Patented Medicine Prices Review Board

2007-2008

Departmental Performance Report

The original version was signed by Leona Aglukkaq

The Honourable Leona Aglukkaq
Minister of Health
Government of Canada

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SECTION I – OVERVIEW

Chairperson's Message

I am pleased to present the 2007-2008 Departmental Performance Report for the Patented Medicine Prices Review Board (PMPRB).

The PMPRB's mandate is two-fold:

Regulatory – To ensure that prices charged by patentees for patented medicines sold in Canada are not excessive, thereby protecting consumers and contributing to Canadian health care.

Reporting – To report on pharmaceutical trends of all medicines, and on R&D spending by pharmaceutical patentees, thereby contributing to informed decisions and policy making.

During the past year, the PMPRB was active in fulfilling its mandate. In keeping with its regulatory role, the Board reviewed the prices of 1,178 patented drug products, including 64 new drugs that came under its jurisdiction in 2007. Two Notices of Hearing were issued under s.83 of the *Patent Act*. The purpose of a hearing is for the Board to determine whether a patented medicine is, or was, being sold in any market in Canada at a price that, in the opinion of the Board, is or was excessive. In addition, proceedings were initiated into the matter of Celgene Corporation and the medicine Thalomid with respect to the Board's jurisdiction over the price of the medicine.

The Board's Excessive Price Guidelines (Guidelines), first developed in 1989 and revised in 1994, have been, and continue to be, the subject of ongoing discussions, in an effort to ensure they remain relevant and appropriate in today's modern pharmaceutical environment. Their review, an important project initiated in 2006, continued to involve intensive efforts on the part of the Board, our staff, and numerous stakeholders.

In 2007, the process included numerous face-to-face bilateral meetings with our stakeholders at which the Board heard the opinions from representatives of all three sectors of the pharmaceutical industry, i.e., innovative pharmaceutical, biotech and generic, relating to the challenges they face within the current environment. Consumer and patient advocacy groups and public and private drug plans have also participated in our consultations and have provided their views regarding affordable and sustainable access to pharmaceuticals in Canada.

In January 2008, the PMPRB released a Discussion Paper requesting feedback on proposed options for changing the Guidelines that were derived from the consultations, as well as on a range of options to address the impact of moving to the mandatory reporting of all benefits as part of the average price of a drug product. The Board has worked diligently to advance work on these fronts.

The PMPRB is committed to fairness and transparency in its role of protecting consumer interests by ensuring that prices of patented medicines in Canada are not excessive. The PMPRB will continue to provide its stakeholders with the opportunity to participate in ongoing consultation activities, which is a critically important part of the Board's efforts to reach decisions that are balanced and fair, and which will serve all Canadians effectively. The Board is also continuing to ensure open communications through its NEWSletter, its Web site and other means, as appropriate.

During 2007-2008, as part the PMPRB's reporting mandate, the *New Drug Pipeline Monitor* was introduced. This report provides drug plan managers and others with information relating to newly emerging drug products that are likely to have a significant impact in drug therapy and drug care. Two studies were also published relating to non-patented prescription drug prices, and the PMPRB initiated a series of new projects under the National Prescription Drug Utilization Information System (NPDUIS) which include research examining the potential impact of long-term demographic change on public drug plans, recent trends in dispensing fees reimbursed by drug plans, and methodological alternatives for measuring volumes of treatment in utilization analysis.

In conclusion, the Board continues to carry out its mandate by ensuring that patentees do not charge excessive prices for patented drugs sold in Canada and by providing timely information on Canadian pharmaceutical price trends.

The original version was signed by Brien G. Benoit, MD

Brien G. Benoit, MD
Chairperson

Management Representation Statement

I submit for tabling in Parliament, the 2007–2008 Departmental Performance Report for the Patented Medicine Prices Review Board.

This document has been prepared based on the reporting principles contained in the *Guide for the Preparation of Part III of the 2007–2008 Estimates on Plans and Priorities and Departmental Performance Reports*:

- It adheres to the specific reporting requirements outlined in the Treasury Board Secretariat guidance;
- It is based on the department's approved Strategic Outcome and Program Activity Architecture that were approved by Treasury Board;
- It presents consistent, comprehensive, balanced and reliable information;
- It provides a basis of accountability for the results achieved with the resources and authorities entrusted to it; and
- It reports finances based on approved numbers from the Estimates and the Public Accounts of Canada.

The original version was signed by Brien G. Benoit, MD

Name: Brien G. Benoit, MD

Title: Chairperson

Summary Information

Department's Reason for Existence

The Patented Medicine Prices Review Board (PMPRB) has a dual role:

Regulatory – To ensure that prices charged by patentees for patented medicines sold in Canada are not excessive, thereby protecting consumers and contributing to Canadian health care.

Reporting – To report on pharmaceutical trends of all medicines, and on R&D spending by pharmaceutical patentees, thereby contributing to informed decisions and policy making.

The PMPRB is an independent, quasi-judicial body created by Parliament as a result of revisions to the *Patent Act* (Act) in 1987 (Bill C-22) which increased patent protection for pharmaceuticals. The PMPRB represents a strategic component of the federal government's policy to balance consumer protection and affordable health care with the trade and industrial development objectives of pharmaceutical patent legislation.

Subsequent revisions to the Act in 1993 (Bill C-91) further increased patent protection for pharmaceutical products by eliminating compulsory licensing. The amendments also gave the PMPRB increased remedial powers and shifted ministerial responsibility for the PMPRB to the Minister of Health. Prior to that, responsibility for the PMPRB rested with the Minister of Consumer and Corporate Affairs (now the Minister of Industry), who has overall responsibility for the Act. The Minister of Health is responsible for the pharmaceutical provisions of the Act as set out in sections 79 to 103.

Financial Resources ($ thousands)

	2007–2008	
Planned Spending	**Total Authorities**	**Actual Spending**
$11,475.0	$11,924.8	$7,432.4[1]

Human Resources

	2007-2008	
Planned	**Actual**	**Difference**
62	50	12

[1] As a result of the June 2006 Treasury Board decision, the PMPRB received an additional $5.0M in 2007-2008, on top of its core A-base of $6.5M. Given the interim funding was sun-setting on March 31, 2008, some positions could not be staffed. As well, some hearings were settled when the patentees unexpectedly submitted Voluntary Compliance Undertakings (VCUs), while other matters that were anticipated to move to a hearing were delayed as a result of further discussions with patentees.

Departmental Priorities

Name	Type	Performance Status
1. Compliance and enforcement	Ongoing	Successfully met
2. Report on pharmaceutical trends a) Information on trends in patentees' prices of patented medicines sold in Canada and on patentees' research-and-development expenditures; b) Reports under the National Prescription Drug Utilization Information System; and c) Monitoring and reporting on non-patented prescription drug prices.	Ongoing	Successfully met

Program Activities by Strategic Outcome

	Expected Results	Performance Status	2007-2008		Contributes to the following priority
			Planned Spending ($thousands)	Actual Spending ($thousands)	
Strategic Outcome: Prices charged by patentees for patented medicines sold in Canada are not excessive and Canadians are informed on pricing trends of medicines, as well as the R&D spending of pharmaceutical patentees.					
Patented Medicine Prices Review	All patentees' prices for new and existing patented medicines sold in Canada are reviewed in a timely manner and in accordance with the PMPRB's Excessive Price Guidelines	Successfully met	$8,589.5	$5,706.5	Priority No. 1
	Canadian consumers and other stakeholders have complete and accurate information on trends in patentees' prices of patented medicines sold in Canada and on patentees' research-and-development expenditures.	Successfully met	$989.1	$945.9	Priority No. 2(a)
	Federal/provincial/ territorial (F/P/T) drug plans and Canada's health system have more accurate information on prescription drug trends and cost drivers	Successfully met	$1,339.9	$545.3	Priority No. 2 (b)

	Expected Results	Performance Status	2007-2008		Contributes to the following priority
			Planned Spending ($thousands)	Actual Spending ($thousands)	
Strategic Outcome: Prices charged by patentees for patented medicines sold in Canada are not excessive and Canadians are informed on pricing trends of medicines, as well as the R&D spending of pharmaceutical patentees.					
Patented Medicine Prices Review	F/P/T Governments and other stakeholders have critical analyses on non-patented prescription drug price trends.	Successfully met	$556.5	$234.7	Priority No.2 (c)

Overall Departmental Performance

Mandate and Jurisdiction

The PMPRB has two roles:

Regulatory: To ensure that prices charged by patentees for patented medicines sold in Canada are not excessive, thereby protecting consumers and contributing to Canadian health care.

The PMPRB is responsible for regulating the prices that patentees charge — the factory gate prices — for prescription and non-prescription patented drugs sold in Canada for human and veterinary use, to ensure that they are not excessive.

The PMPRB has no authority to regulate the prices of non-patented drugs and does not have jurisdiction over prices charged by wholesalers or pharmacies or over pharmacists' professional fees.

Reporting: To report on pharmaceutical trends of all medicines, and on R&D spending by pharmaceutical patentees, thereby contributing to informed decisions and policy making.

In addition, under section 90 of the Act, the Minister of Health has directed the Board to undertake two initiatives:

1) National Prescription Drug Utilization Information System (NPDUIS)

   In 2001, pursuant to an agreement by the federal/provincial/territorial (F/P/T) ministers of health, the Minister directed the PMPRB to conduct research into price, utilization and cost trends of prescription drugs sold in Canada. The purpose of this research is to shed light on how these drugs are being used and to determine sources of cost increases.

2) Non-Patented Prescription Drug Prices (NPPDP)

   In 2005, in consultation with his provincial and territorial colleagues, the Minister directed the PMPRB to monitor and report on prices of non-patented prescription drugs, thereby providing a credible, centralized source of information on trends in the non-patented prescription drug sector.

Issues, Trends and Challenges

Pharmaceuticals are a vital component of healthcare. The use of pharmaceuticals continues to increase worldwide, including in Canada, and represents an increasing share of total health expenditures. Understandably, sustainable access to needed medicines is an important concern of consumers, drug insurance plans and governments.

For its part, the pharmaceutical industry's ability to develop and bring to market innovative new medicines depends on the return on investment it can expect.

Innovation within the pharmaceutical industry appears to be moving toward technological improvements (i.e. new delivery technologies) and away from new breakthrough "blockbuster" drugs. As well, pricing strategies by the brand-name pharmaceutical industry suggest that global pricing is becoming increasingly important.

Associated with this is the issue of cross-border drug sales from Canada to the United States. While these sales appear to have declined, largely due to implementation of Medicare Part D, concerns about significant Canada-U.S. price differentials appear to remain. Changes in pricing and reimbursement policies in Europe are also affecting pricing strategies in Canada.

To effectively meet the challenges of an evolving pharmaceutical environment, the PMPRB increasingly seeks to understand pharmaceutical innovation and the broader environment, while still ensuring that the interests of Canadian consumers are protected.

The PMPRB has faced significant workload pressures, including:

- increased complexity of the reviews of patented drugs for human use and time required to conduct these reviews;
- an unprecedented number of hearings into apparent excessive prices; and
- the need to undertake a comprehensive review of, and hold public consultation on, the Board's Excessive Price Guidelines given recent stakeholder concerns that the Guidelines may no longer be appropriate in light of current trends and developments.

Performance Highlights

- A total of 1,178 patented drug products[2] for human use were under the PMPRB's jurisdiction in 2007.
- There were 64 new patented drugs products (at the level of the Drug Identification Number – DIN)[3] for human use reported to the PMPRB in 2007, of which 20 medicines, representing 34 DINs, were new active substances. As of March 31, 2008, 53 new patented drugs had been reviewed. Of those, 47 were considered to be within the Guidelines while 6 were subject to ongoing investigations.
- Seven new DINs were reported for veterinary use in 2007, all of which were under review on March 31, 2008.

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2 Unless otherwise indicated, reference to the number of patented drug products in this report reflects the calendar year 2007, as the price regulatory cycle for patented drug products is based on the calendar year.

