of medical practitioners found contravening good prescribing practices. At a national level, no shortages were ever documented, although pharmacists reported some delays in receiving stock as needed.<sup>59</sup>

More recently, the pressure has diminished: Implementation of Medicare Part D in the United States has reduced some of the political and media attention. The strengthening of the Canadian dollar against the US dollar has also probably contributed to reduced demand. And manufacturers' activities, which have not been contested by the Canadian competition authorities, have put pressure on pharmacists and physicians to clamp down on cross-border trade. Sales revenues from cross-border trade have dropped, but there is speculation that this may reflect only a shift in trade from brand-name pharmaceuticals to products which are Canadian generic therapeutic equivalents of US products still under patent protection.

<sup>58</sup> In the Prescription Drug Marketing Act of 1988, the US Congress banned the re-importation of U.S.-made prescription drugs to prevent potentially unsafe repackaging and to minimize exposure to counterfeit products. Only medications for approved emergency care, those re-imported by original manufacturers, and those imported in small quantities for personal use are exempt (Ward, 2004).

<sup>59</sup> Personal communication with Health Canada officials.

### 2.3.3. Investments and activities in research and development

173. R&D investments and activities are important features of the pharmaceutical industry. With the adoption of the 1987 amendments to the *Patent Act*, R&D, the organisation representing brand name manufacturers in Canada, made a public commitment to increase their members' annual R&D expenditures as a percentage of domestic sales to 10% by 1996, in exchange for strengthened intellectual property rights protection. As a result, the R&D-to-sales ratio increased to a maximum of 11.5% in 1998 but has since declined to 8.3% in 2005. In 2005, 80 companies reported total R&D expenditures amounting to CAN\$1.23 billion<sup>60</sup>, representing 8.8% of their sales (PMPRB, 2006a).

174. Pharmaceutical companies concentrate their R&D spending in two provinces, Québec and Ontario, which represent 45.6% and 42.9% of Canadian private R&D expenditures, respectively (PMPRB, 2005a).

175. International comparisons of R&D expenditure data raise a number of methodological problems and no complete statistics are available to compare investments in R&D in all OECD countries (OECD, 2005; EFPIA, 2005; Vekeman, 2005; PMPRB, 2002). Moreover, indicators used for decades have begun to lose some significance in the context of globalisation of the pharmaceutical industry. For instance, the ratio of R&D expenditures to domestic sales is of limited value as a metric since multinational pharmaceutical companies finance R&D undertaken in a particular country through their global sales revenue<sup>61</sup>.

176. According to data collected by OECD, Canada spent \$US 985 million (adjusted to reflect cross-national differences in purchasing power parity) for R&D in pharmaceuticals in 2003, ranking 7<sup>th</sup> among OECD countries for which data are available<sup>62</sup> (OECD, 2005). This represents 0.1% of GDP, a level comparable to that of Germany, the United States, Spain, Finland and the Netherlands, but below the shares of GDP observed in Sweden (0.6%), Belgium and Denmark (0.4%), the United Kingdom (0.3%) and France (0.2%). Related to population, pharmaceutical companies' expenditures for R&D in Canada represent US\$27 per capita compared with an OECD average of US\$45. Thus, although Canada figures among the greatest investors in pharmaceutical R&D, its investments related to income or per capita are lower than those of leaders in pharmaceutical R&D. Moreover, R&D investments tended to decline in the recent years, both in absolute terms and in share of domestic sales (PMPRB, 2005).

177. However, other indicators may be used to assess the level of pharmaceutical R&D undertaken in Canada. Overall, Canada's intramural expenditures in pharmaceutical R&D represent about 2% of those of all OECD countries<sup>63</sup>. This corresponds roughly both to its market share on the worldwide pharmaceutical market (2%, according to IMS quoted by Industry Canada, 2006) and to its share of worldwide wealth (1.8%<sup>64</sup>).

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60 Note that PMPRB figures only relate to "patentees", i.e. manufacturers which have at least one patented product. Other manufacturers, notably some generic manufacturers, also invest in R&D (Industry Canada, 2006).

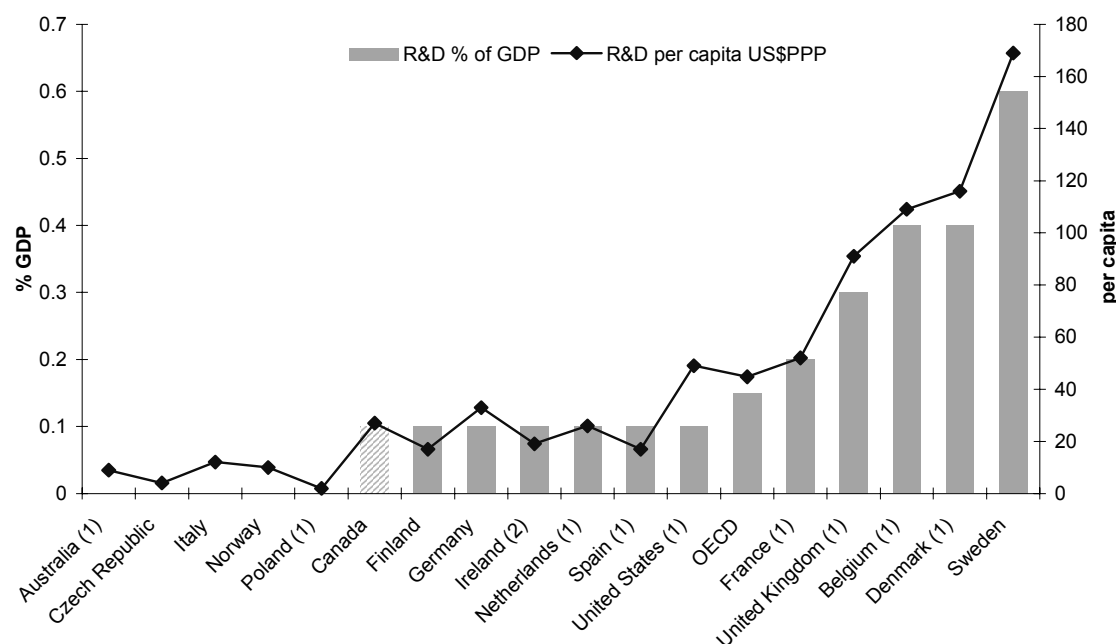
61 This is particularly evident when considering the case of Switzerland where expenditures for R&D are several times higher than domestic sales (see InterpharmaPh, 2005, p. 43 and 47).

62 Data are not available for 14 countries, including Switzerland.

63 Rough estimate based on figures from OECD and from the British Pharmaceutical Industry Competitiveness Task Force (PICTF, 2006).

64 Computed from different official sources presented in Wikipedia ([http://en.wikipedia.org/wiki/List\\_of\\_countries\\_by\\_GDP\\_%28PPP%29](http://en.wikipedia.org/wiki/List_of_countries_by_GDP_%28PPP%29), accessed July 20, 2006)

**Figure 11. Pharmaceutical R&D expenditure in OECD countries, share in GDP and expenditures per capita, 2003 or latest available year.**



(1) 2002.

Source: OECD Health Data, 2005.

178. The productivity of Canadian R&D may be assessed by indicators of industry outputs presented by the PICTF<sup>65</sup> (2006). Between 1991 and 2004, the proportion of new chemical entities launched in the world originating from Canada was less than 0.025%. The proportion of Canadian discoveries is more important when “first or second in class” new molecular entities are considered, which means that Canadian R&D is less inclined to produce ‘me-too drugs’ than are industries in other countries.

179. Canada seems to be better placed for competition in the promising market of pharmaceutical biotechnology. Of 24 biotech drugs approved for sale on the world market, 3 come from Canadian firms (12.5%). The biotech industry benefits from strong federal support.

### **2.3.4. Product launches in Canada**

180. Although it represents only 2% of worldwide pharmaceutical sales (IMS, quoted by Industry Canada, 2006), Canada appears to be a relatively attractive market for prompt launching of new products. Data from the pharmaceutical industry show that manufacturers submit an application for market approval in Canada about 6.1 months, on average, from the time of the first application in any world market (PICTF, 2006). This is about double the average US time (2.9 months), but is lower than any of the other 11 countries included in the study, and comparable to the United Kingdom (6.1 months) and Switzerland (6.5 months). Japan was an outlier with an average lag of 16.6 months.

