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Prescription Drug Systems and Price Control in Canada

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PRESCRIPTION DRUG SYSTEMS AND PRICE CONTROL IN CANADA

Robert S. Nakagawa[*]

INTRODUCTION

This Article presents a brief overview of the regulation of prescription drugs in Canada. Part I provides an overview and the context of the environment in which the system operates; Part II describes the responsibilities of the federal government; Part III reviews the national initiatives that have been undertaken cooperatively between the federal and provincial/territorial governments; and Part IV describes the responsibilities of the provincial governments.

I. OVERVIEW AND CONTEXT

With a relatively small population of 33.1 million people inhabiting 9,984,670 square kilometers (nearly 4 million square miles), Canada is the world's 38th most populous country[1] and the second largest.[2] It is a constitutional monarchy with two

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[1] Central Intelligence Agency, The World Factbook, https://www.cia.gov/cia/publications/factbook/rankorder/2119rank.html (last visited Apr. 12, 2007).

[2] Central Intelligence Agency, The World Factbook, https://cia.gov/cia/publications/factbook/geos/ca.html (last visited Apr. 12, 2007).

[3] Gregory P. Marchildon, *Health Systems in Transition: Canada*, WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies 8 (2005), *available at* http://www.euro.who.int/

constitutionally recognized orders of government: the federal government, and the provinces and territories.[3] The country is divided into 10 provinces and three territories. With an average life span of 79.9 years, Canadians live slightly longer than Americans, whose average life span is 77.5 years, and spend significantly less on health care (9.9 percent versus 15.3 percent of GDP).

Canadians place a high degree of importance on health care. The Commission on the Future of Health Care in Canada (the Romanow Commission) identified Medicare as "a defining aspect of our citizenship and an expression of social cohesion."[4] Public sources fund 70 percent of the costs of the health care system in Canada, while the remaining 30 percent comes from the private sector.[5]

Drug therapy is the cornerstone of modern medical care in Canada. The number of drugs available to treat, diagnose and prevent disease has increased steadily over the last 30 years. As the number of available drugs has increased, so has their use. The Romanow report found that 300 million prescriptions, an average of 10 per person, are filled in Canada annually.[6] Drug expenditures have followed suit. In 1985, the total expenditure on drugs in Canada was $3.8 billion; this figure was forecast to hit $24.8 billion by 2005.[7]

Document/E87954.pdf.

[4] Roy J. Romanow, Q.C., Building on Values: The Future of Health Care in Canada xxi (2002), *available at* http://www.hcsc.gc.ca/english/pdf/romanow/pdfs/HCC_Final_Report.pdf.

[5] Exploring the 70/30 Split: How Canada's Health Care System is Financed. Canadian Institute for Health Information, Ottawa, Ontario 3 (2005), *available at* http://secure.cihi.ca/cihiweb/products/FundRep_EN.pdf.

[6] Romanow, *supra* note 4 at 191.

[7] Drug Expenditures in Canada 1985 to 2004. Canadian Institute for Health Information, Ottawa, Ontario 11 (2005), *available at* http://dsp-psd.pwgsc.gc.ca/Collection/H115-27-2004E.pdf.

A. Who Does What?

Federal, provincial, and national structures and programs are primarily responsible for health care in Canada. National initiatives involve the cooperation of the federal, provincial, and territorial governments. The breakdown of federal, national and provincial responsibilities for prescription drugs is as follows:

Federal

- Approval of new drugs for sale
- Patent drug pricing

National (includes Federal, Provincial and Territorial Participants)

- Evidence-based drug reviews (through the Common Drug Review)
- Formulary recommendations (through the Canadian Expert Drug Advisory Committee)

Provincial

- Drug plan formulary decisions
- PharmaNet Systems

II. FEDERAL GOVERNMENT RESPONSIBILITIES

The federal government's role in the health system involves:

(1) Setting and administering national principles and standards for the health care system. For example, the Canada Health Act requires that medical and hospital services are provided free of charge to Canadians. The five principles of the Canada Health Act are public administration, comprehensiveness, universality, portability and accessibility. Provinces must meet these criteria in the delivery of health care services in order to receive full federal contributions.[8]

(2) Assisting in the financing of provincial health care

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[8] CANADA HEALTH ACT OVERVIEW (November 25, 2002), http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2002/2002_care-soinsbk4_e.html (last visited January 14, 2007).

services through fiscal transfers (there were $32.5 billion in cash and tax transfers during 2006-2007).[9]

(3) Delivering direct health services to specific groups including veterans, native Canadians, persons living on reserves, military personnel, inmates of federal penitentiaries and the RCMP. Their drug plans cover 1.2 million Canadians.