3 A registration number (drug identification number) that the Health Products and Food Branch of Health Canada assigns to each prescription and non-prescription drug product marketed under the *Food and Drug Regulations*. The DIN is assigned using information in the following areas: manufacturer of the product; active ingredient(s); strength of active ingredient(s); pharmaceutical dosage form; brand/trade name; and route of administration.

- The Board completed a total of four hearings, and issued two Notices of Hearing. On March 31, 2008, there were eight ongoing proceedings, including the Nicoderm matter, initiated in 1999.

- The Board approved eight Voluntary Compliance Undertakings (VCUs).

- In addition to in-depth analysis of the key pharmaceutical indices, the PMPRB published two reports under the Non-Patented Prescription Drug Prices initiative.

Sales, Prices and R&D Trends

- Sales of patented drugs in Canada increased by 3.0% to $12.3 billion in 2007. By comparison, annual growth in sales of patented drugs stood at 27.0% in 1999 and remained in double digits until 2003.

- The share of total sales accounted for by patented drugs declined to 66% in 2007, from 68.1% in 2006.

- Drugs treating the respiratory system and antineoplastics and immunomodulating agents (such as drugs used in chemotherapy) are the leading contributing drug classes to sales growth.

- Patentees' prices of patented drugs, as measured by the Patented Medicine Price Index (PMPI), decreased on average by 1% in 2007. This slight decline is attributable to falling prices paid by hospitals. Over the same period, the Consumer Price Index was at 2.1%.

- In 2007, Canadian prices were the second highest of the seven comparator countries used by the PMPRB (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States). This ranking is attributable, in part, to currency conversion at market exchange rates. However, U.S. prices remained substantially higher than prices in Canada or any other comparator country.

- Patentees reported total R&D expenditures of $1,325 million in 2007, an increase of 9.5% over the previous year. Members of the national association of brand-name drug companies, known as Canada's Research-based Pharmaceutical Companies (Rx&D), reported R&D expenditures of $1,184 million in 2007, an increase of 24.4% over 2006.

- The R&D-to-sales ratio for all patentees increased slightly to 8.3% from 8.1% in 2006, as did the R&D-to-sales ratio for members of Rx&D (8.9% compared to 8.5% in the previous year).

SECTION II –
ANALYSIS OF THE PROGRAM ACTIVITY
BY STRATEGIC OUTCOME

Analysis by Program Activity

Strategic Outcome

Prices charged by patentees for patented medicines sold in Canada are not excessive and Canadians are informed on pricing trends of medicines, as well as the R&D spending of pharmaceutical patentees.

Program Activity Name

Patented Medicine Prices Review

Financial Resources ($ thousands)

Planned Spending	Authorities	Actual Spending
$11,475.0	$11,924.8	$7,432.4

Human Resources

Planned	Actual	Difference
62.0	50	12

Priority 1: Compliance and Enforcement

Financial Resources ($ thousands):

Planned Spending	Authorities	Actual Spending
$8,589.5	$8,935.7	5,706.5

Human Resources:

Planned	Actual	Difference
43	37	6

Price Reviews

The PMPRB reviews pricing information filed pursuant to the *Patented Medicines Regulations* (Regulations) for all new and existing patented medicines sold in Canada, both prescription and non-prescription, to ensure that the prices charged by patentees are not excessive - i.e., that they comply with the Excessive Price Guidelines (Guidelines) established by the Board.[4]

These Guidelines are based on the price determination factors in subsection 85(1) of the Act which the Board must consider and were developed by the Board in consultation with stakeholders, including the provincial and territorial Ministers of Health, consumer groups and the pharmaceutical industry.

The price reviewed by the PMPRB is that charged by a patentee at the "factory gate". This encompasses the prices charged in Canada by patentees for both prescription and non-prescription patented drugs, for human and veterinary use, to each class of customer[5] in each province and territory.

In summary, the Guidelines provide that:

- New medicines that are new chemical entities are classified as either breakthrough/substantial improvement, moderate, or little or no therapeutic advantage over comparable medicines; new drug products can also represent a new presentation of an existing medicine in an existing or comparable dosage form (sometimes referred to as line extensions);

- Prices for new breakthrough patented drug products and those that bring a substantial therapeutic improvement are generally limited to the median of the prices charged for the same

[4] The Guidelines are published in the PMPRB's Compendium of Guidelines, Policies and Procedures, which is available on the Web site: www.pmprb-cepmb.gc.ca, under Legislation, Regulations, Guidelines.

[5] Details of pricing information that patentees must file are contained in Section 4 of the Regulations. The Patentees' Guide to Reporting outlines the four classes of customer: hospital, pharmacy, wholesaler and other.

drug in the comparator countries listed in the Regulations (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States);

- Prices for new patented drug products that offer moderate, little or no therapeutic advantage over comparable medicines are limited to the highest price of comparable existing drugs used to treat the same disease or symptoms;

- Prices for new patented drug products that are line extensions of an existing medicine must bear a reasonable relationship to other strengths of the same or comparable dosage forms already on the Canadian market;

- After introduction, price increases are limited to changes in the Consumer Price Index (CPI); and

- The price of a patented drug product in Canada can never exceed the highest price for the same drug product in the foreign countries listed in the Regulations.

The expected result of the price review program is that all patentees' prices for new and existing patented medicines sold in Canada are reviewed in a timely and transparent manner and are in accordance with the Board's Excessive Price Guidelines.

The program activity supports the Government's priority of healthy Canadians by ensuring that Canadians have access to patented pharmaceutical products at prices that are not excessive.

The indicators that show that the PMPRB is achieving its expected results, and in turn contributing to its strategic outcome, are as follows:

- The prices of over 85% of patented medicines sold in Canada in calendar year 2007 were within the Guidelines;

- On average, price increases for existing patented medicines (0.1%) do not exceed and are well below changes in the Consumer Price Index (CPI) (2.1%);

- Enforcement measures (negotiation of Voluntary Compliance Undertakings [VCUs]; issuance of Notices of Hearings) are taken to ensure prices are not excessive; and

- Canadian prices of patented drugs are, on average, only slightly above the median of international prices in the foreign countries listed in the Regulations, with the slight upward trend in Canadian prices relative to those in foreign countries largely due to the appreciating Canadian dollar and exchange rates.

Price Review of New Patented Drugs for Human Use

Sixty-four new patented drugs products[6] (DINs) were introduced for human use in 2007. Of these, 20 medicines were new active substances, representing 34 DINs. By March 31, 2008, the Board had reviewed 53 of the 64 introduced. Of those, 47 were considered to be within the Guidelines while 6 appeared to exceed the Guidelines and were subject to ongoing investigations. At March 31, 2008, of the original 64 new drug products, 11 DINs remained under review.

Price Review of Existing Patented Drugs for Human Use

A total of 1,114 existing patented drug products (or DINs) were sold during 2007.[7] Of these,

- 975 DINs (87.5%) were within the Guidelines

- 14 DINs were subject to investigation due to introductory pricing
  - ✓ 12 were opened in 2006
  - ✓ 1 was opened in 2005
  - ✓ 1 was opened in 2004

- 83 DINs were subject to investigations due to price increase
  - ✓ 37 were opened in 2007
  - ✓ 31 were opened in 2006
  - ✓ 14 were opened in 2005
  - ✓ 1 was opened in 2003

- 22 DINs were, or currently are, the subject of a hearing under section 83 of the Act. (For additional information see Quasi-judicial Activities – Hearings, on page 25.)
  - ✓ 3 pertaining to Nicoderm
  - ✓ 6 pertaining to Adderall XR
  - ✓ 4 pertaining to Concerta
  - ✓ 5 pertaining to Strattera
  - ✓ 1 pertaining to Copaxone
  - ✓ 1 pertaining to Penlac
  - ✓ 1 pertaining to Quadracel
  - ✓ 1 pertaining to Pentacel

- 20 DINs were still under review.

A summary of the review, compliance and investigation status of the new and existing patented drug products for human use in 2007 is provided in Table 1 below.

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[6] For the purposes of the Board's price review, a new patented drug product in 2007 is defined as any patented drug product introduced in Canada, or previously marketed but first patented between December 1, 2006, and November 30, 2007. The same approach is used for all years due to the timing of the filing requirements under the *Patented Medicines Regulations, 1994.*

[7] For the purpose of this report, existing medicines include all patented drug products that were introduced prior to December 1, 2006.

Table 1
Patented Drug Products (DINs) for Human Use Sold in 2007 — Status of Price Review as of March 31, 2008

	New Drugs Introduced in 2007	Existing Drugs	Total
Total	64	1,114	1,178
Within Guidelines	47	975	1,022
Under Review	11	20	31
Under Investigation	6	97	103
Notice of Hearing	0	22	22

Update of the Review of Existing Patented Medicine Prices Reported in the 2006-2007 Departmental Performance Report

In the PMPRB's Performance Report for the fiscal year ending March 31, 2007, it was reported that, of the 1,082 existing patented drug products for human use sold in 2006, the prices of 17 were still under review. The results of those reviews concluded that: 6 drug products were within the Guidelines; 4 drug products were priced at levels that appeared to exceed the Guidelines and therefore investigations were initiated; and 7 are still under review. In addition one further drug has been added to those under review due to failure to file at the time when the drug product came under the PMPRB's jurisdiction.

The PMPRB also reported that 65 DINs were under investigation. Of those, 17 investigations have been concluded: in 13 cases the prices were ultimately found to be within the Guidelines; and for 4 cases, VCUs were approved: Forteo, OctreoScan, Vaniqa, and Zemplar, the latter having been subject to a Notice of Hearing (See Voluntary Compliance Undertakings on page 22).

Patented Drugs for Veterinary Use

The Board has adopted a policy for the review of patented veterinary drug products that differs somewhat from that for human drugs. Board Staff reviews the introductory prices of new patented veterinary drug products according to the current Guidelines and determines whether or not the price is excessive. In subsequent years, however, veterinary drug product prices are subject to formal review only when a complaint is received. Patentees are required to maintain price information for all reporting periods in which the product is under the Board's jurisdiction, but only need to file this information with the PMPRB upon request following a complaint. No complaints were received in 2007. Last year we reported that one patented drug product for veterinary use was under introductory price review, and it remained under review as of March 31, 2008.

In 2007, 7 new patented drug products for veterinary use were reported to the PMPRB. These are under review. Summary reports of the price reviews of drug products for veterinary use are made

available on the PMPRB's Web site under Regulatory; Patented Medicines; Reports on New Patented Drugs for Veterinary Use.

Enforcement Measures

Voluntary Compliance Undertakings

A Voluntary Compliance Undertaking (VCU) is a written undertaking by a patentee to adjust the price of a patented drug product to conform to the Excessive Price Guidelines (Guidelines).

Under the Compliance and Enforcement Policy, patentees are given an opportunity to submit a VCU when Board Staff concludes, following an investigation, that the price at which the patentee is selling or has sold the drug product in Canada appears to have exceeded the Guidelines.

Approval of a VCU by the Chairperson is an alternative compliance mechanism to the commencement of formal proceedings through the issuance of a Notice of Hearing. Under the PMPRB's Compliance and Enforcement Policy, a VCU can also be submitted following the issuance of a Notice of Hearing. A VCU submitted at this point must be approved by the Hearing Panel.

In 2007-2008, VCUs were approved for eight patented medicines:[8]

Airomir, 3M Canada Company

Airomir is used for the treatment of asthma, chronic bronchitis, and other breathing disorders.

On May 14, 2007, the Hearing Panel approved a VCU agreed to by 3M Canada Company (3M Canada) and Board Staff, for the payment in full of revenues alleged by Board Staff to have been excessive, totaling $485,498.58, derived from January 1, 2004 to December 29, 2006. The hearing into the price of Airomir, commenced by the issuance of a Notice of Hearing on February 20, 2006, was concluded with the approval of the VCU. 3M Canada met the terms of the VCU.

Dovobet, LEO Pharma Inc.

Dovobet is a dermatological drug required for bringing psoriasis under control.