<sup>65</sup> The proportion of patents filed per unit of R&D spending is not presented since interpretation may be confounded by companies’ use of strategic patenting.

181. The time from market approval to product launch in the market is also notably short in Canada – just 1.7 months, the lowest of a dozen countries included in a recent pharmaceutical industry report (Association of the British Pharmaceutical Industry, quoted in PICTF, 2006). Delays may be longer in countries where market launch is more closely linked to pricing and reimbursement decisions.

182. The uptake of new products is rather good on the Canadian market, which renders it attractive for the pharmaceutical industry. Indeed, new products launched within the last 5 years represent about 22% of the market, which is close to the equivalent percentages for the French, German and Australian markets, below the US market share (27%) and above that for the Italian, Swiss, British and Japanese markets (16%, for the latest) (IMS world review, quoted by PICTF report, 2006).

### ***2.3.5. Efforts by manufacturers to influence physicians' prescribing behaviour***

183. In order to profit from their investments in the development of new products, manufacturers must do what they can to encourage physicians to prescribe them, irrespective of whether those products represent improvements over other treatments. Manufacturers gain revenues when a physician prescribes their drug instead of the therapeutic alternative or bioequivalent product produced by a competitor, as well as when physicians favour a newer (and more costly) formulation over an older version still on the market. In Canada, therefore, as in other OECD countries, pharmaceutical manufacturers use a range of strategies to influence physicians' prescribing behaviour, ranging from the deployment of sales representatives to physicians' offices (a practice known as detailing) to inform them about products, to sponsorship of continuing medical education activities relating to treatment of conditions and use of pharmaceutical products. Manufacturers also advertise products to physicians through print and other media.

184. There is some indication of a potential increase over time in the level of advertising directed to physicians, which could be explained by a number of factors. The number of advertisements for prescription drugs submitted to Canada's Pharmaceutical Advertising Advisory Board (PAAB) for review increased 13% in 2005, as compared with 2004. In 2005, the Board conducted 4,444 reviews, up from 3,921 in 2004 (Pharmaceutical Advertising Advisory Board, 2006).<sup>66</sup> The total number of annual reviews has nearly doubled since 1998.<sup>67</sup>

### ***2.3.6. Efforts by manufacturers to influence pharmacists' dispensing behaviour***

185. As is true in some other OECD countries, generic drug manufacturers often furnish Canadian pharmacists with rebates and gifts to encourage purchases and/or exclusive purchasing (Skinner, 2004). However, these practices are not allowed in all provinces. In Québec, manufacturers are not allowed to give further reductions to bulk purchase prices and commit themselves not to give rebates or discounts, and not to provide free goods to distributors. Ontario's drug bill 102, passed in 2006, outlaws all supplier-to-pharmacy rebates with the exception of a prompt payment discount and some allowance for professional spending. Moreover, guidelines are provided by the Canadian Generic Pharmaceutical Association (CGPA), but the ability to enforce compliance with guidelines (particularly for non-members) is limited.

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66 The PAAB reviews advertising of prescription and OTC products to health professionals in all media. All advertising materials reviewed by PAAB (including certain promotional materials aimed at consumers – see below) are voluntarily submitted. The PAAB code is used for review and pre-clearance of advertising materials directed at health professionals, whereas Health Canada guidelines are used by the PAAB in reviewing help-seeking and reminder ads aimed at consumers.

67 The current Commissioner of PAAB, Ray Chepesiuk, took office in 1998. He attributes the accelerated growth in reviews beginning in that year to increased compliance by industry.

### 2.3.7. Direct-to-consumer advertising

186. Advertising prescription medicines to prospective patients – so-called direct-to-consumer advertising (DTCA) – is prohibited by Canadian law, as is the case in most other OECD countries<sup>68</sup>. Nevertheless, although advertisements that include both the product name and specific therapeutic claims are forbidden<sup>69</sup>, Canadians are exposed to some DTCA. Indeed, they are an audience for DTCA (television or other media) that originates in the United States<sup>70</sup>, where advertisements that meet established regulatory guidelines are allowed. And in recent years, Canadian advertisements that mention a product name without stating its use ('reminder ads') and those that inform consumers of new but unspecified treatment options of diseases or conditions ('help-seeking advertisements') have become common, following interpretations issued by Health Canada in 1996 and 2000 which first implied and then asserted that these were legally permissible (Gardner *et al.*, 2003).<sup>71</sup> Health Canada has consulted with key stakeholders, health professionals and advocacy groups and has been reviewing the policy on DTCA as part of an overall initiative on health protection legislation renewal.

187. Such advertising is likely to play a non-negligible role in driving up Canadian consumers' demand for medicines.<sup>72</sup> It has been shown to affect prescribing volume as well as product choice (Mintzes *et al.*, 2003).

188. While DTCA and the additional consumption of pharmaceutical products which it gives rise to are believed to have both positive and negative effects on the health of Canadians, the net impact is difficult to assess. Proponents cite the potential value of advertising in boosting detection and appropriate care of under-diagnosed and under-treated health conditions (e.g., hypertension), resulting in benefits to patients. Opponents<sup>73</sup> argue that advertising encourages consumers to seek care for conditions that do not require treatment, pressures physicians to prescribe unsuitable medicines, promotes the use of new medicines for which the post-market safety profile is incomplete, and favours certain therapies in cases where alternative treatments would be more appropriate. DTCA may result in higher prices, to the extent

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68 Exceptions are the United States and New Zealand.

69 A court case challenging this restriction as illegal on commercial freedom-of-speech grounds is pending (cCNC News, June 12, 2006).

70 Regulatory changes there in 1997 opened the door to DTCA on television, something which has supported the dramatic increase in Canadians' exposure to commercial messages regarding prescription drugs due to cross-border media exposure.

71 In addition to formal reviews of advertisements directed at health care professionals and consumers to assess compliance with Pharmaceutical Advertising Advisory Board (PAAB) code and with guidelines issued by Health Canada, the PAAB provides advisory opinions as to whether prospective materials constitute advertisements. The number of full reviews of direct-to-consumer advertisements (including reminder ads, help-seeking ads, consumer brochures, and corporate ads) and advisory opinions issued in recent years remains modest in comparison with the number of so-called patient information aids, which grew from 658 in 2003 to 1,116 in 2005, according to data provided to OECD by Ray Chepesiuk, PAAB Commissioner.

72 Perhaps the best evidence of the success of DTCA is manufacturers' support and willingness to pay for it. In the United States, 32% of total spending by manufacturers on the promotion of prescription drugs went to DTCA in 2000 (National Institute for Health Care Management Foundation, 2001).

73 Based on its assessment of the evidence vis-à-vis Canada, the Canadian Medical Association opposes direct-to-consumer advertising of particular brands of pharmaceuticals as well as the provision of information to consumers from sources with vested commercial interests (Canadian Medical Association, 2002, 2003).

that advertising expenses incurred by manufacturers are not fully met by increased revenues from higher consumption. The question of whether a vehicle intended to promote sales can be regulated adequately to make it a valuable source of information is also at issue.

## **2.4. Supply/distribution of pharmaceuticals**

This section describes and assesses the pharmaceutical supply chain in Canada, as well as policies and other factors that influence (or are intended to influence) the supply of pharmaceuticals.

### ***2.4.1. Recent changes in the distribution chain and impact***

189. In 2005, 58% of pharmaceutical sales by manufacturers were made to distributors and wholesalers, 30% to self-distributing retail chains, and 12% directly to retail pharmacies and hospitals (IMS, quoted by the Canadian Association for Pharmacy Distribution Management<sup>74</sup>)

190. The distribution chain has experienced important changes in the past years. Historically, a large share of sales to pharmacies has been made directly by manufacturers without use of a wholesaler as intermediary: in 1993, direct sales accounted for 44% of total manufacturers' sales. During the 1990s, there has been a shift from direct supply towards sales to big wholesalers, as well as changes in the retail sector, with fewer independent pharmacies and the entrance of mass merchandisers and grocers (PMPRB, 2005c). In the same period, manufacturers' behaviors have changed. According to the PMPRB, manufacturers are now less inclined to accept orders from retail pharmacies and tend to implement or increase levels of "minimum purchase". On average, minimum purchase sizes increased from CAN\$242 in 1997 to CAN\$2,167 in 2004.

