# Patented Medicine Prices Review Board

## 2006-2007

### Departmental Performance Report

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The Honourable Tony Clement
Minister of Health and the Minister for Federal Economic Development Initiative for Northern Ontario

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# SECTION I – OVERVIEW

## Chairperson's Message

I am pleased to present the 2006-2007 Departmental Performance Report for the Patented Medicine Prices Review Board (PMPRB).

The PMPRB's mandate is two-fold:

1) 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; and

2) To report on pharmaceutical trends and on the research and development (R&D) spending by pharmaceutical patentees, in order to contribute to informed decisions and policy-making.

During the past year, the PMPRB was very active in supporting both these outcomes. In keeping with our regulatory mandate, we reviewed the prices of more than 1100 patented drug products, including 99 new drugs that came under our jurisdiction in 2006. Linked to these reviews, eight 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 the spring of 2006, the Board followed through on its plans to issue a discussion guide on its *Excessive Price Guidelines* (Guidelines) and, later in the year, held face-to-face consultations with stakeholders to hear their views on potential needs to revise the Guidelines. The key issues being addressed by this review include the categorization of new drugs for price review purposes, price tests, potential reviews of "any market," "re-benching" (i.e., relating to whether re-setting the benchmark price may be appropriate), and guiding principles for the price review process. Subsequent to these consultations, the Board expanded the Guidelines review to also encompass other price factors in the Act (i.e., – the prices of comparator medicines in other countries, and the cost of making and marketing) and the Board's current approach to applying the Consumer Price Index (CPI) factor.

In addition, the PMPRB undertook a number of new studies and analyses. We released two studies under the National Prescription Drug Utilization Information System (NPDUIS): the *Budget Impact Analysis Guidelines* and the *New Drug Pipeline Monitor*. In support of the National Pharmaceuticals Strategy and our recent additional responsibility to monitor and report on non-patented prescription drug prices, we released three other reports — *Canadian and Foreign Price Trends, Trends in Canadian Sales and Market Structure* and *Markets for New Off-Patent Drugs*.

The Board continues to ensure that all of its activities are transparent and that stakeholders are well informed through our Web site, quarterly NEWSletters and other notices and publications.

In conclusion, the Board remains keenly aware of its mandate to serve Canadians through an appropriate, efficient and modern patented drug price regulatory scheme and through timely information on Canadian pharmaceutical price trends.

Brien G. Benoit, MD
Chairperson

## Management Representation Statement

I submit for tabling in Parliament, the 2006–2007 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 2006–2007 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.

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 and on the R&D spending by pharmaceutical patentees, in order to contribute 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)**

| 2006-2007 | | |
|---|---|---|
| **Planned Spending** | **Total Authorities** | **Actual Spending** |
| $6,512.0 | $11,690.0[1] | $7,365.3[2] |

[1] As a result of the decision of the Treasury Board Meeting of June 22, 2006, the PMPRB received funding through Supplementary Estimates (A) of $4,914,625 to conduct public hearings and to modernize the Excessive Price Guidelines.

[2] As a result of the June 2006 Treasury Board Meeting, the PMPRB received the additional funding referred to in note 1 through Supplementary Estimates A. Provisions had been approved by Treasury Board for the PMPRB to access Vote 5 should it be unable to cash manage through to December 2006. In order to mitigate the need to access Vote 5, some activities related to Guidelines modernization were delayed (e.g. consultation meetings with stakeholders were deferred to November). In addition, while the total projected number of hearings for 2006-2007 did materialize by the end of the fiscal year, the timing of the issuance of the Notices of Hearing was later than expected. Finally, given the time delay in staffing of new approved positions, work in other areas (i.e. analytical studies on pharmaceutical trends) was delayed as staff were assigned to meet more pressing demands. Therefore, as a result of all of the above, actual spending was less than approved authorities.

**Total Human Resources**

| 2006-2007 | | |
|---|---|---|
| **Planned** | **Actual** | **Difference** |
| 48 | 43 | 5 |