On January 19, 2008, the Chairperson of the Board approved a VCU submitted by LEO Pharma Inc., for the medicine Dovobet. A Board Order issued on September 17, 2007, following a hearing, required LEO Pharma to price Dovobet at a non-excessive level, and to offset the excess revenues derived from the sale of Dovobet in Canada from 2002 through to December 2005. (For more information on the hearing in this matter, see Quasi-judicial Activities – Hearings, on page

[8] The full text of each VCU is available on the Web site: www.pmprb-cepmb.gc.ca, under Regulatory, Voluntary Compliance Undertakings.

25.) For the period January 1, 2006 through December 31, 2006, Board Staff calculated the MNE price in accordance with the Board Order. In 2006, the average transaction price (ATP) of Dovobet exceeded the 2006 price, resulting in excess revenues of $870,425.68. To offset these excess revenues, LEO Pharma submitted a VCU and made a payment in full to the Government of Canada.

Forteo, Eli Lilly Canada Inc.

Forteo is indicated for the treatment of postmenopausal women with severe osteoporosis who are at high risk of fracture or who have failed or are intolerant to previous osteoporosis therapy; and to increase bone mass in men with primary or hypogonadal severe osteoporosis who have failed or are intolerant to previous osteoporosis therapy.

On June 28, 2007, the Chairperson accepted a VCU for Forteo submitted by Eli Lilly Canada Inc. (Lilly). The VCU included a reduction of the price of Forteo below the MNE price for 2007 in order to offset excess revenues. In the event that all excess revenues had not been offset by December 31, 2007, Lilly had undertaken to make a payment to the federal government in the amount of the remainder of the excess revenues that had not been offset. Excess revenues were offset by December 31, 2007.

Lantus, sanofi-aventis Canada Inc.

Lantus (insulin glargine) is indicated for once-daily subcutaneous administration in the treatment of adult patients with Type 1 or Type 2 diabetes mellitus and pediatric patients (age 6-17 years) with Type 1 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

On March 14, 2008, the Chairperson of the Board approved a VCU submitted by sanofi-aventis Canada Inc. (sanofi-aventis) for the medicine Lantus. In addition to reducing the price of Lantus to a non-excessive level, sanofi-aventis offset the cumulative excess revenues it received from sales of Lantus as of September 18, 2006 by making a payment to the Government of Canada in the amount of $694,239.50 and by reducing the price of another medicine, ALTACE HCT. In the event that the full amount of excess revenues, totaling $3,969,554.83, has not been completely offset by December 31, 2008, sanofi-aventis has undertaken to make a further payment to the Government of Canada.

OctreoScan, Bristol-Myers Squibb Canada Co.

OctreoScan is a radiopharmaceutical agent used for the diagnosis of brain diseases and tumors.

On September 19, 2007, the Chairperson of the Board accepted a VCU for OctreoScan submitted by Bristol-Myers Squibb Medical Imaging, a Division of Bristol-Myers Squibb Canada Co. (Bristol-Myers Squibb). In addition to reducing the price of OctreoScan to a non-excessive level, Bristol-Myers Squibb offset the excessive revenues accrued, in the amount of $387,181.87, by

making payments to the hospitals that purchased OctreoScan and by making a payment to the Government of Canada for the remaining excess revenues in the amount of $7,439.82.

Risperdal Consta, Janssen-Ortho Inc.

Risperdal Consta is a new formulation of an existing compound (risperidone) indicated for the management of the manifestations of schizophrenia and related psychotic disorders.

On June 7, 2007, the Hearing Panel approved a VCU agreed to by Janssen-Ortho Inc. and Board Staff to, among others, reduce the price of Risperdal Consta to a non-excessive level and to offset excess revenues in the amount of $4,386,172.99. By Order of the Board, the proceeding that was commenced with the issuance of a Notice of Hearing on January 30, 2006, was thereby concluded. Janssen-Ortho Inc. met the terms of the VCU.

Vaniqa, Barrier Therapeutics Canada Inc.

Vaniqa (eflornithine hydrochloride) is indicated for slowing the growth of unwanted facial hair in women. It is recommended as an adjunct to any hair removal technique.

On February 28, 2008, the Chairperson of the Board approved a VCU submitted by Barrier Therapeutics Canada Inc., for the medicine Vaniqa. Barrier reimbursed the excess revenues accrued over the period of November 2005 to December 2007, by making a payment to the Government of Canada, in the amount of $70,860.59. Vaniqa is no longer sold in Canada.

Zemplar, Abbott Laboratories Limited

Zemplar is indicated for the prevention and treatment of secondary hyperparathyroidism associated with chronic renal failure.

On September 26, 2007, the Hearing Panel approved a VCU agreed to by Abbott Laboratories Limited (Abbott) and Board Staff to ensure that, among others, the price of Zemplar is not excessive and to offset alleged excess revenues in the amount of $58,741.67. The Chairperson had issued a Notice of Hearing on July 24, 2007, pertaining to the allegations of Board Staff that Zemplar had been, and was being, sold by Abbott at prices exceeding those indicated by the Board's Guidelines. With the Hearing Panel's approval of the above-mentioned VCU, which proposed to resolve all issues raised by the Notice of Hearing, by Order of the Board, the proceeding was thereby concluded. Abbott met the terms of the VCU.

Quasi-judicial Activities – Hearings

Under section 83 of the Act, the Board can hold a public hearing to determine whether a patented medicine is being or has been sold at an excessive price and, if it finds that the price is or was excessive, it may issue an Order to reduce the patentee's price and to offset the excess revenues.

On April 1, 2007, there were eleven ongoing hearings carried over from previous years. Between that date and March 31, 2008 the Board issued two Notices of Hearing into the matters of Apotex (and its status as a patentee under the PMPRB's jurisdiction) and Zemplar. It also initiated proceedings into the matter of Celgene Corporation and the medicine Thalomid with respect to its jurisdiction over the price of the medicine. Of these 14 hearings, three were resolved by way of VCUs: Airomir, Riserpdal Consta and Zemplar. More details on these VCUs are available in the VCU section of this report. Board Orders, concluding the proceedings, were issued in the Dovobet and Copaxone matters (although the Order for Copaxone was not issued until fiscal year 2008-2009). The Thalomid matter was also concluded when the Hearing Panel ruled that it has jurisdiction over the price of the medicine.

Adderall XR, Shire BioChem Inc.

Adderall XR is a medicine indicated for the treatment of Attention Deficit Hyperactivity Disorder.

The Board issued a Notice of Hearing in this matter on January 18, 2006. The Hearing Panel issued its decision on the merits on April 10, 2008. Although not during the period of this review, the Board issued an Order on August 27, 2008, concluding these proceedings.

On December 15, 2006, the Hearing Panel issued a decision dismissing Shire's motion for an order that the Board amend its Notice of Hearing to limit its inquiry to the period following the date of issuance of Shire's patent 2,348,090, namely, April 13, 2004. Shire filed an application for judicial review with the Federal Court. The FC issued its decision on December 19, 2007, dismissing the matter. Shire has appealed the FC decision. The Federal Court of Appeal has not yet heard the parties on this issue.

Airomir, 3M Canada Company

Airomir is used for the treatment of asthma, chronic bronchitis, and other breathing disorders. The proceeding into the matter of 3M Canada Company and the price of Airomir commenced with the issuance of a Notice of Hearing on February 20, 2006 and was concluded with the approval of a Voluntary Compliance Undertaking (VCU) on May 14, 2007.

Apotex Inc.

The Board issued a Notice of Hearing in the matter of Apotex Inc. on March 3, 2008, concerning that company's status as a patentee and the information filing requirements pursuant to the *Patent Act* and the *Patented Medicines Regulations*. The Hearing Panel is scheduled to hear this matter on October 6, 2008.

Concerta, Janssen-Ortho Inc.

Concerta is indicated for the treatment of Attention Deficit Hyperactivity Disorder.

The Board issued a Notice of Hearing in this matter on July 24, 2006. The Board's decision is pending.

Note: Janssen-Ortho was granted the status of intervener in the judicial review application launched by Shire with regard to the Board's December 15, 2006 decision (Shire and the issue of pre-patent, as described under Adderall XR above). Janssen-Ortho has also appealed the December 19, 2007 Federal Court decision dismissing the case.

Copaxone, Teva Neuroscience G.P.-S.E.N.C.

Copaxone is indicated for use in ambulatory patients with Relapsing-Remitting Multiple Sclerosis to reduce the frequency of relapses.

The Board issued a Notice of Hearing into the matter of Copaxone on May 8, 2006. After hearing the parties, the Hearing Panel issued its decision and reasons in this matter on February 25, 2008, including instructions that the parties file a proposed Board Order. The Panel received separate submissions on a proposed Board Order. In its Order issued on May 12, 2008, having found that Copaxone had been sold at an excessive price, the Board required Teva to reimburse $2,417,223.29 in excess revenues. Teva Neuroscience has filed a Notice of Application with the FC seeking judicial review. A hearing date has not yet been announced.

Dovobet, LEO Pharma Inc.

Dovobet is a dermatological drug administered to bring psoriasis under control.

The Board issued a Notice of Hearing in the matter of LEO Pharma Inc. and the medicine Dovobet on November 29, 2004. This matter was concluded with the issuance of a Board Order, on September 17, 2007, requiring LEO Pharma to price Dovobet at a non-excessive level, and to offset the excess revenues derived from the sale of Dovobet in Canada from 2002 through to December 2005 in the amount of $3,736,398.71.

Nicoderm, Hoechst Marion Roussel Canada Inc.

Nicoderm is indicated for smoking cessation.

The Board issued a Notice of Hearing in this matter in April 1999. Following extended proceedings before the Federal Court, the matter was returned before the Board. The Hearing Panel heard the parties on the resolution of this matter on July 3, 2008, following a joint submission by the parties to terminate the hearing. In its decision of July 21, 2008, the Board indicated that it was not persuaded that this proceeding should be discontinued and instructed the parties to continue with the proceeding and issued a schedule to that effect. The hearing will resume on November 21, 2008.

Penlac, sanofi-aventis Canada Inc.

Penlac is indicated as part of a comprehensive nail management program in immunocompetent patients with mild to moderate onychomycosis without lunula involvement.

The Board issued a Notice of Hearing in this matter on March 26, 2007. Hearing sessions were initiated in June 2007 and continued in 2008. The hearing in this matter is to resume on December 8, 2008.

Quadracel and Pentacel, sanofi pasteur Limited

Quadracel is indicated for the primary immunization of infants, at or above the age of 2 months, and as a booster in children up to their 7th birthday against diphtheria, tetanus, whooping cough (pertussis) and poliomyelitis.

Pentacel is indicated for the routine immunization of all children between 2 and 59 months of age against diphtheria, tetanus, whooping cough (pertussis), poliomyelitis and haemophilus influenzae type b disease. It is sold in Canada in the form of a reconstituted product for injection combining one single dose vial of Act HIB (Lyophilized powder for injection) and one single (0.5 mL) dose ampoule of Quadracel (suspension for injection).

The Board issued a Notice of Hearing in this matter on March 27, 2007. Following the Hearing Panel's decision of November 26, 2007 denying sanofi pasteur's Motion that the Panel replace its counsel in this proceeding, sanofi pasteur filed a judicial review application with the FC. The application for judicial review was dismissed. The Panel reconvened this hearing on June 13, 2008. The hearing will resume on November 25, 2008.

Risperdal Consta, Janssen-Ortho Inc.

Risperdal Consta is a new formulation of an existing compound (risperidone) indicated for the management of the manifestations of schizophrenia and related psychotic disorders.

The Board issued a Notice of Hearing in the matter of Janssen-Ortho Inc. and the medicine Risperdal Consta on January 30, 2006. The matter was concluded on June 7, 2007, with the Hearing Panel's approval of a VCU agreed to by Janssen-Ortho Inc. and Board Staff to, among others, reduce the price of Risperdal Consta to a non-excessive level and offset excess revenues in the amount of $4,386,172.99. For more information on the VCU, see Voluntary Compliance Undertakings, on page 22.

Strattera, Eli Lilly Canada Inc.

Strattera is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6 years of age and over, adolescents and adults.