(4) Health protection, disease prevention and health promotion.

(5) Regulating the safety, efficacy and quality of drugs. The Therapeutic Products Directorate is responsible for ensuring that prescription drugs marketed in Canada are safe and effective. The Directorate is committed to ensuring that decisions made are evidence-based and timely.[10]

(6) The price of patented medicines (through the Patented Medicines Prices Review Board).

While not its primary role, the federal government is responsible for the delivery of health care services provided to the military, First Nations, corrections, and veterans groups.

A. Federal Price Controls[11]

Price control of patented medicines is the responsibility of the Patented Medicines Prices Review Board (PMPRB). The PMPRB is an independent body created by Parliament in 1987 under the Patent Act. It was established at the same time that patent protection was extended for pharmaceuticals as a safety net to ensure that Canadians were not paying an excessive price

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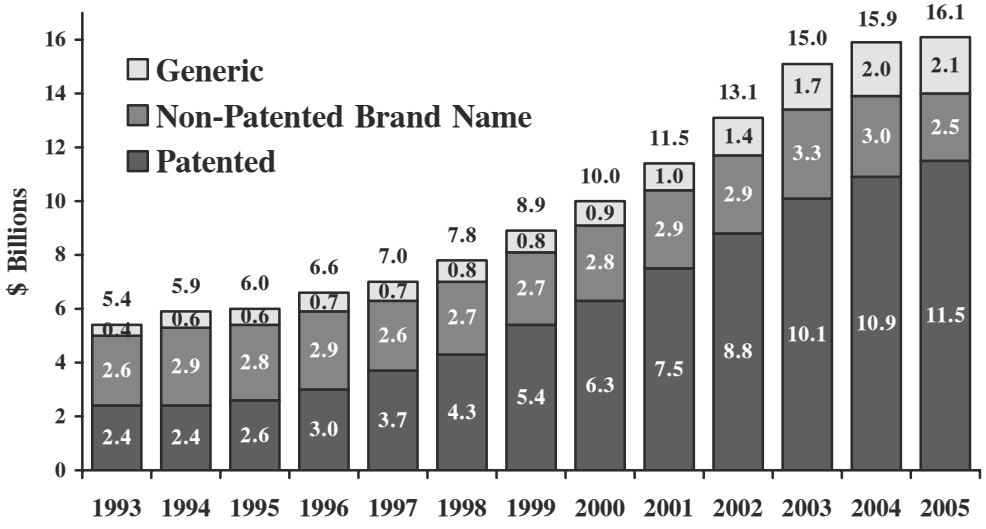
[9] GOVERNMENT OF CANADA: DEPARTMENT OF FINANCE, CANADA HEALTH TRANSFER (FEDERAL TRANSFERS TO PROVINCES AND TERRITORIES, May 2006), http://www.fin.gc.ca/FEDPROV/chte.html (last visited Jan. 13, 2007).

[10] GOVERNMENT OF CANADA: HEALTH, DRUGS AND HEALTH, http://www.hc-sc.gc.ca/dhp-mps/index_e.html (last visited Jan. 14, 2007).

[11] GOVERNMENT OF CANADA: PATENT MEDICINE PRICES REVIEW BOARD, WELCOME!, http://www.pmprb-cepmb.gc.ca/english/home.asp?x=1 (last visited Jan. 13, 2007).

at the same time that manufacturers enjoyed a longer duration of market exclusivity. The PMPRB is a quasi-judicial tribunal that sets price guidelines and has the power to roll back prices that are deemed excessive. Figure 1 shows the amount of prescription drug sales in Canada from 1993 to 2005.