**Departmental Priorities**

| **Status on Performance** | | | **2006-2007** | |
|---|---|---|---|---|
| | | | **Planned Spending ($ 000)** | **Actual Spending ($ 000)** |
| **Strategic Outcome:**<br>Prices charged by manufacturers of patented medicines sold in Canada are not excessive. | | | | |
| **Government of Canada Outcome**:<br>Healthy Canadians | | | | |
| **Priority No. 1**<br>Compliance and enforcement | **Activity**:<br>Review prices for new and existing patented medicines sold in Canada and<br><br>update Board Guidelines as needed<br><br>**Expected result**:<br>All manufacturers' prices for new and existing patented medicines sold in Canada are reviewed in a timely manner and in accordance with the Board's Excessive Price Guidelines. | **Performance**<br>Met expectations<br><br>The Board issued a discussion guide on its Guidelines and held face-to-face consultations with stakeholders. Further work is ongoing | 3,107.0 | 5,551.9 |

| Status on Performance | | | 2006-2007 | |
|---|---|---|---|---|
| | | | **Planned Spending ($ 000)** | **Actual Spending ($ 000)** |
| **Strategic Outcome:**<br>Prices charged by manufacturers of patented medicines sold in Canada are not excessive. | | | | |
| **Government of Canada Outcome**:<br>Healthy Canadians | | | | |
| **Priority No. 2**<br>Report on pharmaceutical trends | **Activity:**<br>Identify and provide more informative information on key pharmaceutical issues of interest to Canadian consumers and other stakeholders.<br><br>**Expected results:**<br>Canadian consumers and other stakeholders have complete and accurate information on trends in manufacturers' prices of patented medicines sold in Canada and on patentees' research-and-development expenditures. | **Performance**<br>Met expectations | 1,455.0 | 1,016.8 |
| | **Activity:**<br>Provide critical analyses of price, utilization and cost trends for prescription drugs sold in Canada.<br><br>**Expected results:**<br>F/P/T drug plans and Canada's health system will have more accurate information on how prescription drugs are being used and on sources of cost indices through critical analyses of price utilization and cost trends. | Met expectations | 1,350.0 | 557.3 |

| Status on Performance | | | 2006-2007 | |
|---|---|---|---|---|
| | | | **Planned Spending ($ 000)** | **Actual Spending ($ 000)** |
| **Strategic Outcome:**<br>Prices charged by manufacturers of patented medicines sold in Canada are not excessive. | | | | |
| **Government of Canada Outcome**:<br>Healthy Canadians | | | | |
| **Priority #2**<br>Report on pharmaceutical trends – cont. | **Activity:**<br>Monitor and report on non-patented prescription drug prices in Canada.<br><br>**Expected results:**<br>F/P/T Governments and other stakeholders will have critical analyses and comprehensive information on non-patented prescription drug prices. | **Performance**<br>Partially met expectations. | 600.0 | 239.3 |

## 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 heath 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 retailers, 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. This initiative provides a credible, centralized source of information for the First Ministers National Pharmaceuticals Strategy.

### 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, this causes concern for 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.

Recently, 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 the industry is seeking to move toward a global pricing scheme.

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.

In June 2006, the F/P/T Ministerial Task Force released a progress report on the National Pharmaceuticals Strategy. Ministers noted that the challenges and opportunities Canada faces in the area of pharmaceuticals management relate to three fundamental themes: 1) Access; 2) Safety, Effectiveness and Appropriate Use; and 3) System Sustainability. Pricing and Purchasing, particularly focused on non-patented prescription drugs, is one of the Task Force's key priorities and is complicated by the complex array of payers, incentives and interests.

To effectively meet the challenges of an evolving pharmaceutical environment, the PMPRB increasingly needs 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:

- an increased number of patented drugs for human use requiring review, complicated by increases in late reporting by patentees;
- an unprecedented number of Notices of Hearing issued under the *Patent Act*; and
- the need to undertake a comprehensive review of, and 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 1181 patented drug products for human use were under the PMPRB's jurisdiction in 2006. In addition, 48 patented drugs for veterinary use were under the Board's jurisdiction.
- Ninety-nine new patented drugs products (at the level of the Drug Identification Number – DIN)[3] for human use were reported to the PMPRB in 2006, of which 29 medicines, representing 43 DINs, were new active substances. As of March 31, 2007, 79 new patented drugs had been reviewed. Of those, 68 were considered to be within the Guidelines while 11 were subject to ongoing investigations.
- Six new DINs were reported for veterinary use in 2006, all of which remained under review.

[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 issued eight Notices of Hearing, bringing the total ongoing proceedings to ten. The Dovobet and Nicoderm matters, initiated in previous years, remained before the hearing panels for final resolution.

- The Board approved five Voluntary Compliance Undertakings (VCUs), including one in May and June 2007, both in the context of a hearing, and each of which concluded one of the ten aforementioned hearings.

- Several new studies and analyses were released relating to the Board's responsibilities under NPDUIS (the *Budget Impact Analysis Guidelines* and the *New Drug Pipeline Monitor*) and NPPDP (*Canadian and Foreign Price Trends, Trends in Canadian Sales and Market Structure*, and *Markets for New Off-Patent Drugs*).

**Sales, Prices and R&D Trends**

- Sales of patented drugs in Canada increased by 3.7% to $12 billion in 2006. In recent years, the annual rate of sales growth has decreased.