191. The PMPRB measured the impact of these changes in the distribution channels on distribution costs<sup>75</sup> for 7 public plans, assuming an average wholesale margin of 5%. The Board estimated that these changes lead to an additional cost of 40% over the 1997-2004 period for provincial plans and their beneficiaries (PMPRB, 2005c). Distribution costs estimated by the PMPRB for 2003-2004 added on average from 10.8% (NIHB) to 24% (BC) to ingredient costs in public plans' expenditures.

### ***2.4.2. Role of pharmacies and pharmacists***

192. There are several types of pharmacies in Canada. Independent pharmacies are pharmacies owned by a proprietor who does not own more than five pharmacies. Banner pharmacies are independent pharmacies which are affiliated with a central office and pay fees for the right to use a recognized name and to participate in central buying, marketing, professional programs, etc. Franchises are run by operators who do not necessarily own the physical store or fixtures, and franchise arrangements vary across Canada. There are also chain pharmacies, supermarket pharmacies (departments of supermarkets) and mass-merchandiser/department store pharmacies, which are pharmacy departments within large retail outlets, such as Wal-Mart. In all these cases, pharmacy managers are employed to implement policies defined by head offices, who direct functions such as buying, marketing, professional programs, etc. (Trends and Insights, 2005). In 2003, the top five pharmacy chains and banners dispensed 40% of all prescriptions in Canada (PMPRB, 2005c).

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74 [http://www.capdm.ca/industry\\_facts/facts.asp](http://www.capdm.ca/industry_facts/facts.asp), accessed on May 14, 2006.

75 Distribution costs defined by the PMPRB do not include pharmacists' margins or fees, but only covers the cost of 'intermediaries' between the manufacturer and the retailer.

193. The number of pharmacies in Canada has increased steadily in recent years, growing from a total of 7,144 (1 per 4,342 people) in 2001 to 7,585 (1 per 4,212 people) in 2004.<sup>76</sup> During that period, the number of independent pharmacies declined (from 2069 to 1638), while the number of chain pharmacies increased (from 3,914 to 4,444), as did the relatively small but rapidly growing share of pharmacies located in stores focused on food or mass merchandise (up from 544 to 1,503) (IMS Health Canada, 2006).

194. The distribution of pharmacies across Canada's largest provinces is relatively consistent, at about 1 pharmacy per 5,000 people. In absolute terms, Ontario has the most pharmacies, 2,869 in 2004 (approximately 1 pharmacy per 5,000 residents) and Nunavut, with 3 pharmacies in 2004 (approximately 1 pharmacy per 10,000 residents), the fewest (IMS Health Canada, 2006b).

195. The fees charged by pharmacists for dispensing a prescription medicine, along with retail mark-ups, affect the prices paid by consumers, as do the reimbursement policies of any third-party payers involved in the transaction. Dispensing fees vary across pharmacies and provinces, as do the norms regarding prescription amounts or sizes, which determine how often a patient will need to have a prescription refilled. Third-party payers also establish schedules by which dispensing fees and mark-up rates will be reimbursed by the payer.

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76 In addition, there were an estimated 278 Internet pharmacies based in Canada as of June 2005 (Skinner, 2006). Cross-border sales (primarily to US customers) represented about 70% of the sales of these pharmacies.

### 3. ACHIEVEMENT OF POLICY GOALS

196. This section describes the degree to which certain policy goals relating to pharmaceuticals are being achieved in Canada and attempts to assess the impact of Canada's pharmaceutical pricing policies on the attainment of these goals.

#### 3.1. Containment of drug expenditures

197. In recent years, Canada's real annual growth in pharmaceutical spending has been among the highest in the OECD, despite the fact that Canada's real growth in health spending as a whole has been comparable to the OECD average. This trend, common to most OECD countries, may be partly due to some substitution between components of health care (pharmaceuticals versus hospitalisation) as well as the extension of efforts to prevent health risks by employing pharmaceuticals as part of long-term treatments for chronic health conditions such as high cholesterol, hypertension, and diabetes. The trend might also reflect policy decisions to focus cost-containment efforts on the relatively more costly hospital sector, or could indicate that cost-containment efforts directed towards the hospital or other sectors have had relatively better success. It could also be related to the impact on Canadian drug prescribing and consumption patterns of US-originated Direct-to-Consumer Advertising, much of which Canadians are exposed to via their access to American television advertising and Internet sources.

198. Unlike many other OECD countries, there have not been explicit policy goals at the national level in Canada pertaining to containment of pharmaceutical expenditures. This likely relates to the relatively limited direct role of the federal government in the administration and delivery of drug coverage for pharmaceuticals. The rationale for government intervention was primarily guided by consideration as to whether there is a need to offset the monopoly power of manufacturers of patented products in order to protect consumers. Thus, it follows that Canada has not employed policy levers such as the PMPRB in explicit cost-containment endeavours such as across-the-board price freezes or general price reductions on existing products, an approach used for cost-containment in many other OECD countries where ensuring adequate public financing for a higher share of pharmaceutical costs is a matter of national government concern. The PMPRB has no mandate to ensure low prices for prescription drugs in Canada, but is concerned rather with ensuring prices are not "excessive," according to an arguably generous standard. Indeed, in this respect the PMPRB is successful, as Canadian prices of patented drugs vary in a range of 10% from the median price in comparator countries.

199. However, the situation has changed recently. In both the 2000 Communiqué on Health and the 2003 Accord on Health Care Renewal, First Ministers identified pharmaceuticals management as a priority. In September 2004, First Ministers affirmed their commitment to a range of pharmaceuticals management actions under the National Pharmaceuticals Strategy, a part of the 10-Year Plan to Strengthen Health Care. The NPS includes a number of cost control and expenditure-management related elements and addresses interconnected pharmaceutical policy issues around coverage and costs. Further, cost control and expenditure management is a key aspect of earlier Federal-Provincial-Territorial collaborative pharmaceuticals initiatives such as the Common Drug Review, of which the federal government is both a funder and an active participant, as well as a direct beneficiary for the public plans under its jurisdiction.

200. Until now, concern about drug costs has been decentralised in Canada to the level of third-party payers, whether public or private, and to the hospitals which purchase medicines for in-patient use under



the constraint of a defined drug budget. To date, private payers have had minimal incentive to implement cost-control activities, but reported growing cost concerns from the employers who sponsor coverage for most Canadians may indicate a changing trend in future. In the publicly-funded drug plans, cost-containment efforts are used to various degrees, but most measures influence expenditures by constraining the type and amount of drugs reimbursed, rather than the reimbursement price paid.

201. With respect to purchasers, there is some activity on the pricing side of the equation: Reimbursement prices have been frozen on at least one occasion in at least two Canadian provinces, for example. But the fact that there is little variation in prices paid across Canada – taking into account both passive private insurers and less passive public payers – suggests that price-related activities undertaken by drug purchasers are not particularly important.

202. On the other hand, to greater or lesser degrees, Canada's publicly-financed drug plans have been using formulary management in order to contain costs, as well as to support appropriate and cost-effective prescribing and utilisation. Increasing use of programmes to provide exceptional access to drugs not included in provincial formularies suggests that such controls may be tightening. Although many private plans have traditionally operated under an "open access" scheme, plans are increasingly offering restricted formulary alternatives for employers concerned about cost-containment. Canadian jurisdictions with relatively tight formularies have lower use of medicines and lower per capita drug expenditures.

203. Similarly, Canada's third-party payers make use of patient cost-sharing requirements which have the effect of shifting some of the cost burden for prescription drug expenditures to individuals. Evidence shows that some Canadian cost-sharing levels are high enough to suppress demand notably for medicines, including drugs considered essential as well as less important or more discretionary medicines (Tamblyn *et al.*, 2001). Limited use of reference pricing schemes and tiered co-payments suggests that these measures are not generally used to steer demand to the most cost-effective choices.

### **3.2. Sustainability and equity of financing for pharmaceuticals**

204. Like most OECD countries, Canada has recorded rapid growth in pharmaceutical expenditures over the past 15 years. This trend has encouraged policy makers to take steps to increase the efficiency of expenditures in order to maintain the sustainability of the system.