The Board issued a Notice of Hearing in this matter on December 15, 2006. The hearing will resume on October 25, 2008.

Thalomid, Celgene Corporation

Thalomid does not have a Notice of Compliance but patients in Canada have been purchasing Thalomid from Celgene in the United States since 1995 through Health Canada's Special Access Programme. Thalomid is used to slow the progress of multiple myeloma, a form of cancer.

On August 23, 2007, a Hearing Panel of the Board heard submissions from Celgene Corporation and Board Staff on the Board's jurisdiction in the matter of the price of Thalomid. In its decision of January 21, 2008, the Board ruled that it has jurisdiction over the price of Thalomid. Celgene Corporation filed a Notice of Application with the Federal Court for a judicial review of the Panel's decision. A hearing date has not yet been announced.

Zemplar, Abbott Laboratories Limited

Zemplar is indicated for the prevention and treatment of secondary hyperparathyroidism associated with chronic renal failure.

The Board issued a Notice of Hearing in this matter on July 24, 2007. The matter was concluded on September 26, 2007, with the approval of a VCU agreed to by Abbott Laboratories Limited and Board Staff to ensure that, among others, the price of Zemplar is not excessive and to offset alleged excess revenues in the amount of $58,741.69. For more information on the VCU, see Voluntary Compliance Undertakings on page 22.

Amendments to the *Patented Medicines Regulations*

The regulatory amendments to the *Patented Medicines Regulations, 1994* (Regulations) were registered on March 6, 2008 and received final publication in the *Canada Gazette*, Part II, on March 19, 2008. These amendments modernize the Regulations by increasing efficiency and timeliness in the price review process for patented medicines.

This regulatory initiative began in January 2005 with the publication of a Notice and Comment proposal to amend the Regulations, followed by the initial pre-publication of the proposed regulatory amendments in *the Canada Gazette*, Part I, on December 31, 2005. Following extensive stakeholder consultations, a revised regulatory package was pre-published in the Canada Gazette, Part I, on October 6, 2007. Several stakeholder submissions were received during the second pre-publication consultation period. These submissions remain posted on the PMPRB Web site for the information of all interested parties.

In response to stakeholder concerns, the final amendments contained two changes from the proposed amendments which were pre-published on October 6, 2007:

1. the proposed requirement that patentees identify the type of reductions used in the calculation of average price per package or net revenue from sales was removed; and

2. the date of the coming into force of the electronic filing requirement was changed from January 1, 2009 to July 1, 2008, as the electronic forms no longer needed to be revised to accommodate the filing of reduction information by type.

The amendments also put into place the following changes regarding reporting information to the PMPRB:

Regulatory Filing

- Information identifying the medicine (Form 1) shall now be accompanied by the product monograph for the medicine or, if a notice of compliance (NOC) has not been issued in respect of the medicine, by information similar to that contained in a product monograph.

- Information identifying the medicine (Form 1) shall now be provided no later than the earlier of seven days after the day on which the first NOC is issued in respect of the patented drug product, and seven days after the day on which the product is first offered for sale in Canada.

Patented Prescription Drug Products

- Where a patented prescription drug product is for human use, information on the prices of the product (Form 2) shall now be provided for the day on which the product is first sold in Canada, within 30 days after that day; this replaces the previous requirement that information be provided on the first 30 day sales.

Veterinary and Over-the-Counter Drug Products

- For veterinary and over-the-counter drug products, information on the prices of the product (Form 2) shall now be provided on a complaints-based approach, wherein a patentee shall provide to the Board the necessary information for each six-month period, beginning on January 1 and July 1 of each year, within 30 days after the date on which the Board sends a request in response to a complaint respecting the price of the product, and during the two years following the request, within 30 days after each six-month period.

Electronic Filing

- Patentees are now required to provide information for all three forms (1, 2 and 3, which pertains to information on sales and research and development [R&D] expenditures) to the Board using specified electronic documents in their original format and file type, bearing the electronic signature of an authorized individual, certifying that the information set out in the documents is true and complete.

Patentees were required to comply with the amended Regulations as of their final publication on March 19, 2008, with the exception of the electronic filing requirement which must be complied

with as of July 1, 2008 for the July-to-December 2008 reporting period. Board Staff provided information sessions to patentees in May and June 2008 to explain how to fully comply with the regulatory amendments.

Review of the Board's Excessive Price Guidelines

Throughout 2007-2008, the Board was actively engaged in the review of its Excessive Price Guidelines (Guidelines) to ensure that they remain relevant and appropriate in the context of the current pharmaceutical environment.

The activities undertaken as part of the Guidelines review in 2007-2008 built on the work of the previous year, which began with the release of the Discussion Guide on the Board's Excessive Price Guidelines in May 2006. This was followed by a series of national consultations in November 2006, where the Board met with close to 140 members of various stakeholders groups.

On May 31, 2007, the Board released a Stakeholder Communiqué outlining its preliminary decisions and directions on the issues under consultation to date, as well as the next steps over the remainder of the year. The Stakeholder Communiqué also signaled the launch of three new Working Groups: one to determine definitions and levels of evidence for various categories of therapeutic improvement; one to determine appropriate therapeutic comparators for domestic drug products in other countries; and one to seek input from experts on how to define the costs of making and marketing a drug product (subsection 85(2) of the *Patent Act*).

In the midst of the more general review of the Guidelines, in March 2007, the Federal Court (FC) issued a decision in response to a judicial review application in the matter of LEO Pharma Inc. and the price of the patented medicine Dovobet. In April 2007, the PMPRB published an article in its NEWSletter informing stakeholders of the implications and impacts of the FC decision. Stakeholders were instructed that all benefits (as defined by the *Patented Medicines Regulations, 1994* (Regulations) in subsections 4(4) and 4(5), hereinafter referred to simply as "benefits", must now be included in the calculation of the average price of a patented medicine. Communiqués on this matter were issued in May and June, indicating the Board's desire to further consider and consult with stakeholders.

Significant concern was expressed by the patented pharmaceutical industry regarding the potential disincentives the decision would have on the willingness of companies to offer, or continue to provide, various benefits to their customers. Representatives of the innovative pharmaceutical and biotechnology industries were then given the opportunity to comment on the implications of the FC decision during face-to-face meetings with the Board during the summer of 2007.

On September 10-12, 2007, the Board held a series of bilateral consultation meetings with stakeholder groups, representing sectors of the pharmaceutical industry (innovative, biotechnology and generic), federal/provincial/territorial (F/P/T) governments and consumers. The purpose of these meetings was to provide participating stakeholders with an opportunity to

raise their comments directly with Board Members in relation to the issues regarding reporting of benefits, as well as other concerns they may or may not have raised in previous consultations on the Guidelines. In October 2007, the Board released a communiqué indicating it would not insist on full reporting of benefits until January 1, 2009, to permit the opportunity for further consideration with stakeholders.

On January 31, 2008, the Board released the Discussion Paper – Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines. In total, the Board received 43 submissions from a wide range of stakeholders. In keeping with the Board's commitment to openness and transparency, all stakeholder submissions can be found on the PMPRB Web site.

In early April 2008, the Board also received the final reports of both the Working Group on Therapeutic Improvement, and the Working Group on International Therapeutic Class Comparison. Building on the efforts of the previous two Working Groups, the Board launched an additional Working Group to develop advice and options for possible changes to the PMPRB's price tests.

In addition, throughout this period a sectoral Working Group involving representatives of the Canadian Generic Pharmaceutical Association and Board Staff met to consider unique market issues faced by patented generic drug products and to develop options and advice for the Board on possible selected tailored Guidelines, which would respond to these challenges. This Working Group's report can be found on PMPRB's Web site, along with reports on the above four work areas.

Recognizing that this first major review of the Guidelines since 1994 may create a degree of uncertainty for patentees and other stakeholders regarding the future of the price review process, the Board is committed to ongoing open communication through its NEWSletter, its Web site and other means, as appropriate. In addition, the Board released a Communiqué on August 18, 2008, summarizing the information patentees will need to report on beginning with the January-June 2009 period and highlighting the next steps in the consultations on the Guidelines, including a Notice and Comment on draft revised Guidelines that was released on August 20, 2008.

Priority 2: Report on Pharmaceutical Trends

Financial Resources ($ thousands):

Planned Spending	Authorities	Actual Spending
$2,885.5	$2,989.1	$1,725.9

Human Resources:

Planned	Actual	Difference
19	13	6

Price Trends

The PMPRB's second priority is to report on pharmaceutical price trends relating to all medicines, and on R&D spending by pharmaceutical patentees. This priority contributes to informed decisions and policy-making among stakeholders.

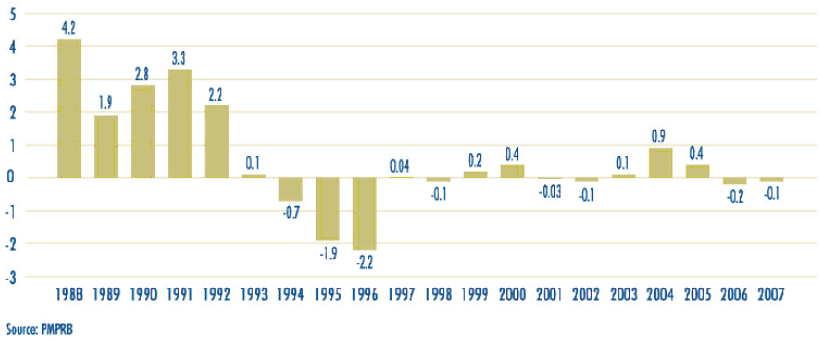
Section 100 of the *Patent Act* (Act) requires the Board to annually submit to the Minister of Health a report on its activities during the preceding calendar year. The report must include a summary of pricing trends in the pharmaceutical industry, and patentees' expenditures on research and development as a proportion of total revenues from sales of medicines in Canada. The Minister is required to table the report before Parliament. The PMPRB's 2007 Annual Report was tabled before Parliament on June 18, 2008.

The PMPRB uses the Patented Medicine Price Index (PMPI) to monitor and report on trends in prices of patented drugs. The PMPI is a price index measuring the average year-over-year change in the ex-factory prices of patented drugs sold in Canada. The PMPI does not measure changes in the utilization of patented drugs: a quantity index, the PMQI, is calculated for this purpose. The PMPI does not measure the cost-impact of changes in prescribing patterns or the introduction of new medicines. By design, the PMPI isolates the component of sales growth attributable to changes in the prices of patented drugs.

Figure 1 provides year-over-year changes in the PMPI for the years 1988 through 2007. As measured by the PMPI, prices of patented drugs declined on average by 0.1% between 2006 and 2007.

Figure 1

Annual Rates of Change, Patented Medicine Price Index (PMPI), 1988 – 2007



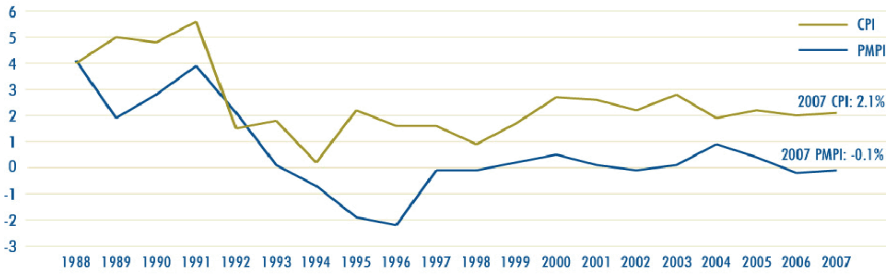
Source: PMPRB

Comparison of PMPI and CPI

Section 85 of the Act provides that, among other factors, the PMPRB shall consider changes in the Consumer Price Index (CPI) in determining whether the price of a patented drug is excessive.

Figure 2 plots year-over-year rates of change in the PMPI against corresponding changes in the CPI. Inflation, as measured by the CPI, has exceeded the average increase in patented drug prices almost every year since1988. This pattern continued in 2007, with the CPI rising by 2.1% as the PMPI fell by 0.1%. That the PMPI has not kept pace with the CPI is not surprising. The Board's Guidelines allow the price of a patented drug to rise by no more than the CPI over any three-year period. (The Guidelines also impose a cap on year-over-year price increases equal to one-and-one-half times the current year rate of CPI-inflation.)