Figure 1



Source: PMPRB and IMS Health

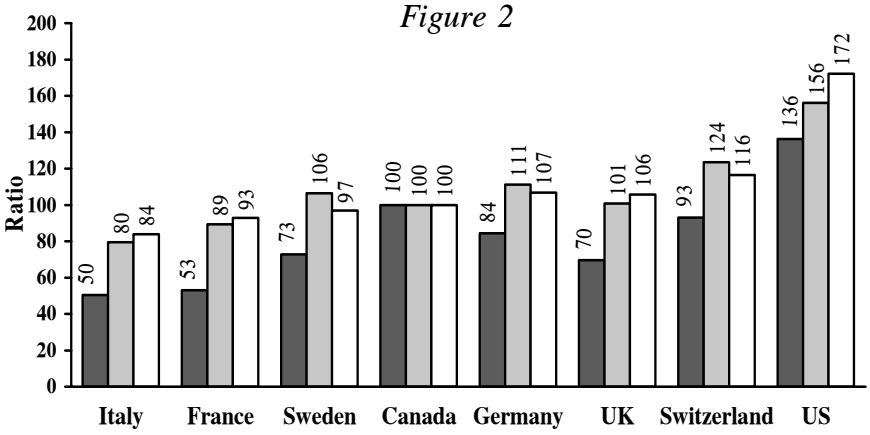
It should be noted that the PMPRB only has jurisdiction over patented prescription drugs, and as such does not have the authority to regulate non-patented drugs including generic drugs, prices charged by wholesalers or retailers, or pharmacists' professional fees. Rather, the PMPRB determines whether a price set by a manufacturer is excessive by employing the following guidelines:

- Existing patented drug prices cannot increase by more than the Consumer Price Index;
- New patented drug prices are limited so that the cost of therapy is in the range of the cost of therapy for existing drugs used to treat the same disease; and
- Breakthrough drug prices are limited to the median of

the prices for the same drugs charged in other specified industrialized countries that are set out in the Regulations under the Patent Act (France, Germany, Italy, Sweden, Switzerland, the U.K. and the U.S.). The determination of "breakthrough" is made by an expert advisory committee established by the PMPRB.

The impact of the PMPRB on patented drug prices in Canada relative to the defined comparator countries is shown in Figure 2. The ratio indicated along the y-axis represents the ratio of foreign prices to Canadian prices for patented drugs in the years 1987, 1997 and 2005. The relative price of prescription drugs in Canada has been reduced from 73 percent to 58 percent of the U.S. price. It is clear that the U.S. pays the highest price for prescription drugs among the comparator countries.

Figure 2



Increases in health spending relative to increases in other publicly funded services in Canada are a growing concern. In British Columbia, the Ministry of Health spent almost 42 percent of the provincial budget in the fiscal year of 2004-2005 on health care.[12] Average annual increases in expenditures have

[12] PROVINCE OF BRITISH COLUMBIA: MINISTRY OF HEALTH,

been approximately 8 percent per year, while Provincial revenues are anticipated to grow by approximately 3 percent per year. This 5 percent difference between revenues and expenditures is a significant concern to the government of British Columbia. At that rate, health expenses have the potential to consume all provincial expenditures other than education by the fiscal year 2018.[13]

Prescription drug expenses in British Columbia are increasing at an even greater rate. Over the last five years, the average increase in spending has been approximately 9 percent per year. This could be considered a worthwhile investment in health if the drugs funded generally represented significant advances in therapy, and resulted in better patient outcomes (reduced physician visits, hospitalizations and emergency department visits). However, this is not the case. While some drugs are true therapeutic breakthroughs, most of them are not. *Prescrire,*[14] a French publication, is one of the few publications that places a value on new medicines, rating them on a scale ranging from "not acceptable" to "bravo." Figure 3 shows that over the period 1981 to 2005, of 3,122 reviewed drugs or indications, more than two-thirds of them were "nothing new." Only 2 percent were considered to be real advances, and a mere seven drugs (0.22 percent) were considered to be worthy of a "bravo" rating.[15]

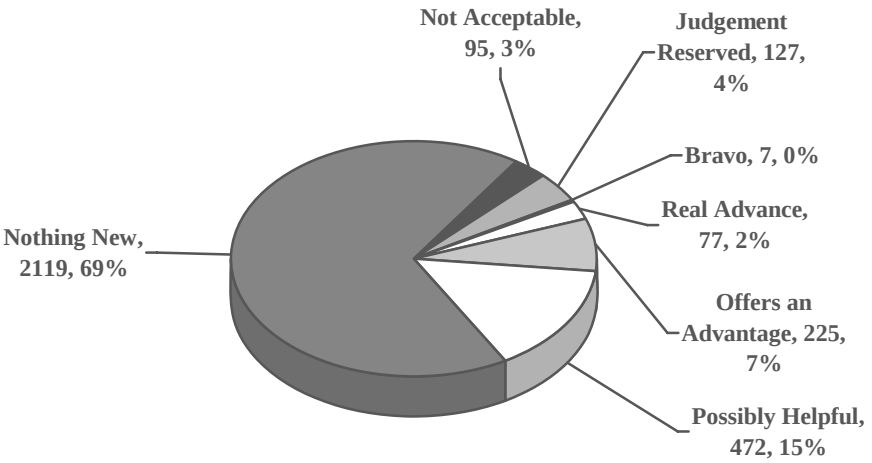
CONVERSATION ON HEALTH, http://www.bcconversationonhealth.ca/428/368/ (last visited Jan. 13, 2007).