205. The fact that financing is spread over several sources, public and private, may encourage payers to shift costs to other sources in reaction to cost pressure. For example, patients have been required to pay higher shares of expenditures.

206. The significant inequity in financing across jurisdictions, which contributes to the large differences in pharmaceutical coverage and accessibility seen in Canada, is an important policy concern. Reform proposals currently under discussion, including a move to a national formulary and even consideration of a uniform national system of coverage, suggest that inequitable financing and the resulting outcomes are a particular policy problem in Canada.

### **3.3. Efficiency of expenditures in the pharmaceutical sector**

207. Attention is increasingly being paid to the question of cost-effectiveness and value of pharmaceutical expenditures – in particular, on the public expenditure side – but there appears to be scope for improving the policy initiatives undertaken along these lines so as to achieve better value for money.

208. At a macro level, there is cause for considering that gaps or shortfalls in coverage – particularly, but not only, the estimated 2% of Canadians lacking insurance (Fraser Group & Tristat Resources, 2002) –

could lead to costly adverse events in cases where drug use is foregone due to financial barriers, or to substitution with more expensive health services (see Box 6 above).

209. As in other OECD countries, the impact of having multiple payers for different services and/or sector-specific budgets raises concerns due to its potential creation of incentives to shift cost in ways that may promote inefficiencies in health care delivery. Health systems where one payer has primary responsibility for paying both hospital and drug bills have greater incentives to consider the overall cost-effectiveness of healthcare delivery by promoting substitution of less-expensive medicines for more costly surgeries, where appropriate, for example.

210. On another level, however, there are policies to promote value for money in drug expenditures for those with publicly financed coverage. Notably, the Common Drug Review, which plays an important role in the coverage decisions affecting accessibility of drugs in Canada, entails centralized assessment of a product's cost-effectiveness relative to therapeutic alternatives. Considering that about half of the drug reviews by the CDR as of August 24, 2006, have resulted in recommendations to the participating federal, provincial, and territorial drug plans that the drug in question not be listed, the hurdle of acceptance is not insignificant. As many of the recommendations not to list are made on the grounds that the drug is not shown to be cost-effective at the offered price, the CDR is an important tool in the effort to obtain value for money in public expenditures on prescription drugs.

211. Following the Common Drug Review, which is a non-binding advisory service for participating plans, the publicly financed plans have formulary consideration processes to make reimbursement decisions. While provincial reimbursement decisions that have been made are generally consistent with CDR recommendations, variations exist. These decisions may reflect different standards for cost-effectiveness, concerns about the potential budgetary impact of a product (even one considered to be cost-effective), or other local factors.

212. Once a drug has cleared these hurdles, there are very few policy levers used to promote cost-effective prescribing, dispensing and use of medicines by patients, however. Federal initiatives such as the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) are quite new and remain focused on fostering change by providing information and evidence, lacking levers for rewards or penalties. Efforts to steer choice of medicines to the product offering highest value for money through reference-price schemes or lowest-cost alternative reimbursement methods are not widely used.

213. Evidence suggests that Canada is taking advantage of opportunities to obtain value from generic products, although there is scope for improvement here as well. Canada is one of only a few countries with high penetration of generic products in its pharmaceutical market. On the price side, the story is more mixed. While, in most cases, generic products are available at prices significantly lower than originators, this is not universally true and many or most comparator countries have lower prices for generic products. Lack of competition among manufacturers of generic drugs may be one explanation for the shortcomings in price competition. Furthermore, lack of regulation in many provinces of discounts and rebates provided by manufacturers to pharmacies suggests that there are rents being captured at the retail level that do not carry over to low consumer prices for generic drugs.

### **3.4. Availability of pharmaceuticals**

214. An important policy question is the extent to which state-of-the-art medicines are available for purchase in Canada. Factors affecting availability include product approval timing and outcomes, as well as manufacturers' launch decisions and marketing strategies. Although the evidence is mixed, a reasonable conclusion is that, in general, the vast majority of new pharmaceuticals are launched in Canada promptly. In comparison with other high-income OECD countries, availability of medicines in Canada appears quite

comprehensive and timely. On the other hand, there are exceptional cases of non-availability, some of which reflect peculiar characteristics of the Canadian policy environment (e.g., product launch decisions affected either by PMPRB pricing regulation and/or the cross-border trade with the United States). These exceptional cases receive considerable attention in the media, where often concerns are conflated with accessibility problems<sup>77</sup> (discussed below).

215. Some evidence of timely market availability of drugs in Canada comes from an evaluation of the average time from the first world application for marketing approval to launch in various markets, considering products launched between 1999 and 2003 (ABPI quoted by PICTF, 2006). By this measure, Canada does not appear to have an unusual delay in availability.<sup>78</sup> Further evidence of good availability comes from a study by Danzon and Furukawa (2003) that documented the availability of 249 molecules with strong US market presence in 1999. 95% of these molecules were available in Canada, and only Germany and the United Kingdom had a higher match (respectively 97% and 98%). Moreover, corresponding products accounted for 61% of sales in the Canadian market, which is equivalent to the market share of these molecules in the United States. This indicates consistency with the US market as far as top-selling drugs are concerned.

216. On the other hand, a study using more recent data found evidence of some delayed availability in Canada, as compared with the United States, including in the case of some drugs assessed as improvements over existing therapies (Lexchin, 2006).<sup>79</sup> Of the 37 drugs in the sample, 32 were not available in Canada. Of those not available, 19 were judged to bring 'little or no improvement' compared to available therapies. However, 6 were considered to bring moderate improvement and 1 drug offered an improvement classified as significant.<sup>80</sup>

217. As noted, there is also anecdotal evidence of instances in which availability of new products appears impaired in Canada, by comparison to the United States or other markets. Recently, several newspapers related the case of a cancer drug whose manufacturer has opted not to launch it in Canada because it is not willing to comply with PMPRB requirements on price.<sup>81</sup> The drug sells in Western Europe for about €4,000 per month and in the United States for more than twice that price. Because the drug is not available on the Canadian market, availability of the drug has been limited to successful applicants to

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77 In many, but not all OECD countries, availability and accessibility of medicines are quite closely linked, as in the case of countries with a single national formulary (where decisions not to list a drug can have very significant impact on sales prospects). In Canada, these dimensions of policy performance are more distinct, given the multiplicity of payers (including some with open access) and formularies, and thus are treated separately here.

78 Drugs introduced between 1999 and 2003 were available in Canada an average of 26.8 months after the manufacturer placed its first application for marketing anywhere in the world. While the United States had the shortest time lag, at 19 months, followed by Germany (24.4 months) and the United Kingdom (24.5 months), Canada's lag was comparable to that of Switzerland (25.2 months), Sweden (25.5 months) and the Netherlands (27.2 months), and considerably shorter than that of Spain (30.3 months), Australia (30.4 months), Italy (31.5 months), France (32.2 months) and Japan (43.9 months).

79 The sample was composed of products for which assessment had been published in the Canadian edition of the Medical Letter between May 12, 2003 and June 21, 2004. The therapeutic value of the drug was rated by two clinical pharmacologists and compared with the US Food and Drug Administration (FDA) criteria for priority review.

80 Two other drugs belong to the first and second categories according to different indications, two others belong to the second and third categories and two were not rated because of a lack of information.

81 This situation is summarised in a news article by Lisa Priest, published in the Globe and Mail (2006).

Health Canada's Special Access Programme. In an unusual step, Ontario has decided to reimburse the costs of treatment for certain patients who receive the treatment in US hospitals. The price paid by Ontario is high (\$3.6 million for 34 patients treated in the 2005-2006 fiscal year), including the cost of treatments in US hospitals on the top of the drug cost. This choice suggests a possible discrepancy between the standards used by the PMPRB for judging when a price is excessive and the willingness-to-pay of jurisdictions.