Figure 2
Annual Rate of Change, Patented Medicines Price Index (PMPI) and Consumer Price Index (CPI), 1988 – 2007



Source: PMPRB and Statistics Canada

This effectively establishes CPI-inflation as an upper bound on the rate at which the PMPI may rise over any period of three years. Increases in the PMPI normally do not reach this upper bound because many patentees do not raise their prices by the full amount permitted under the Guidelines.

Price Change by Therapeutic Class

Table 2 provides average rates of price change among patented drugs at the level of major therapeutic classes. Results in this Table were obtained by applying the PMPI methodology to data segregated by the World Health Organization's (WHO) Atomic Therapeutic Chemical (ATC) Level I class. The last column provides a decomposition of overall PMPI change, with each entry representing the component of the overall change attributable to drugs in the corresponding therapeutic class. By this measure, drugs treating blood and bloodforming organs were the largest contributor (in absolute magnitude) to overall price change in 2007.

Table 2
Change in the Patented Medicine Price Index (PMPI) by Major Therapeutic Class, 2007

Therapeutic Class	Share of Sales (%)	PMPI Change: 2006 to 2007 (%)	Contribution to Overall Change (%)
A: Alimentary Tract and Metabolism	13.0	-0.5	-0.1
B: Blood and Blood Forming Organs	7.2	-2.2	-0.2
C: Cardiovascular System	25.1	0.2	0.0
D: Dermatological	1.0	0.3	0.0
G: Genito-urinary System and Sex Hormones	3.4	0.7	0.0
H: Systemic Hormonal Preparations	0.8	-1.1	0.0
J: General Antiinfectives for Systemic Use; and P: Antiparasitic Products[9]	9.5	0.6	0.1
L: Antineoplastics and Immunomodulating Agents	13.6	0.0	0.0
M: Musculo-skeletal System	4.0	0.1	0.0
N: Nervous System	13.0	-0.4	-0.1
R: Respiratory System	7.7	0.7	0.0
S: Sensory Organs	1.3	-0.5	0.0
V: Various	0.5	-1.0	0.0
All Therapeutic Classes	100.0*	-0.1	-0.1

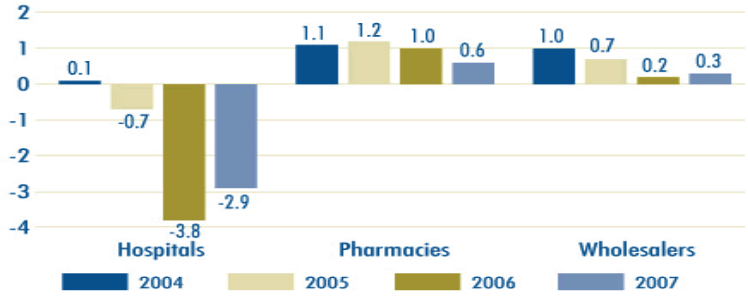
Source: PMPRB
* Values in this column may not add to 100.0 due to rounding.

[9] These groups have been combined for reasons of confidentiality.

Price Change by Class of Customer

Figure 3 presents average rates of price change by class of customer[10]. These results were obtained by applying the PMPI methodology to data on sales of patented drugs made specifically to hospitals, to pharmacies and to wholesalers[11].

Figure 3
Annual Rate of Change, Patented Medicine Price Index (PMPI), by Class of Customer, 2004 — 2007



Source: PMPRB

Rates of 2006-to-2007 price change ranged from -2.9% for sales to hospitals to 0. % for direct sales to pharmacies. Not surprisingly, the rate of price change for sales to wholesalers (which accounts for about three-quarters of all sales) is closest to the overall change in the PMPI. Note that in all customer classes, rates of price change were substantially less than CPI-inflation of 2.1%.

It is clear from Figure 3 that the slight decline in the overall PMPI was the result of falling prices paid by hospital customers: a PMPI covering only sales to pharmacies and wholesalers would have risen by approximately 0.3% between 2006 and 2007.

[10] The *Patented Medicines Regulations* require patentees to file information according to customer classes in each province and territory; these classes, which are hospitals, pharmacies, wholesalers and other, are specified in the Patentees' Guide to Reporting developed by the Board.

[11] Results for the fourth customer class, "Other", are not provided. Primarily, it is made up of healthcare institutions other than hospitals, such as clinics and nursing homes, and may include physicians, etc.

Price Change by Province/Territory

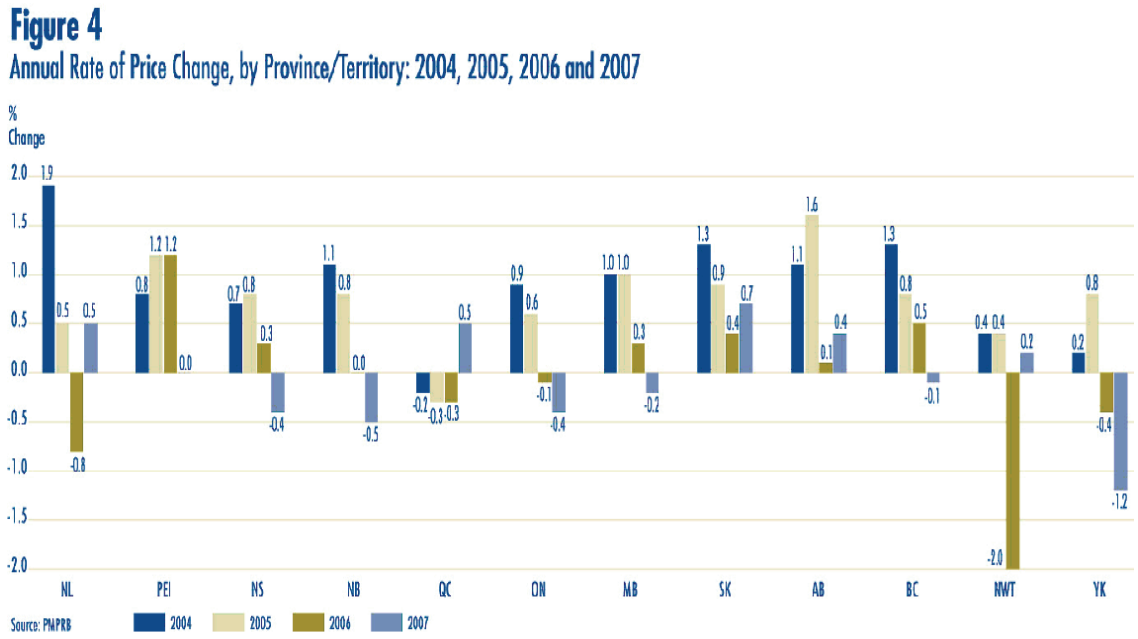
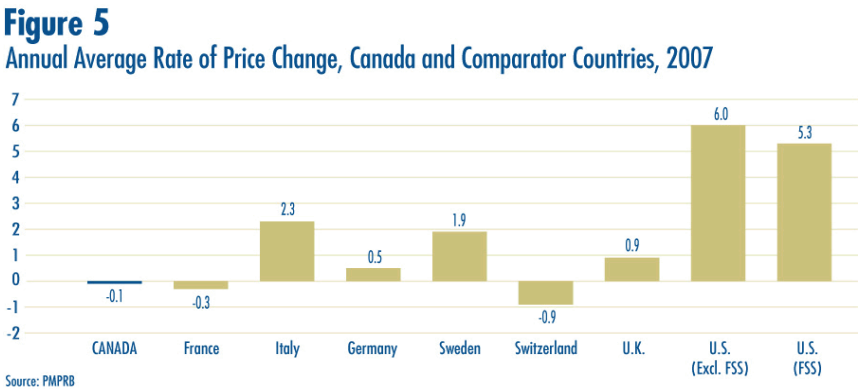


Figure 4 presents average rates of price change by province/territory. These results were obtained by applying the PMPI methodology to data segregated by the province/territory in which the sale took place. Rates of price change range from -1.2% in the Yukon to 0.7% in Saskatchewan. Average price increases in five of the twelve provincial/territorial jurisdictions were offset by the modest decline in Ontario, resulting in the average national price decrease of 0.1%.

Price Change in Canada and Comparator Countries

In accordance with the Act and the Regulations, patentees must report publicly available ex-factory prices of patented drugs in seven foreign countries. These countries are: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. The PMPRB uses this information to conduct the international price comparison tests specified in the Guidelines and to compare the Canadian prices of patented drugs with those in other countries.

Figure 5 gives average annual rates of price change for Canada and each of the seven comparator countries. These results were obtained by applying the PMPI methodology (with weights based on Canadian sales patterns) to international price data submitted to the



PMPRB. Note that two results are presented for the U.S. The first of these is restricted to published U.S. "market" prices, typically wholesale acquisition costs. The second incorporates prices from the U.S. Federal Supply Schedule (FSS).

Five of seven comparator countries registered overall price increases between 2006 and 2007, the exceptions being France and Switzerland. Switzerland saw the largest average decline (-0.9%). In contrast, U.S. prices rose by nearly 6%.

Bilateral Comparison of Foreign Prices to Canadian Prices

Table 3 provides bilateral comparisons of prices in each of the PMPRB's seven comparator countries to corresponding Canadian prices. Focusing on the results with currency conversion at market exchange rates (and calculated as a geometric mean), it appears that Canada's prices of patented drugs are slightly higher than prices in all countries other and the U.S. Prices in Italy and France are, on average, appreciably less than Canadian prices. As in previous years, 2007 U.S. prices were substantially higher than prices in Canada and every other comparator country.

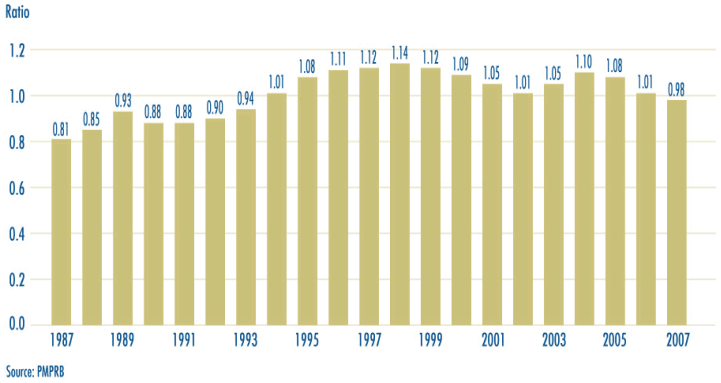
Table 3
Average Foreign-to-Canadian Price Ratios, Bilateral Comparisons, 2007

(i) At Market Rates	Can	Fra	Ita	Ger	Swe	Swi	U.K.	U.S.
Geometric Mean	1.00	0.85	0.77	0.98	0.94	0.99	0.98	1.64
Arithmetic Mean	1.00	0.90	0.82	1.07	0.99	1.06	1.03	1.76
Number of DINs	1,145	748	744	840	816	797	835	985
Net Revenues ($M)	12,3437	10,620	10,339	10,711	10,843	11,101	11,179	11,4790
(ii) At PPPs	**Can**	**Fra**	**Ita**	**Ger**	**Swe**	**Swi**	**U.K.**	**U.S.**
Geometric Mean	1.00	0.76	0.72	0.92	0.78	0.76	0.84	1.71
Arithmetic Mean	1.00	0.81	0.78	1.00	0.82	0.82	0.88	1.85
Number of DINs	1,145	748	744	840	816	797	835	985
Net Revenues ($M)	12,3437	10,620	10,339	10,711	10,843	11,101	11,179	11,4790

Multilateral Price Comparisons

Focusing again on results at market exchange rates (and obtained using the geometric mean), the average Median International Price (MIP)-to-Canadian price ratio stood at 0.98 in 2007. By this measure, MIPs were on average slightly less than corresponding Canadian prices. Last year's Annual Report gave a value of 1.01 for 2006, indicating MIPs were slightly higher than Canadian prices. Figure 6 puts this result in historical perspective. MIPs were on average 19% less than corresponding Canadian prices in 1987. By 1998, MIPs were on average 14% higher than Canadian prices. The average MIP-to-Canadian price ratio had remained above parity from 1994 through to 2006.