[13] PROVINCE OF BRITISH COLUMBIA: MINISTRY OF FINANCE, ECONOMIC AND FISCAL UPDATE (Sept. 15, 2006), http://www.fin.gov.bc.ca/qrt-rpt/qr06/q1powerpoint.pdf (last visited Jan. 11, 2007).

[14] PRESCRIRE INTERNATIONAL, *available at* http://www.prescrire.org/signature/productions/international.php.

[15] *A review of new drugs in 2004: Floundering innovation and increased risk-taking*, PRESCRIRE INTERNATIONAL, April 2005, vol.14, n. 76 pp. 68-73.

Figure 3
New Products Ratings 1981–2005



Based on La Revue Prescrire with 3,122 drugs or new indications; does not include over-the-counter medications or product line extensions

Prescrire Rating Scale:

Bravo—The drug is a major therapeutic innovation in an area where previously no treatment was available.

A Real Advantage—The product is an important therapeutic innovation but has certain limitations.

Offers an Advantage—The product has some value but does not fundamentally change the present therapeutic practice.

Possibly Helpful—The product has minimal additional value, and should not change prescribing habits except in rare circumstances.

Judgment Reserved—The editors postpone their judgment until better data and a more thorough evaluation of the drug are available.

Nothing New—The product may be a new molecule but is superfluous because it does not add to the clinical possibilities offered by previous products available. In most cases it concerns a me-too product.

Not Acceptable—Product without evident benefit but with potential or real disadvantages.

III. NATIONAL INITIATIVES

The following sections describe the national initiatives, including the National Pharmaceuticals Strategy and the pooling of resources for drug plan reviews through the Common Drug Review and the Canadian Expert Drug Advisory Committee.

A. The National Pharmaceuticals Strategy[17]

First Ministers (the Prime Minister of Canada and the Premiers of each of the provinces and territories) agreed to implement a 10-year plan to strengthen health care in Canada. The National Pharmaceuticals Strategy is an important part of this plan. The following nine elements are involved in this strategy:

- Develop, assess and cost options for catastrophic pharmaceutical 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 evaluation of real-world drug safety and effectiveness;
- Pursue purchasing strategies to obtain best prices for Canadians for drugs and vaccines;
- Enhance action to influence the prescribing behaviour [sic] 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 through accelerated development and deployment of the Electronic Health Record;
- Accelerate access to non-patented drugs and achieve

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[17] FEDERAL/PROVINCIAL/TERRITORIAL MINISTERIAL TASK FORCE, NATIONAL PHARMACEUTICALS STRATEGY PROGRESS REPORT 4 (2006), *available at* http://www.hc-sc.gc.ca/index_e.html.

international parity on prices of non-patented drugs; and
- Enhance analysis of cost drivers and cost-effectiveness, including best practices in drug plan policies.

In September 2006, a progress report was released.[18] The report outlined the current status and progress of each of the NPS elements as well as highlighting the priority work for the next year. In addition, there was a commitment by the governments to involve stakeholders to a greater degree in the development of initiatives.

B. Drug Plan Formulary Decisions

There are 19 publicly funded drug plans in Canada: one for each of the 10 provinces and three territories, as well as six federal plans. Beneficiaries under each of these plans are determined by the jurisdiction. While most of the plans provide coverage for seniors and low-income families, some are more universally available with varying degrees of deductibles and co-pays. Until 2002 each plan undertook its own review of the drug's therapeutic and economic profile.[19]

C. The Common Drug Review[20]

In 2002, a Common Drug Review (CDR) process was established to provide a single drug review to serve as the basis for drug formulary decisions in each of the drug plans. Manufacturers of public drug plans submit requests for drugs to be reviewed by the CDR for new drugs that have been approved for sale in Canada by Health Canada, and have not previously been available.[21] The staff prepares a common drug review

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[18] *Id.*

[19] Health Canada, Common Drug Review, http://www.hc-sc.gc.ca/hcs-sss/pharma/mgmt-gest/cdr-emuc/index_e.html (last visited Mar. 22, 2007).