218. Decisions not to launch a product may reflect the categorisation process used by the PMPRB, which does not recognise marginal improvements<sup>82</sup> in effectiveness in a therapeutic class as a legitimate rationale for price differentials. A further reason for delays in product launches may be manufacturer's concerns about the potential for cross-border trade, particularly in the case of high-cost drugs. There might also have been delays reflecting the timing of marketing approval reviews and decisions by Health Canada, although average and median review times have improved significantly following the launch in 2003 of Health Canada's Therapeutics Access Strategy, major elements of which were designed to improve the performance, efficiency and timeliness of the drug review process. Prompt applications from manufacturers for approval to participate in the Canadian market have compensated for any delays to a great extent, meaning that drugs are launched on a timely basis, by international standards.

219. There is little information on the question of whether the health or well-being of Canadians is affected by unavailability of certain products on the Canadian market. The Special Access Programme, in practice if not by design, serves partly to compensate for some shortfalls in availability of medicines that offer some possible benefits to those with a serious or life-threatening condition. Some commentators have suggested that limits or delays in availability of medicines is a minor problem in terms of impact, as compared with the broader problem of insufficient drug coverage for many populations and gaps in coverage. These issues are considered below.

### 3.5. Accessibility of pharmaceuticals

220. Timely market availability is only one determinant of accessibility of drugs to patients, however; affordability is another one.<sup>83</sup> A number of features combine to suggest that there are real limits on accessibility of pharmaceuticals in Canada, and that accessibility varies widely, depending on jurisdiction and type of coverage.

221. In this respect, the lack of universal coverage for medicines is an important issue in Canada. While programs such as those established by each of Canada's jurisdictions for high-risk or low-income groups help to ensure that those most in need are covered, those who do not qualify for coverage may suffer compromised access to medicines with possible negative implications for their health status.

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82 There is great debate as to what constitutes a "significant improvement" and, particularly, whether this is considered adequately from the patient perspective. An example was the treatment of Viagra, which was categorised for price evaluations with an existing injectible product which provided the same effect with less convenience and more discomfort for patients.

83 The significant level of use of the Special Access Program suggests this is an important tool for securing timely access to those drugs that are of potential benefit to patients with a serious or life-threatening condition, yet accessibility at an affordable price is not ensured through this programme, as payers are not obligated to cover their enrollees' costs for drugs made available through the SAP. Nevertheless, this is not believed to be a significant problem, as some payers (plans or hospitals) choose to provide coverage. Furthermore, many drugs approved through the programme are still in development and provided free of charge by manufacturers. Where the drugs are sold, prices are subject to approval by the PMPRB.

222. Beyond this, Canadians with coverage may experience mediated access to medicines to the extent that reimbursement policies restrict coverage of certain medicines through decision-making criteria, and/or formulary policy, both of which vary across provinces and territories.

223. Delays by publicly-financed drug plans in making reimbursement decisions are another factor suggesting impaired access for those Canadians with this form of coverage. Many plans allow physicians to apply for special-use permission for drugs not listed on a formulary, which promotes accessibility of drugs not covered or not yet covered by a patient's insurer. However, these processes are reportedly cumbersome for the physician, acting as a disincentive to application.

224. Increasing levels of controls and restrictions by third-party payers on use of covered medicines, along with increased cost-sharing for medicines, are another source of concern as to drug accessibility in Canada. The level of drug benefits furnished by provincial plans has eroded over time. Cost-sharing levels are in some cases high enough to impair use of medicines.

### **3.6. Quality of care, health outcomes**

225. There is very little evidence by which to assess the quality of care and health outcomes relating to use of pharmaceuticals in Canada, much less to make the link between findings and policies. It is likely that shortcomings in coverage – particularly the prevalence in parts of Canada of persons who are uninsured or underinsured for pharmaceuticals provided outside hospitals – has an impact on quality of care and health outcomes to the extent that persons go without using medicines that would have been beneficial in preventing or treating health conditions.

226. Beyond this, errors resulting from the misuse of pharmaceuticals, including medication errors in hospitals, physicians' prescribing errors, errors in prescription medications dispensing, and patient errors in using medicines appropriately – have been shown to be common in all OECD countries for which assessment has been undertaken, and a leading source of preventable injury to patients. Health Canada cites studies (e.g., Wilson, 2001) reporting that medication errors are the most common single preventable cause of patient injury. The toll of such errors, in terms of patient safety and patient care costs, is considered to be significant.

227. Although evidence is limited, there is no particular reason to think the problem is better or worse in Canada. For instance, a recent survey by the Commonwealth Fund of sicker adults in several OECD countries found no significant difference in the share (10%) of sicker Canadian adults who said they had been given the wrong medication or the wrong dosage (Schoen *et al.*, 2005).

228. As in many OECD countries, policy makers in Canada have paid increasing attention to the problem of medication errors. Improved surveillance systems and innovative payment schemes, such as Québec's policy of reimbursing pharmacists who refuse to dispense a medicine so as to prevent a potential error, are examples of policies used to improve quality of care and health outcomes associated with pharmaceutical use. As part of 2004 Patient Safety commitments, Health Canada is providing funding for the implementation of a new Canadian Medication Incident Reporting and Prevention System (CMIRPS) and for the Canadian Patient Safety Institute (CPSI), newly established to address overall medical error.

### **3.7. Public satisfaction with pharmaceutical policies and outcomes**

229. An extensive survey, conducted for use by the Romanow Commission, revealed Canadian views and values in the area of pharmaceutical policy. For example, 85% of Canadians favoured policy changes to ensure universal drug coverage, although respondents had different views as to whether gaps in coverage should be addressed within the current system or the current system should be replaced with a national program offering universal coverage. When asked about alternative forms of cost-control, 94%

said they supported government use of purchasing power to negotiate lower prices, while only 76% supported limiting reimbursement to the cheapest effective version of a drug. When asked to choose whether decreasing the cost of drugs to governments or supporting research and development of new drugs should have higher priority in Canada, 63% named the former, compared with 19% choosing the latter. Among the highest users of the health-care system, 24% named R&D as the highest priority.

230. Pharmaceutical policy and decision-making in Canada, as in many other OECD countries, is not particularly transparent, nor are many channels for involvement by patients or consumer representatives evident. The Romanow Commission report (2002) concluded that intergovernmental mechanisms in Canada lack adequate public input. Since then, initiatives have been promoted by the Federal government and Health Canada to improve openness, transparency and public access to information on regulatory decisions and on clinical trials. These initiatives include steps to enable public input to the regulatory review process for drugs and other health products, and implementation of public registration and disclosure of clinical trials information. On June 14, 2006, CADTH announced a decision to expand CEDAC membership from 11 to 13, with the inclusion of 2 public representatives, in order to improve consumer/patient representation in this instance. Because the interests of Canadian drug consumers and patients are so diverse and diffuse, is a very difficult task to ensure that their views are represented adequately in the policy-making process. There is a risk that channels created for public input can be monopolized by the drug industry, which has the most concentrated economic interests in policy outcomes and strong incentives to wield what influence it can. Finding appropriately open and transparent processes that provide opportunities for input from all stakeholders is a difficult challenge for Canada and all countries seeking optimal outcomes in pharmaceutical policy-making.

231. Finally, there is some evidence to suggest that Canada's pharmaceutical policies tend to undervalue improvements in treatments that are marginal or non-existent from a therapeutic perspective, but significant in terms of patient convenience or other factors. Specifically, the PMPRB categories do not permit price premiums for new medicines for which patients may be willing to pay a higher price. This discourages the marketing of innovations of this kind (e.g., line extensions, new delivery technology), possibly leading to consumer welfare loss and lower public satisfaction than might otherwise be possible (particularly if patients become aware of the availability of such products elsewhere).

### **3.8. Industrial policy goals**

232. Like many OECD countries, Canada has an explicit goal of attracting business activities with high R&D intensity and in the biotech industry in particular.

233. The competitiveness of Canada for pharmaceutical companies can be evaluated according to several dimensions pertaining to geographical location, human resources skills and labour costs, corporate taxes, access to capital and, more specifically, to comparative advantages in the pharmaceutical or biotechnological sectors, and to pharmaceutical market dynamics (Government of Canada, 2005; PICTF, 2006; OECD, 2006, KPMG, quoted by Government of Canada, 2005).