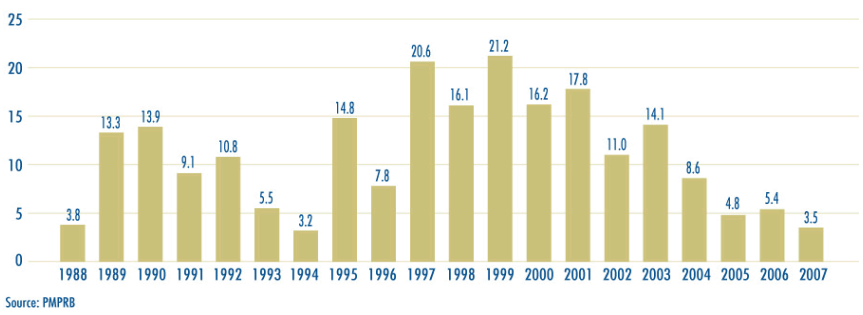
Figure 6
Average Ratio of Median International Price (MIP) to Canadian Price, Patented Drugs, 1987 – 2007



Utilization of Patented Drugs

The price and sales data used to calculate the PMPI also allow the PMPRB to examine trends in the quantities of patented drugs sold in Canada. The PMPRB maintains the Patented Medicine Quantity Index (PMQI) for this purpose. Figure 7 displays average rates of utilization growth, as measured by the PMQI, from 1988 through 2007. These results confirm that growth in the utilization of patented drugs has been the primary source of rising sales, with rates of utilization growth roughly tracking rates of sales growth in recent years. This pattern continued in 2007, with utilization of patented drugs growing by 3.5%. (Sales growth also slowed in 2007 compared with previous years and stood at 3%.)

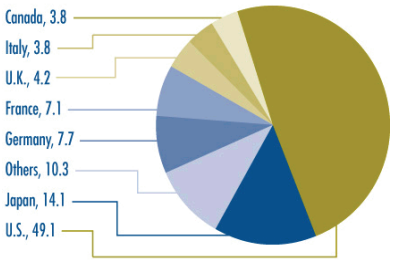
Figure 7
Annual Rate of Change, Patented Medicine Quantity Index (PMQI), 1988 – 2007



Canadian Sales in the Global Context

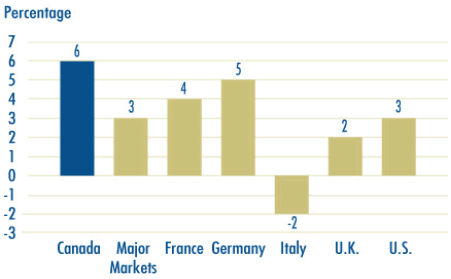
IMS Health regularly reports on patentees' sales to the retail sector across a wide range of countries. IMS reports that, in 2007, sales amounted to $450.3 billion among major markets.[12] Figure 8 shows how this amount was distributed among these markets. Drug sales in Canada accounted for 3.8% of total major-market sales. The U.S. market is by far the largest, with drug sales nearly equal to the combined sales of all other major markets.

Figure 8
Distribution of Drug Sales Among Major National Markets, 2007



Source: IMS Health

Figure 9
Growth in Pharmaceutical Sales: 2006 to 2007, by Major Markets



Source: IMS Health

Figure 9 gives rates of 2007-over-2006 sales growth for individual major markets. Based on IMS data, Canadian sales growth exceeded growth observed in all other comparator countries including the U.S.

Analysis of Research and Development Expenditures

With the adoption of the 1987 amendments to the *Patent Act* (Act), Canada's Research-Based Pharmaceutical Companies (Rx&D) made a public commitment at that time that brand name manufacturers would increase their annual research and development (R&D) expenditure to 10% of sales revenue by 1996. Under the Act, the PMPRB monitors and reports on R&D spending, but has no regulatory authority over the amount or type of research spending by patentees.

The Act requires each patentee to report its revenue from sales of drugs (including revenue from sales of non-patented drugs and from licensing agreements) and R&D expenditure in Canada related to medicines. The Regulations require that R&D data submitted to the PMPRB be accompanied by a certificate stating that the submitted information is "true and correct". The PMPRB does not audit submissions, but it does review submitted data for anomalies and inconsistencies, seeking corrections or clarifications from patentees where necessary. To confirm that Board Staff has correctly interpreted submitted data, each patentee is given the opportunity to review and confirm the accuracy of its own R&D-to-sales ratio before publication of the Board's Annual Report. Companies without sales of patented medicines in Canada need not

[12] IMS Health's Retail Drug Monitor, 2007 (www.imshealth.com). IMS Retail Drug Monitor provides estimates of direct (i.e., from the manufacturing company) and indirect (i.e., through a wholesaler) drug purchases by pharmacies in 13 major markets: Argentina, Australia, Brazil, Canada, France, Germany, Italy, Japan, Mexico, New Zealand, Spain, the U.K. and the U.S. These figures are ex-manufacturer prices and include all prescription and certain over-the-counter data.

report on their R&D activity. For this reason, as new patents are granted and others expire, the set of companies required to file R&D data may change from year to year.

In 2007, a total of 82 companies selling patented human and veterinary drug products filed reports on their R&D expenditure. Of these, 35 were members of Canada's Research Based Pharmaceutical Companies (Rx&D).

Sales Revenue

For reporting purposes, sales revenue is defined as all revenue from sales in Canada of medicines and from licensing agreements (e.g., royalties and license fees from sales in Canada by licensees).

As shown in Table 4, patentees reported total 2007 sales revenue of $15.9 billion, up 7.3% from 2006. Sales revenue reported by Rx&D members was $13.4 billion, accounting for 83.7% of the total. Less than 1% of reported sales revenue was generated by licensing agreements.

R&D Expenditure

As shown in Table 4, total R&D expenditure reported by patentees was $1,325.0 million in 2007, an increase of 9.5% over 2006. Rx&D members reported R&D expenditure of $1,184.0 million in 2007, an increase of 24.7% over last year. Rx&D members accounted for 89.4% of all reported R&D expenditure.

Patentees that were not members of Rx&D reported R&D expenditure of $141 million in 2007, a decrease of 45.9% over last year.

R&D-to-Sales Ratios

The ratio of R&D expenditure to sales revenue among all patentees was 8.3% in 2007, up from 8.1% in 2006[13]. The ratio for members of Rx&D was 8.9%, up from 8.5% in the previous year. R&D-to-sales ratios for all patentees and for Rx&D members had declined in recent years, after rising from 1988 to the mid-1990's. As of 2007, the ratio for all patentees has remained below 10% for seven consecutive years, while the ratio for Rx&D members has been less than 10% for the last five years.

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[13] The R&D-to-sales ratios presented in Table 4 include research expenditure funded by government grants. If the government-funded component is excluded, the ratios for all patentees and for the members of Rx&D in 2007 are 8.0% and 8.6%, respectively.

Table 4 Total R&D Expenditure and R&D-to-Sales Ratios of Reporting Companies, 1988 – 2007

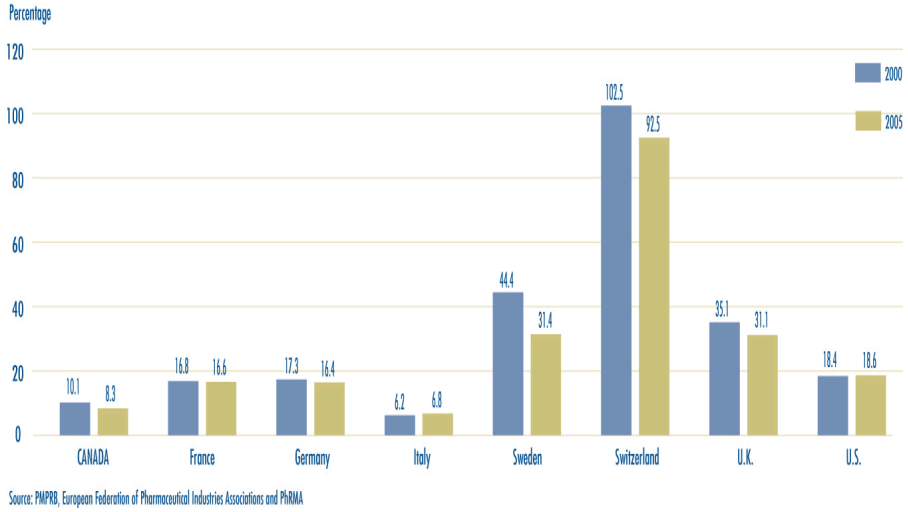
Year	Companies Reporting	Total R&D Expenditure ($M)	Change from Previous Year (%)	Total Sales Revenue ($M)	Change from Previous Year (%)	R&D-to-Sales Ratio All Patentees (%)	R&D-to-Sales Ratio Rx&D Patentees (%)
2007	82	1,325.0	9.5	15,991.0	7.3	8.3	8.9
2006	72	1,210.0	-1.9	14,902.0	4.7	8.1	8.5
2005	80	1,234.3	5.5	14,231.3	0.5	8.7	8.8
2004	84	1,170.0	-2.0	14,168.3	4.0	8.3	8.5
2003	83	1,194.3	-0.4	13,631.1	12.8	8.8	9.1
2002	79	1,198.7	13.0	12,081.2	12.5	9.9	10.0
2001	74	1,060.1	12.6	10,732.1	15.3	9.9	10.6
2000	79	941.8	5.3	9,309.6	12.0	10.1	10.6
1999	78	894.6	12.0	8,315.5	19.2	10.8	11.3
1998	74	798.9	10.2	6,975.2	10.9	11.5	12.7
1997	75	725.1	9.0	6,288.4	7.4	11.5	12.9
1996	72	665.3	6.4	5,857.4	9.9	11.4	12.3
1995	71	625.5	11.5	5,330.2	7.5	11.7	12.5
1994	73	561.1	11.4	4,957.4	4.4	11.3	11.6
1993	70	503.5	22.1	4,747.6	14.0	10.6	10.7
1992	71	412.4	9.6	4,164.4	6.9	9.9	9.8
1991	65	376.4	23.2	3,894.8	18.1	9.7	9.6
1990	65	305.5	24.8	3,298.8	11.0	9.3	9.2
1989	66	244.8	47.4	2,973.0	9.4	8.2	8.1
1988	66	165.7	-	2,718.0	-	6.1	6.5

Source: PMPRB

The Global Context

Figure 10 compares Canadian R&D-to-sales ratios to those in the PMPRB's seven comparator countries for the years 2000 and 2005. As noted in Figure 10, Canada's ratio stood at 10.1% in 2000. Only Italy, at 6.2%, had a lower ratio in that year. Switzerland had the highest ratio at 102.5%, followed by Sweden at 44.4%. France, Germany and the U.S. were in the 16-18% range, while the U.K. was more than double (35.1%). A very similar pattern emerges in the investment-to-sales ratios for 2005. Italy (6.8%) remained at the bottom of the range, with Canada second lowest at 8.3%. Ratios in all other comparator countries remained well above Canada's ratio.

Figure 10
R&D-to-Sales Ratio, Canada and Seven PMPRB Comparator Countries, 2000 and 2005



Source: PMPRB, European Federation of Pharmaceutical Industries Associations and PhRMA

Analytical Studies of Pharmaceutical Trends

National Prescription Drug Utilization Information System

The National Prescription Drug Utilization Information System (NPDUIS) provides critical analyses of price, utilization and cost trends in Canada. The Canadian Institute for Health Information (CIHI) and the PMPRB are partners in this initiative.

The NPDUIS initiative involves two major elements:

- development of a database incorporating data on individual claims made against public drug plans; and

- production of analytical reports using information in this database.

CIHI is responsible for the first of these elements while the PMPRB (as requested by the Minister of Health under section 90 of the *Patent Act*) is principally responsible for the second. A steering committee, comprised of representatives of participating public drug plans (all jurisdictions except Quebec) and Health Canada, advises the PMPRB on its research agenda and individual studies.