[20] Canadian Agency for Drugs and Technology in Health, Canadian Expert Drug Advisory Committee. http://www.cadth.ca/index.php/en/cdr/committees/cedac (last visited Mar. 22, 2007).

[21] The submission requirements are available at http://www.cadth.ca/media/cdr/process/CDR_SubmissionGuidelines_2006_ Sept20.pdf.

document based on the submission and independent literature searches. The drug manufacturer then comments on the review before it is finalized.

D. Canadian Expert Drug Advisory Committee[22]

The Canadian Expert Drug Advisory Committee (CEDAC) is an 11-member independent advisory body with expertise in drug therapy and drug evaluation, and has two new public members as of the fall of 2006. The CEDAC is responsible for reviewing the final CDR and developing formulary recommendations for consideration by each of the public drug plans. Listing recommendations are provided confidentially to the drug plans and the manufacturer under embargo to allow for comment. The final recommendations, along with the basis for said recommendations, are posted on the website.

IV. PROVINCIAL GOVERNMENT RESPONSIBILITIES

In general, the provincial governments are responsible for managing and delivering health care services within their jurisdiction, which involves planning, financing, and evaluation and provision of hospital care, physician and allied health care services, as well as the regulation of the practices of the health professions. Although payment for prescription drugs is not required under the Canada Health Act, every province offers some form of drug insurance to their citizens. The beneficiary and drug coverage parameters vary widely among the plans.

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[22] Government of British Columbia PharmaCare, PharmaNet, http://www.healthservices.gov.bc.ca/pharme/pharmanet/netindex.html (last visited Mar. 22, 2007).

A. Drug Plan Decisions

Each of the drug plans make listing and coverage decisions based on:

- CEDAC's recommendation
- Their mandates, priorities and resources
- Generic price limits and drug substitution requirements
- The availability of therapeutic reference-based pricing
- The availability of policies that ensure that more expensive drugs are only provided when pre-determined criteria (Special Authorization, Prior Authorization) are met

B. PharmaNet—Provincial Pharmacy Network[23]

British Columbia has one of the most comprehensive pharmaceutical databases in the world. Since 1995, pharmacists have been required by law to enter all community prescriptions into the database. This legislation was targeted at ensuring better patient safety by reducing preventable adverse events and hospital admissions by the early identification of drug interactions, allergies and other therapeutic problems by the pharmacist. It was felt that a pharmacist would not be able to safely dispense a prescription drug without access to a complete drug profile for the patient. The current drug database now includes all prescriptions dispensed in British Columbia pharmacies since 1995.

In addition to these clinical benefits, the PharmaNet system allows pharmacists to monitor for prescription drug abusers and prevent prescription fraud. Work is currently underway to establish a pan-Canadian standard for drug information systems to support the development of PharmaNet systems throughout

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[23] Canada Health Infoway, Drug Information Systems, http://www.infoway-inforoute.ca/en/WhatWeDo/DrugsInfo.aspx (last visited Mar. 22, 2007).

Canada. This is being developed with support from Canada Health Infoway and supported by both the federal, provincial and territorial governments.[24]

CONCLUSION

Health care in Canada is provided largely through support from the federal, provincial and territorial governments. The federal government is responsible for the approval of new drugs for sale in Canada as well as the regulation of patent drug pricing. Provincial governments are responsible for their own drug plan design and for determination of the drugs for which they will provide payment. They also operate independent prescription drug systems, such as PharmaNet, to ensure the safe and efficient dispensing of prescription drugs.

There are many aspects of the Canadian health care system that may be of interest to U.S. policy makers. Drug price regulation for patented medicines could provide more accessible prescription drugs in the U.S. Cooperation between the federal and provincial/territorial governments to advance the national pharmaceutical agenda and share rigorous reviews of new drugs has been valuable in Canada. Similar cooperation in the U.S. may provide similar benefits. Finally, government sponsored, comprehensive electronic prescription databases may provide an additional element of safety for patients, protecting them from untoward drug effects resulting from drug interactions or other sensitivities.

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[24] *Id.*