234. Canada presents a number of attractive features for business enterprises: the proximity to the US market, allied with NAFTA provisions easing trade with the United States: a highly educated and relatively low-cost labour force; a lower marginal rate of corporate tax than the United States and Japan; and a high level of access to venture capital (Government of Canada, 2006; OECD, 2006, KPMG quoted by the government of Canada, 2005). All these elements, combined with a favourable perception among business executives regarding Canada's business environment, contribute to a good ranking of Canada in the World Competitiveness Yearbook of the Institute for Management Development (7th among 61 countries, behind

the United States, Hong Kong, Singapore, Iceland, Denmark and Australia)<sup>84</sup> (Institute for Management Development, 2006).

235. Although pharmaceutical industry activities continue to grow in Canada, notably in terms of production and employment (Industry Canada, 2006), the attractiveness of Canada for the location of pharmaceutical activities in the global context is not easy to assess. Although there are no major pharmaceutical firms' headquarters in Canada, the proximity with the United States and relatively low labour costs seem to be attractive characteristics for the generic industry, which has a notable presence in Canada. Actually, 40% of sales of the generic industry are accounted for by exports, of which 80% go to the United States.

236. The attractiveness for R&D activities is less evident: R&D expenditures of companies in Canada increased (in absolute terms) until 2002 but declined in 2003 and 2004 (PMPRB, 2006). Although pharmaceutical market factors are important determinants of a firm's sales revenues, the importance of such factors in driving firms' location and R&D investment activities is likely to be secondary to other factors. The productivity of Canadian R&D expenditures, assessed by the number of new molecular entities launched in the world and originating from Canada, is not particularly high, except in the biotech sector.

237. Nevertheless, it seems that Canada can be judged an attractive market for pharmaceutical manufacturers. Manufacturers can expect to obtain prices that are relatively high from a global perspective, and in line with Canada's income levels, and to obtain per capita sales volumes that are comparable to those of other markets. Factors that may reduce the attractiveness of the Canadian market, from the perspective of manufacturers, include policies that restrict utilisation of certain medicines through formulary restrictions and other controls, particularly in publicly financed plans, to the extent that such restrictions could result in lower expected sales revenues. However, the fact that the delay between first approval in the world and application for approval in Canada by the manufacturer is among the shortest in the world suggests that the Canadian market is considered an attractive market for pharmaceuticals.

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84 <http://www01.imd.ch/documents/wcc/content/overallgraph.pdf>

## KEY FINDINGS AND CONCLUSIONS

238. This paper has undertaken a comprehensive review and assessment of Canada's pharmaceutical pricing and reimbursement policies and the market and policy environment in which those policies operate. The findings point to a number of successful accomplishments, as well as outstanding challenges. Among the key findings are these:

- Regulation has very likely been responsible for bringing the prices of patented medicines in Canada roughly in line with European comparators. Of course, this raises the question as to whether European price levels are themselves at an appropriate level --- an issue beyond the scope of this case study, but an important consideration in the larger policy project to which this case study will contribute.
- Reimbursement and other policies have no doubt played a role in the high penetration rate of generic products in the Canadian market, yet relatively high generic prices persist, suggesting that there is scope for increased efficiency of spending and cost control through policy adjustments.
- Canadian third-party payers have largely refrained from undertaking price negotiations with manufacturers, foregoing prospective opportunities for containing costs and improving the cost-effectiveness of drug expenditures.
- In Canada as elsewhere, changes in the mix of medicines that are prescribed and consumed favouring new and higher-priced products over old ones are contributing to expenditure growth. Canadian pricing policies and the reimbursement policies, such as formulary management, that are employed by public plans, seek to ensure that the resulting cost increases are justified in terms of added value.
- While the weight of the evidence indicates that availability of medicines on the Canadian market has been both comprehensive and prompt, some very recent studies and anecdotal reports suggest that maintaining this standard may be an emerging challenge, particularly in the case of certain new medicines which succeed in obtaining a very high premium price in US markets.
- While all of Canada's coverage schemes promote access to medicines, differences in cost-sharing requirements, timeliness of formulary inclusion decisions and other factors result in differences in access to medicines across schemes.
- Canada's mix of schemes leave a small share of the population without financial protection against the risk of catastrophic spending on drugs.

239. These findings regarding Canadian pricing and reimbursement policies have been drawn on the basis of an assessment of the direct impact of the policies in Canada. However, an important consideration of ongoing work in the area of pharmaceutical pricing policy is the so-called global and cross-national impact of policies. Impacts of interest include the hypothetical effect of pricing and reimbursement policies in one country on prices and availability of medicines elsewhere, and the impact of pricing and reimbursement policies on investment in pharmaceutical R&D and the resulting impact on pharmaceutical innovation. These issues have been alluded to in this report without being directly assessed. This case study of Canada will provide input into OECD work to assess the hypothetical global and cross-national impact of different pricing and reimbursement schemes and policies.



## ANNEX: CROSS-COUNTRY COMPARISONS OF PHARMACEUTICAL PRICE LEVELS

240. One of the most critical issues of price comparison studies is that they often present bilateral comparisons between a reference country (A) and other countries (B, C, etc.). This means practically that the basket of pharmaceuticals used in the comparison between country A and country B is not the same basket of goods used to compare prices in A and C, and it implies that direct comparisons between price indexes for B and C are not valid. Therefore, studies presenting bilateral comparisons with Canada as the country of reference and studies presenting multilateral comparisons (the basket of selected pharmaceuticals is the same in all countries) are the focus of this review (see Table 4). Studies presenting bilateral comparisons with the United States as the reference country were also reviewed.

241. A study by Danzon & Furukawa (2003) compares US prices of 249 molecules among the US top 300 in 1999 to prices in eight countries, including Canada. The basket of pharmaceuticals contains both generic and patented drug, matched by molecule and indication<sup>85</sup> (ATC class) and represents 56% of the Canadian market. The authors use IMS data to compare manufacturers' prices, with price discounts furnished to big purchasers in the United States estimated at 8%. Price indexes were calculated using US volumes of sales as weights. Canadian prices appear to be 33% lower than US prices. Prices of originator products are 35% lower than in the United States while prices of generics are only 6% lower.

242. A study published in 2004 by the US Department of Commerce (ITA, 2004) compares the prices of patented products in the United States with prices in ten OECD countries (bilateral comparisons) in 2003. The sample is composed of the US top 54 patented prescription products containing a single molecule, further extended to all products containing this molecule (on- or off-patent). It represents 26% of drug sales across OECD countries, but the share of the market covered in Canada is not known. Fisher Indexes have been calculated based on ex-manufacturer price per standard unit. Canadian prices appear to be 46% below US prices. As US discounts have been ignored, the price differential between Canada and the United States is overestimated.

243. Annual reports from the PMPRB (see 2005 report) present bilateral comparisons of Canadian ex-factory prices of patented drugs with prices in the seven countries referred to in the regulation defining excessive prices (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States). Bilateral comparisons are based on patented products available in Canada and in the comparator country. The average foreign-to-Canadian price ratio for each product is computed, weighted by sales in Canada. Prices are converted by current exchange rates.<sup>86</sup> In the 2005 report, prices of patented drugs are

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85 The paper presents also a price comparison when products are matched by molecule and form-strength. In this case, only 35% of the Canadian market is covered, which shows how different are presentations in these two markets. Price differentials between the two countries are less important, by 2 to 3%, when "identical" products are compared.

86 PMPRB uses a fully-lagged 36-month moving average of spot exchange rates for this purpose. This means that long-term exchange-rate movements will be fully reflected in PMPRB's average price ratios only 36 months after they occur, while a short-term fluctuation will influence the ratios up to 36 months after it has been reversed.

44% lower in Canada than in the United States<sup>87</sup>. Prices in the United Kingdom and Switzerland are 13 to 16% higher than in Canada; Swedish and German prices are very close to Canadian prices; and France and Italy have lower prices than Canada (respectively 10% and 17%). It is important to note that these price comparisons are based on “publicly available ex-factory prices” obtained by manufacturers in foreign countries and provided to PMPRB for the review of excessive price (PMPRB, 2002). This means that further confidential discounts or rebates consented by the manufacturers are not taken into account, which could lead to under- or over-estimates of differentials between Canadian and foreign prices.