A major new NPDUIS periodical report was inaugurated in 2007. The New Drug Pipeline Monitor (NDPM) summarizes information on new drugs that are expected to be launched in Canada within the next two to five years and could have a significant impact on the expenditures of public drug plan expenditures. The first report was released in June 2007.

As well, a report entitled Budget Impact Analysis Guidelines was released in May 2007. This report provides a best-practices framework for predicting the likely financial impact on a drug plan of listing a new medicine.

At the end of March 2008, several new NPDUIS reports were being prepared for release in the near future.

- The 2008 edition of the Pharmaceutical Trends Overview Report (PTOR) will update the PMPRB's previous analyses of expenditure trends among public drug plans in Canada.

- A second issue of the NDPM report will update the set of "pipeline" drugs, while providing a special review of oncology drugs in development.

- A new study will examine the impact of long-term demographic change on public drug plans in Canada.

- A new study will analyze recent trends in reimbursement of dispensing fees and other costs incurred at the retail level.

- Obtaining meaningful measures of treatment volumes is a critical step in cost-driver and utilization analysis. A new study will critically evaluate methodological options for doing this.

In addition, best-practices guidelines are being developed for the forecasting of drug plan expenditures at the level of therapeutic class. It is expected these guidelines will be published by the end of 2008.

All studies conducted under the NPDUIS are available on the PMPRB Web site, as is a list of ongoing projects.

Monitoring and Reporting of Non-Patented Prescription Drug Prices

In October 2005, the federal/provincial/territorial Ministers of Health announced the endorsement of the PMPRB to monitor and report on non-patented prescription drug prices (NPPDP). In November 2005, the PMPRB received direction from the federal Minister of Health, on behalf of himself and his colleagues, to undertake this monitoring and reporting. To-date, four reports have been released:

- Canadian and Foreign Price Trends (July 2006), which examined domestic and international price and sales trends of non-patented prescription drugs;

- Trends in Canadian Sales and Market Structure (October 2006), which analyzed annual growth rates in sales, sources of growth, market shares, sales concentration, and international price comparisons by level of concentration;

- Market for New Off-Patent Drugs (June 2007), which examined market-entry and pricing behaviour among drugs that had recently gone off-patent; and

- Non-Patented Single-Source Drugs in Canada (November 2007), which examined price trends among non-patented drugs with only a single Canadian supplier.

Two new NPPDP reports are being prepared for release in 2008. These will update the first two reports listed above, applying several methodological refinements, and focusing on generic drugs.

As of April 2008, NPPDP studies are conducted under the umbrella of the NPDUIS.

SECTION III – SUPPLEMENTARY INFORMATION

Financial Table 1: Comparison of Planned to Actual Spending (including FTEs)

($ thousands)	2005-2006 Actual	2006–2007 Actual	2007–2008			
			Main Estimates	Planned Spending	Total Authorities	Total Actuals
Patented Medicine Prices Review Board	5,326.5	7,365.3	11,475.0	11,475.0	11,924.8	7,432.4
Total	**5,326.5**	**7,635.3**	**11,475.0**	**11,475.0**	**11,924.8**	**7,432.4**
Less: Non-respendable revenue[(1)]	(1,413.3)	(210.0)	-	-	-	(10,566.5)
Plus: Cost of services received without charge	791.6	807.9	933.2	933.2	933.2	899.8
Total Departmental Spending	**4,704.8**	**7,963.2**	**12,408.2**	**12,408.2**	**12,858.0**	**(2,234.3)**
Full Time Equivalents	**42**	**43**	**62**	**62**	**62**	**50**

(1) The money reported as non-respendable revenue does not represent revenues generated by the PMPRB. This money is a result of payments made by patentees to the Government of Canada through Voluntary Compliance Undertakings (VCUs) or Board orders to offset excess revenues. The Minister may enter into agreements with any province respecting the distribution to that province of amounts received by the Receiver General, less any costs incurred in relation to the collection and distribution of those amounts.

Financial Table 2: Voted and Statutory Items

Vote or Statutory Item	Truncated Vote or Statutory Wording	2007–2008 ($thousands)			
		Main Estimates	Planned Spending	Total Authorities	Total Actuals
25	Operating expenditures	10,584.0	10,584.0	11,033.8	6,722.5
(S)	Contributions to employee benefit plans	891.0	891.0	891.0	709.9
	Total	**11,475.0**	**11,475.0**	**11,924.8**	**7,432.4**

Financial Table 3: Sources of Non-Respendable Revenue

For supplementary information on the PMPRB's source of non-respendable revenue, please visit http://www.tbs-sct.gc.ca/dpr-rmr/2007-2008/index-eng.asp

Financial Table 4: Financial Statements of the Patented Medicine Prices Review Board

Statement of Management Responsibility

Responsibility for the integrity and objectivity of the accompanying financial statements for the year ended March 31, 2008 and all information contained in these statements rests with management. These financial statements have been prepared by management in accordance with Treasury Board accounting policies which are consistent with Canadian generally accepted accounting principles for the public sector.

Management is responsible for the integrity and objectivity of the information in these financial statements. Some of the information in the financial statements is based on management's best estimates and judgment and gives due consideration to materiality. To fulfil its accounting and reporting responsibilities, management maintains a set of accounts that provides a centralized record of the Board's financial transactions. Financial information submitted to the *Public Accounts of Canada* and included in the Board's *Departmental Performance Report* is consistent with these financial statements.

Management maintains a system of financial management and internal control designed to provide reasonable assurance that financial information is reliable, that assets are safeguarded and that transactions are in accordance with the *Financial Administration Act*, are executed in accordance with prescribed regulations, within Parliamentary authorities, and are properly recorded to maintain accountability of Government funds. Management also seeks to ensure the objectivity and integrity of data in its financial statements by careful selection, training and development of qualified staff, by organizational arrangements that provide appropriate divisions of responsibility, and by communication programs aimed at ensuring that regulations, policies, standards and managerial authorities are understood throughout the Board.

The financial statements of the Board have not been audited.

The original version was signed by Brien G. Benoit, MD	The original version was signed by Barbara Ouellet
Brien G. Benoit, M.D. Chairperson Patented Medicine Prices Review Board	***Barbara Ouellet*** Executive Director & Senior Financial Officer Patented Medicine Prices Review Board
Date: August 6, 2008	Date: August 5, 2008

Statement of Operations (unaudited)

for the year ended March 31	2008	2007
(in dollars)		
Expenses		
Salaries and employee benefits	**5,293,726**	4,815,847
Professional and special services	**1,481,908**	1,951,204
Accommodation	**587,873**	489,894
Utilities, material and supplies	**422,397**	484,531
Travel and relocation	**141,263**	181,186
Information	**127,129**	122,086
Purchased repair and maintenance	**101,343**	124,330
Communication	**100,790**	83,510
Rentals	**12,107**	16,014
Amortization	**0**	3,101
Other	**47,557**	55,634
	8,316,093	**8,327,337**
Revenues		
Voluntary compliance undertakings	**10,566,629**	**210,043**
Net cost of operations	**(2,250,536)**	**8,117,294**
The accompanying notes form an integral part of the financial statements		

Statement of Financial Position (unaudited)

As at March 31	2008	2007
(in dollars)		
Assets		
Financial assets		
Accounts receivable and advances (Note 4)	**971,299**	108,595
	971,299	108,595
	971,299	**108,595**
Liabilities and Equity of Canada		
Liabilities		
Accounts payable and accrued liabilities	**601,416**	784,600
Vacation pay and compensatory leave (Note 6)	**245,549**	266,437
Employee severance benefits (Note 7)	**754,113**	733,660
	1,601,078	1,784,697
Equity of Canada	**(629,779)**	(1,676,102)
	971,299	**108,595**
The accompanying notes form an integral part of the financial statements		

Statement of Equity (unaudited)

As at March 31	2008	2007
(in dollars)		
Equity of Canada, beginning of year	**(1,676,102)**	(1,259,759)
Net cost of operations	**2,250,536**	(8,117,294)
Current year appropriations used (Note 3)	**7,432,416**	7,365,303
Revenues not available for spending	**(10,582,172)**	(218,605)
Change in net position in the Consolidated Revenue Fund (Note 3)	**1,045,787**	(253,685)
Services received without charge from other government departments (Note 8)	**899,756**	807,938
Equity of Canada, end of year	**(629,779)**	**(1,676,102)**
The accompanying notes form an integral part of the financial statements		

Statement of Cash Flow (unaudited)

For the year ended March 31	2008	2007
(in dollars)		
Operating activities		
Net cost of operations	**(2,250,536)**	8,117,294
Non-cash items:		
Amortization of capital assets (Note 5)	**0**	(3,101)
Services provided without charge from other government departments (Note 8)	**(899,756)**	(807,938)
Variations in Statement of Financial Position:		
Increase in accounts receivable and advances	**862,703**	72,776
Decrease (increase) in liabilities	**183,620**	**(**486,018)
	(2,103,969)	**6,893,013**
Financing activities		
Net cash provided by Government of Canada	**2,103,969**	(6,893,013)
	2,103,969	**(6,893,013)**
The accompanying notes form an integral part of the financial statements		

Notes to the Financial Statements (unaudited)

1. Authority and purpose

The Patented Medicine Prices Review Board (PMPRB) is an independent quasi-judicial body established by Parliament in 1987 under the Patent Act (Act).

Although the PMPRB is part of the Health Portfolio, it carries out its mandate at arms-length from the Minister of Health. It also operates independently of other bodies such as Health Canada, which approves drugs for safety and efficacy, and public drug plans, which approve the listing of drugs on their respective formularies for reimbursement purposes.

The PMPRB has a dual role:

- Regulatory: To ensure that prices charged by patentees for patented medicines sold in Canada are not excessive thereby protecting consumers and contributing to Canadian health care;
- Reporting: To report on pharmaceutical trends and on the R&D spending by pharmaceutical patentees, thereby contributing to informed decisions and policy making.

Jurisdiction

Regulatory - The PMPRB is responsible for regulating the prices that patentees charge, the "factory-gate" price, for prescription and non-prescription patented drugs sold in Canada, to wholesalers, hospitals or pharmacies, for human and veterinary use to ensure that they are not excessive. The PMPRB regulates the price of each patented drug product, including each strength of each dosage form of each patented medicine sold in Canada. This is normally the level at which Health Canada assigns a Drug Identification Number (DIN).

The PMPRB has no authority to regulate the prices of non-patented drugs, including generic drugs sold under compulsory licenses, and does not have jurisdiction over prices charged by wholesalers or retailers nor over pharmacists' professional fees. Also, matters such as distribution and prescribing are outside the purview of the PMPRB.

2. Significant accounting policies

The financial statements have been prepared in accordance with Treasury Board accounting policies which are consistent with Canadian generally accepted accounting principles for the public sector.

Significant accounting policies are as follows:

(a)Parliamentary appropriations

The Board is financed by the Government of Canada through Parliamentary appropriations. Appropriations provided to the Board do not parallel financial reporting according to generally accepted accounting principles since appropriations are primarily based on cash flow requirements. Consequently, items recognized in the statement of operations and the statement of financial position are not necessarily the same as those provided through appropriations from Parliament. Note 3 provides a high-level reconciliation between the bases of reporting.

(b) Net Cash Provided by Government

The Board operates within the Consolidated Revenue Fund (CRF), which is administered by the Receiver General for Canada. All cash received by the Board is deposited to the CRF and all cash disbursements made by the Board are paid from the CRF. The net cash provided by Government is the difference between all cash receipts and all cash disbursements including transactions between departments of the federal government.

(c) Change in net position in the Consolidated Revenue Fund

The change in net position in the Consolidated Revenue Fund is the difference between the net cash provided by Government and appropriations used in a year, excluding the amount of non respendable revenue recorded by the Board. It results from timing differences between when a transaction affects appropriations and when it is processed through the CRF (See note 3(c) for a reconciliation between net cash provided by Government and current year appropriations used).