244. Although the price-regulation mandate of the PMPRB is limited to patented drugs, the Board has published international price comparisons for non-patented medicines. The first report (2003) analyses the ex-factory prices of non-patented single-source<sup>88</sup> drugs in Canada and the seven “official comparator countries” for fiscal year 1998/1999 (see Box 9). These products represent only a small part of provincial expenditures (13%). The study conducted on these products revealed that Canadian prices<sup>89</sup> were 22% higher than international median prices and 55% above median European prices (PMPRB, 2003a, p.24 & p. 25). In bilateral comparisons, Canadian prices were higher than prices in any European country (from 100% above Italy’s prices to 15% above German prices). When comparisons focus on brand-name products only in all countries (i.e. exclude generics which are available in comparator countries), Canadian prices are 21% above the median international price and 54% above median European prices.

245. Multiple-source drugs are produced by several manufacturers; they may be originator brand-name drugs or generic equivalents. PMPRB studied the prices of these drugs in 2000. International comparisons were conducted on 496 products (for 64 molecules) representing 40% of the generic market in six provinces. They showed that in Canada generics were priced 35% below originator products on average, the gap increasing with time after generic entry. This difference was slightly greater than in most comparator countries, except Germany (where the difference between originator and generic price is 41%), New Zealand (47%) and the United Kingdom (42%). In bilateral comparisons, multiple-source product prices are higher in Canada than in most comparator countries, except the United Kingdom (where prices are 12% higher), Switzerland (30% higher), and the United States (where prices are 259% higher when the Red Book was considered but 50% below Canadian prices when prices from the Federal Supply Schedule are used). Overall brand-name multiple-source products are priced 12 to 13% above median international prices (depending on prices considered in the US) and generic drugs are priced 14 to 32%<sup>90</sup> above median international price.

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87 To estimate the US-to-Canadian price ratio, the PMPRB uses an average of publicly available prices supplied by the patentee and of prices from the Federal Supply Schedule (FSS) published by the Veterans Administration. The FSS seldom has more than a 50% weight in the average, and often has a much smaller weight (personal communication with PMPRB).

88 Single-source drugs are those sold by only one manufacturer. Single-source products have been identified in the Ontario Drug Benefit formulary. These products may be sold by several manufacturers in other jurisdictions of Canada and in other countries. Non-patented products include products which have never been patented as well as products whose patent has expired.

89 The Canadian price is approximated by the Ontario Drug Benefit Formulary price, justified by the fact that there are few inter-provincial variations in prices.

90 With other assumptions, brand-name multiple-source products appear to be priced up to 45 to 46% above median international price and generic drugs 43 to 62% above median international price.

**Box 9. Methods used in PMPRB price comparisons**

PMPRB studies of single and multiple-source non-patented products (2003) present multiple variants to test sensitivity to different assumptions and/or samples. For instance, three methods are used to consider US prices: the use of the Federal Supply Schedule only, the use of the Red Book only or the use of both sources. Two different samples of products are considered: a set of drugs which are available in at least one comparator country and a set of drugs which are available at least in three countries. Finally, the average Canadian price to median international price ratio is computed as a geometric mean, according to three weighting methods: unweighted, weighted by “Canadian” expenditures and weighted by “Canadian” utilisation. Indeed, expenditures and utilisation in the Ontario Drug Benefit were used as a proxy of Canadian expenditures and utilisation and ODB formulary prices were used as a proxy for Canadian prices.

In PMPRB studies, different package sizes of equivalent molecule- form-strength in a country are dealt with by using the median unit price of these packages (and not the average). Ex-manufacturer prices are considered.

The impact of methods and sample on results is very important. For instance, for single-source non-patented products, Canadian prices are assessed to be 5% to 44% higher than the median international price, depending on assumptions. The first result is computed as the unweighted average Canadian price to median international price ratio for the largest sample of products (56) and using the Red Book for US prices, and the second one is the expenditures-weighted average for the smaller sample of products (39) and using both FSS and Red Book for US prices.

Results presented in this annex are for the utilisation-weighted average Canadian price to median international price computed with the sample of products available at least in three countries, using both FSS and Red Book.

246. Comparisons with prices in the United States have been given particular attention in recent years, partly because of the growth in cross-border trade. In 2001, Palmer D’Angelo Consulting International (2002) compared the prices of 27 top-selling generic drugs representing 39% of generic drug sales in Canada. The study used the Federal Supply Schedule for the US price and the Québec government formulary for the Canadian price to define the ex-manufacturer price of the ‘most representative presentation in Canada’ (strength and dosage form) of each product. The conclusion was that Canadian prices for generics were above US FSS prices, whatever the methodology used (mean, median, weighted or not), by 37 to 100%. However, the use of the Federal Supply Schedule can be considered as an important caveat, since it certainly underestimates US prices.

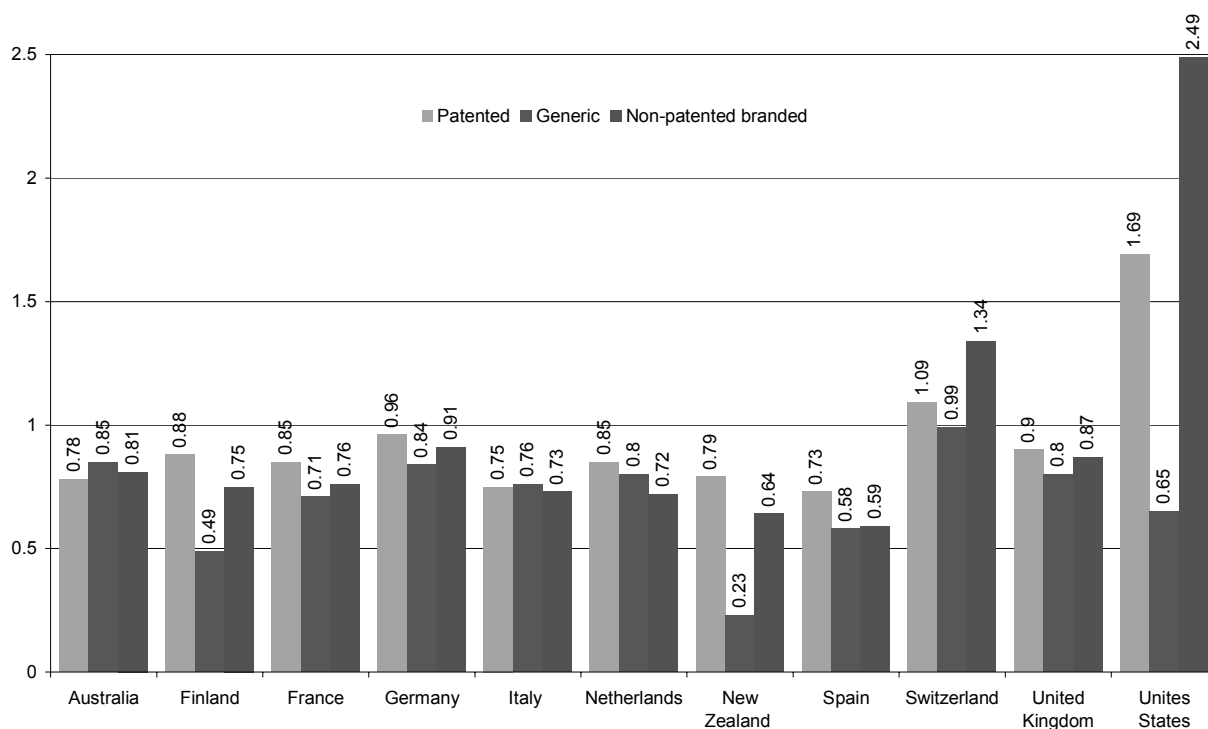
247. In 2005, Skinner compared the 2003 retail prices of prescription drugs in Canada and in the United States, from a sample of 100 brand-name drugs and 100 generics (Canada’s 100 top-selling drugs in volumes). Retail prices in Canada were computed using the IMS CompuScript database which provides both volume of sales and corresponding sales at retail prices, while retail prices in the United States were estimated by the author using several publicly available sources. Generic prices appear to be 78% higher than US ones, while branded products (patented or not) were 43% lower (Skinner, 2005).