(d) Revenues

Revenues are accounted for in the period in which the underlying transaction or event occurred that gave rise to the revenues. Patented Medicine Prices Review Board revenues represent monies collected as a result of payments made by patentees to the Government of Canada through Voluntary Compliance Undertakings (VCUs) or Board orders to offset excess revenues.

(e) Expenses

Expenses are recorded on an accrual basis:

- Vacation pay and compensatory leave are expensed as the benefits accrue to employees under their respective terms of employment.
- Services provided without charge by other government departments for accommodation and the employer's contribution to the health and dental insurance plans are recorded as operating expenses at their estimated cost.

(f) Employee future benefits

i. Pension benefits: Eligible employees participate in the Public Service Pension Plan, a multiemployer administered by the Government of Canada. The Board's contributions to

the Plan are charged to expenses in the year incurred and represent the total obligation to the Plan by the Board. Current legislation does not require the Board to make contributions for any actuarial deficiencies of the Plan.

ii. Severance benefits: Employees are entitled to severance benefits under labour contracts or conditions of employment. These benefits are accrued as employees render the services necessary to earn them. The obligation relating to the benefits earned by employees is calculated using information derived from the results of the actuarially determined liability for employee severance benefits for the Government as a whole.

(g) Accounts receivable

Accounts receivable are stated at amounts expected to be ultimately realized. They are mainly comprised of amounts to be recovered from other gorvernment Departments and the recovery is considered certain. As a result, no provision has been recorded as an offset against these amounts.

(h) Tangible Capital Assets

All tangible capital assets having an initial cost of $10,000 or more are recorded at their acquisition cost. The Board does not capitalize intangibles, works of art and historical treasures that have cultural, aesthetic or historical value, assets located on Indian Reserves and museum collections.

Amortization of capital assets is done on a straight-line basis over the estimated useful life of the asset as follows:

Asset Class	Sub-asset Class	Amortization Period
Machinery and equipment	Computer equipment	3-5 years

(i) Measurement uncertainty

The preparation of these financial statements in accordance with Treasury Board accounting policies which are consistent with Canadian generally accepted accounting principles for the public sector requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses reported in the financial statements. At the time of preparation of these statements, management believes the estimates and assumptions to be reasonable. The most significant items where estimates are used are the liability for employee severance benefits and the useful life of tangible capital assets. Actual results could significantly differ from those estimated. Management's estimates are reviewed periodically and, as adjustments become necessary, they are recorded in the financial statements in the year they become known.

3. Parliamentary Appropriations

The Board receives most of its funding through annual Parliamentary appropriations. Items recognized in the statement of operations and the statement of financial position in one year may be funded through Parliamentary appropriations in prior, current or future years. Accordingly, the Board has different net cost of operations for the year on a government funding basis than on an accrual accounting basis. The differences are reconciled in the following tables:

(a) Reconciliation of net cost of operations to current year appropriations used:	**2008**	2007
(in dollars)		
Net cost of operations	**(2,250,536)**	8,117,294
Adjustments for items affecting net cost of operations but not affecting appropriations:		
Add (Less):		
Revenues not available for spending	**10,582,172**	218,605
Services provided without charge from other government departments	**(899,756)**	(807,938)
Amortization	**0**	(3,101)
Legal services recovered by Justice Canada	**0**	(4,979)
Proceeds from disposals of crown assets	**101**	26
Allowance for vacation pay accrual	**9,783**	(54,429)
Allowance for time-off in lieu accrual	**11,105**	(11,589)
Allowance for severance benefits	**(20,453)**	(88,586)
	9,682,952	(751,991)
Current year appropriations used	**7,432,416**	7,365,303

(b) Appropriations provided and used:	2008	2007
(in dollars)		
Operating expenditures- Vote 30	**10,584,000**	10,978,025
Statutory Amounts	**710,011**	622,760
Transfer from Treasury Board - Vote 15	**42,000**	0
Transfer from Treasury Board - Vote 22	**275,000**	0
Transfer from Treasury Board - Vote 23	**132,753**	0
Less:		
Lapsed appropriations	**(4,311,348)**	(4,235,482)
Current year appropriations used	**7,432,416**	**7,365,303**

(c) Reconciliation of net cash provided by Government to current year appropriations used	2008	2007
(in dollars)		
Net cash provided by Government	**(2,103,969)**	6,893,013
Revenue not available for spending	**10,582,172**	218,605
	8,478,203	7,111,618
Change in net position in the Consolidated Revenue Fund		
Variation in accounts receivable and advances	**(870,782)**	**(**72,776)
Variation in accounts payable and accrued liabilities	**183,184**	331,414
Other Adjustments	**(8,179)**	(4,953)
	(1,045,787)	253,685
Current year appropriations used	**7,432,416**	7,365,303

4. Accounts receivable and advances

(in dollars)	2008	2007
Receivables from other Federal Government departments and agencies	**205,700**	0
Receivables from external parties	**765,099**	108,095
Employee advances	**500**	500
	971,299	108,595

5. Tangible capital assets

Cost (in dollars)	**Opening Balance**	**Acquisitions**	**Disposals and write-offs**	**Closing balance**
Machinery and equipment	91,242	-	-	**91,242**
	91,242	-	-	**91,242**

Accumulated Amortization (in dollars)	**Opening Balance**	**Amortization**	**Disposals and write-offs**	**Closing balance**
Machinery and equipment	91,242	-	-	**91,242**
	91,242	-	-	**91,242**
Net book value	-	-	-	**-**

6. Vacation pay and compensatory leave

(in dollars)	**2008**	2007
Allowance for vacation	**243,317**	253,100
Allowance for compensatory leave	**2,232**	13,337
	245,549	266,437

7. Employee benefits

(a) Pension benefits

The Board's employees participate in the Public Service Pension Plan, which is sponsored and administered by the Government of Canada. Pension benefits accrue up to a maximum period of 35 years at a rate of 2 percent per year of pensionable service, times the average of the best five consecutive years of earnings. The benefits are integrated with Canada/Québec Pension Plans benefits and they are indexed to inflation.

Both the employees and the Board contribute to the cost of the Plan. The expense presented below represents approximately 2.1 times (2.2 in 2006-07) the contributions by employees.

(in dollars)	**2008**	2007
Expense for the year	**517,524**	458,955
	517,524	458,955

The Board's responsibility with regard to the Plan is limited to its contributions. Actuarial surpluses or deficiencies are recognized in the financial statements of the Government of Canada, as the Plan's sponsor.

(b) Severance benefits

The Board provides severance benefits to its employees based on eligibility, years of service and final salary. These severance benefits are not pre-funded. Benefits will be paid from future appropriations. Information about the severance benefits, measured as at March 31, is as follows:

(in dollars)	2008	2007
Accrued benefit obligation, beginning of year	**733,660**	645,076
Expense for the year	**95,116**	147,991
Benefits paid during the year	**(74,663)**	(59,407)
Accrued benefit obligation, end of year	**754,113**	733,660

8. Related party transactions

The Board is related as a result of common ownership to all Government of Canada departments, agencies, and Crown corporations. The Board enters into transactions with these entities in the normal course of business and on normal trade terms. Also, during the year, the Board received services which were obtained without charge from other Government departments as presented in part (a).

(a) Services provided without charge

During the year the Board received without charge from other departments. These services without charge have been recognized in the Board's Statement of Operations as follows:

(in dollars)	2008	2007
Accommodation	**587,873**	489,894
Employer's contribution to the health and dental insurance plans	**300,612**	299,709
Justice Canada	**11,271**	18,335
	899,756	807,938

The Government has structured some of its administrative activities for efficiency and cost-effectiveness purposes so that one department performs these on behalf of all without charge. The costs of these services, which include payroll and cheque issuance services provided by Public Works and Government Services Canada and audit services provided by the Office of the Auditor General , are not included as an expense in the Board's Statement of Operations.

(b) Payables outstanding at year-end with related parties:

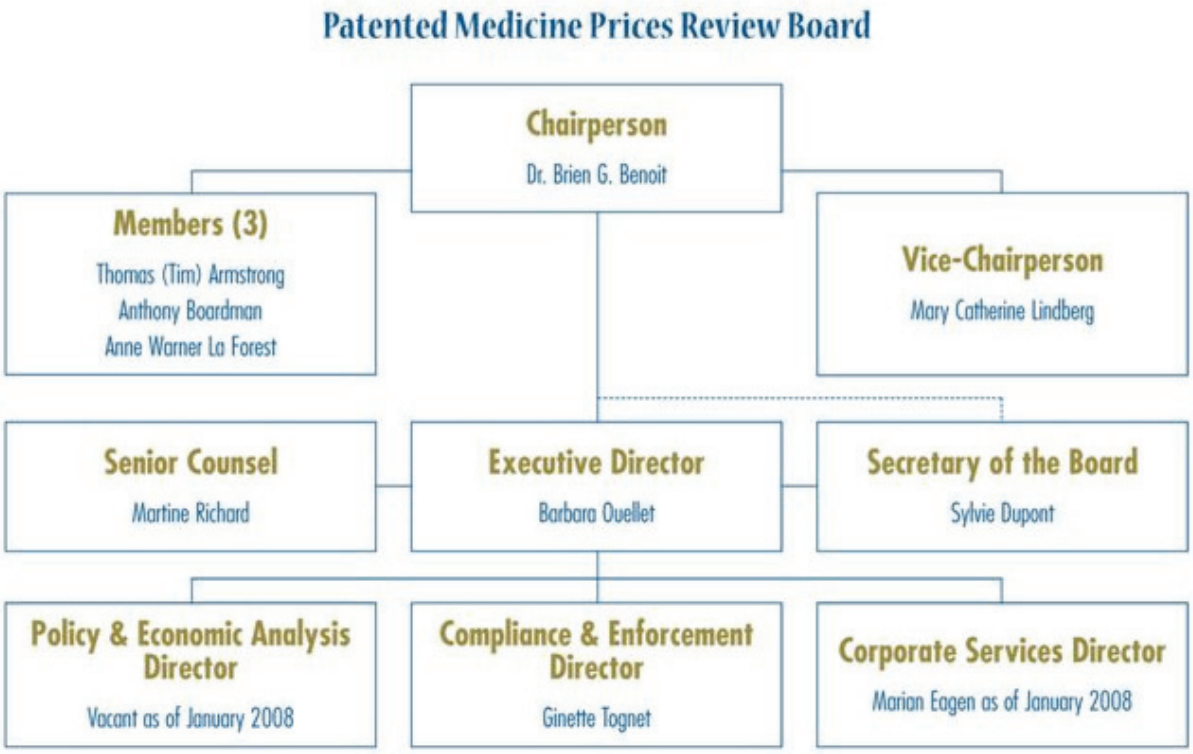
(in dollars)	2008	2007
Accounts payable to other government departments and agencies	**45,251**	32,043

9. Comparative information

Comparative figures have been reclassified to conform to the current year's presentation

SECTION IV – OTHER ITEMS OF INTEREST

Organizational Information



The Board consists of not more than five members who serve on a part-time basis, appointed by the Governor-in-Council, including a Chairperson and Vice-Chairperson. The Chairperson is designated under the *Patent Act* as the Chief Executive Officer of the PMPRB with the authority and responsibility to supervise and direct its work. The Executive Director manages the work of the staff. Senior staff consists of the Executive Director, the Director of Compliance and Enforcement, the Director of Policy and Economic Analysis, the Director of Corporate Services, the Secretary of the Board and Senior Counsel.

The Compliance and Enforcement Branch is largely responsible for the review of prices of patented medicines and the application of the Compliance and Enforcement Policy. The Policy and Economic Analysis Branch is largely responsible for undertaking policy analysis and leading the review of and consultation on the Excessive Price Guidelines, and for conducting analyses and preparing reports on price trends and other economic studies. The Secretariat supports the operations of the Board, provides overall direction to the Communications Program and coordinates the Access to Information and Privacy Programs. The Senior Counsel provides legal advice on statutory interpretation and on regulatory and policy issues. The Corporate Services Branch provides direction and administrative support with regard to information management, technology, business planning, finance and human resources.