248. Another study compares United States and Canadian generic retail prices for the 1999-2005 period (D’Cruz *et al.* 2005). The sample covers all presentations (strength, form and package size) which are available in both countries, which probably leads to an overestimate of US prices by excluding large package sizes with lower unit costs. This sample represents an increasing share of the Canadian market (from 39% in 1999 to 56% in 2005). Prices in both countries were evaluated using IMS data, at ex-manufacturer level. Purchasing power parities were used to convert US prices to Canadian dollars. A ratio for Canadian-to-US prices was computed for each product and then averaged, using Canada’s market shares as weights. According to this study, US generic prices used to be higher than Canadian generic prices in 1999-2000, were slightly lower in 2001-2002 and were equivalent in 2004-2005.

249. In 2006, the PMPRB produced a report on prices of non-patented prescription drugs (PMPRB, 2006c). Using IMS data, the PMPRB compared ex-factory prices of generics and other non-patented drugs

using “average foreign-to-Canadian prices ratios” (arithmetic mean). In bilateral comparisons, generic prices were found to be systematically lower in foreign countries<sup>91</sup> than in Canada. On a bilateral comparison, Canada’s prices for generics exceeded those in each of the 11 comparison countries. Canadian prices for non-patented drugs also exceeded those in all comparator countries except Switzerland and the United States (See Figure 12).

**Figure 12. Average foreign-to-Canadian price ratio at market exchange rates in 2005, bilateral comparisons**



Source: PMPRB, 2006c.

91 Foreign countries studied were the seven comparator countries less Sweden, plus Australia, Finland, the Netherlands, New Zealand, and Spain.

**Table 4. Summary of findings from selected studies comparing Canadian pharmaceutical price levels with those of other countries**

Study	Price comparison	Methodology	Findings
Danzon and Furukawa (2003)	1999 manufacturers' prices for 249 molecules among the US top-selling 300	Prices weighted using US sales volume. US discounts estimated at 8%.	Canadian prices found to be 33% lower than US prices. Originator products 35% lower and generics 6% lower.
US Department of Commerce (2004)	2003 manufacturers' prices for the US 54 top-selling patented medicines	Fisher Indexes calculated based on price per standard unit. No adjustment for US discounts.	Canadian prices found to be 46% lower than US prices.
PMPRB (2005)	2004 manufacturers' prices in Canada and seven designated comparator countries for patented medicines available in both Canada and the comparator country.	Average ratio-to-Canadian price computed for each product, weighted by sales in Canada. Prices converted by current exchange rates. US Federal Supply Schedule prices used as point of comparison.	Canadian prices found to be 44% lower than US prices. Compared with Canada, prices in the United Kingdom are 13% higher; prices in Switzerland are 16% higher; prices in France are 10% lower; prices in Italy are 17% lower; Swedish and German prices are comparable.
PMPRB (2003)	Fiscal year 1988-1989 manufacturers' prices for non-patented single-source drugs that are available in at least three of seven designated comparator countries. Study universe represents only 13% of provincial drug expenditures.	Average Canadian price to median international price ratio is computed as a geometric mean. Findings weighted by Canadian utilisation. (See Box 9 for more detail on methods, alternative calculations and sensitivity to assumptions.)	Canadian prices for non-patented single-source drugs found to be 22% higher than international median prices and 55% above median European prices.  When originator brand-name products only are taken into account in all countries, Canadian prices are 21% above the median international price and 54% above median European prices.
PMPRB (2003)	2000 manufacturers' prices for 496 multiple-source drugs (64 molecules) representing 40% of the generic market in six Canadian provinces.	Bilateral comparisons made between Canada and designated comparator countries.	Canadian prices for multiple-source drugs were higher than most comparator countries with the exception of the United Kingdom, Switzerland and the United States. Canadian prices for generics were 35% below Canadian brand-name products, on average, a larger price differential than found in most comparator countries, with the exception of Germany (41%), New Zealand (47%) and the United Kingdom (42%).

Palmer D'Angelo Consulting International (2002)	2001 prices for 27 top-selling generic drugs representing 39% of generic drug sales in Canada. Quebec formulary price used for Canada. Federal Supply Schedule used for United States.	Several methodologies used to compute mean, median, weighted and unweighted price indexes.	Canadian prices for generics were found to be above US prices according to several alternative methodologies used, although choice of US price for comparison suggests differential is overstated.
Skinner, 2005	2003 retail prices of top-selling generic drugs in Canada, bilateral comparison with the United States	Average of ratio of Canadian to US prices.  Prices converted with PPPs.	Canadian prices of generics appear to be 78% higher than US ones, while branded products (patented or not) were 43% lower
Cruz <i>et al</i> , 2005	1999 to 2005 manufacturers' prices, in Canada and the US.  Sample of all presentations (strength, form and package size) which are available in both countries, 56% of the market in 2005. IMS data	Average ratio of Canadian-to-US prices, weighted by Canada's market shares.  Conversion by PPPs.	According to this study, US generic prices were higher than Canadian generic prices in 1999-2000, were slightly lower in 2001-2002 and are equivalent in 2004-2005.
PMPRB, 2006c	2005 manufacturers' prices of non-patented originator brand-name drugs and generic drugs. Bilateral comparisons with 11 countries. IMS data.	Canadian-sales-weighted arithmetic average of Foreign-to-Canadian price ratio.	Canadian prices are always higher than foreign prices for generics (average ratio ranging from 0.23 for New Zealand to 0.99 for Switzerland).  Foreign prices of non-patented originator drugs are almost always lower (average ratio ranging from 0.59 for Spain to 0.91 in Germany) than Canadian prices, except for Switzerland (average price ratio of 1.34) and the United States (2.46).

## LIST OF ACRONYMS

<b>AAC</b>	Actual Acquisition Cost
<b>ABPI</b>	Association of the British Pharmaceutical Industry
<b>ARC</b>	Advance Ruling Certificate
<b>ATC</b>	Anatomical Therapeutic Chemical
<b>ATP</b>	Average Transaction Price
<b>CAPDM</b>	Canadian Association for Pharmacy Distribution Management
<b>CADTH</b>	Canadian Agency for Drugs and Technology in Health
<b>CCOHTA</b>	Canadian Coordinating Office for Health Technology Assessment
<b>CDR</b>	Common Drug Review
<b>CEDAC</b>	Canadian Expert Drug Advisory Committee
<b>CGPA</b>	Canadian Generic Pharmaceutical Association
<b>CLIHA</b>	Canadian Life and Health Insurance Association
<b>CMA</b>	Canadian Medical Association
<b>COMPUS</b>	Canadian Optimal Medication Prescribing and Utilisation Service
<b>CPSI</b>	Canadian Patient Safety Institute
<b>DBL</b>	Drug Benefit List
<b>DDD</b>	Defined Daily Dose
<b>DQTC</b>	Drug Quality and Therapeutics Committee
<b>DTCA</b>	Direct-to-consumer-advertising
<b>DURs</b>	Drug Utilisation Reviews
<b>FDA</b>	Food and Drug Administration
<b>FP&amp;TC</b>	Federal Pharmacy and Therapeutics Committee
<b>FSS</b>	Federal Supply Schedule
<b>GATT</b>	General Agreement on Tariffs and Trade
<b>HDAP</b>	Human Drug Advisory Panel
<b>HPFB</b>	Health Products and Food Branch
<b>ICR</b>	Individual Clinical Review
<b>NAFTA</b>	North American Free Trade Agreement
<b>NCE</b>	New Chemical Entities
<b>NIHB</b>	Non-insured Health Benefits
<b>NOC</b>	Notice of Compliance
<b>NOC/c</b>	Notice of Compliance with Conditions
<b>NPS</b>	National Pharmaceuticals Strategy
<b>ODB</b>	Ontario Drug Benefit
<b>OTC</b>	Over-the-counter
<b>PAAB</b>	Pharmaceutical Advertising Advisory Board
<b>PDMA</b>	Prescription Drug Marketing Act
<b>PICTF</b>	Pharmaceutical Industry Competitiveness Task Force
<b>PMPI</b>	Patented Medicines Price Index
<b>PMPRB</b>	Patented Medicine Prices Review Board
<b>PPPs</b>	Purchasing Power Parities

<b>PRA</b>	Provincial Reimbursement Advisor
<b>SAP</b>	Special Access Programme
<b>SR&amp;D</b>	Scientific Research & Development
<b>VCU</b>	Voluntary Compliance Undertaking
<b>WTO</b>	World Trade Organisation



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