- The share of total sales accounted for by patented drugs declined to 68.1% in 2006, from 71.4% in 2005.

- The antineoplastics and immunomodulating agents (such as drugs used in chemotherapy) remained the leading drug class contributing to sales growth.

- Patentees' prices of patented drugs, as measured by the Patented Medicine Price Index (PMPI), decreased on average by 0.2% in 2006. This slight decline was attributable to falling prices paid by hospitals. Over the same period, the Consumer Price Index was at 2.0%.

- Analysis by therapeutic class, by class of customer, by province/territory, and by comparator country, demonstrated considerable variability in price changes.

- In 2006, the ratio of Canadian prices to the international median for comparator countries was slightly below parity, meaning that, on average, Canadian prices remained slightly below the median of international prices observed in the seven comparator countries used by the PMPRB (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States).

- Patentees reported total R&D expenditures of $1.2 billion in 2006, a slight decrease of 1.9% over the previous year, in part explained by the decrease in the number of reporting patentees, from 80 in 2005 to 72 in 2006. 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 $0.949 billion in 2006, down 8.7% from the $1.0 billion in expenditures in 2005.

- The R&D to sales ratio for all patentees declined to 8.1% from 8.7% in 2005, as did the R&D-to-sales ratio for members of Rx&D (down to 8.5% compared to 8.8% in the previous year).

# SECTION II –
# ANALYSIS OF THE PROGRAM ACTIVITY
# BY STRATEGIC OUTCOME

## Analysis by Program Activity

**Strategic Outcome:**

Prices charged by manufacturers of patented medicines sold in Canada are not excessive.

**Program Activity Name:**

Patented Medicine Prices Review

The PMPRB has one program - Patented Medicine Prices Review. This program has two priorities:

1) compliance and enforcement

2) report on pharmaceutical trends

The objectives of the program are to protect consumer interests and contribute to Canadian health care.

**Financial Resources ($ thousands):**

| 2006-2007 | | |
|---|---|---|
| **Planned Spending** | **Authorities** | **Actual Spending** |
| $6,512.0 | $11,690.0 | $7,365.3 |

**Human Resources:**

| 2006-2007 | | |
|---|---|---|
| **Planned** | **Actual** | **Difference** |
| 48 | 43 | 5 |

## Priority 1: Compliance and Enforcement

**Financial Resources ($ thousands):**

| 2006-2007 | | |
|---|---|---|
| **Planned Spending** | **Authorities** | **Actual Spending** |
| $3,107.0 | $8,225.1 | $5,551.9 |

**Human Resources:**

| 2006-2007 | | |
|---|---|---|
| **Planned** | **Actual** | **Difference** |
| 25 | 30 | (5) |

**Price Reviews**

The PMPRB reviews pricing information filed pursuant to the *Patented Medicines Regulations, 1994* (Regulations) under the *Patent Act* (Act) 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 section 85 of the Act 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 are classified as either breakthrough/substantial improvement, or moderate, little or no therapeutic advantage over comparable medicines, or are new DINs of an existing or comparable dosage form of an existing medicine (sometimes referred to as line extensions);
- Prices for new breakthrough patented drug products and those that bring a substantial improvement are generally limited to the median of the prices charged for the same drug in the

[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.

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 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 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 vast majority of prices of patented medicines sold in Canada are within the Guidelines;

- The vast majority of price increases for existing patented medicines are not higher than changes in the CPI;

- Enforcement measures are taken to correct prices that exceed the Guidelines; and

- Canadian prices of patented drugs are, on average, below the median of international prices in the foreign countries listed in the Regulations.

**Price Review of New Patented Drugs for Human Use in 2006**

Ninety-nine new patented drugs products[6] (DINs) were introduced for human use in 2006. Of these, 29 medicines were new active substances, representing 43 DINs. By March 31, 2007, the Board had reviewed 79 of the 99 introduced. Of those, 68 were considered to be within the

[6] For the purposes of the Board's price review, a new patented drug product in 2006 is defined as any patented drug product introduced in Canada, or previously marketed but first patented between December 1, 2005, and November 30, 2006. The same approach is used for all years due to the timing of the filing requirements under the *Patented Medicines Regulations, 1994.*

Guidelines while 11 appeared to exceed the Guidelines and were subject to ongoing investigations. At March 31, 2007, of the original 99 new drug products, 20 DINs remained under review.

**Price Review of Existing Patented Drugs for Human Use**

A total of 1,082 existing patented drug products (or DINs) were sold during 2006.[7] Of these

- 973 DINs (89.9%) were within the Guidelines
- 6 DINs were subject to investigations due to introductory pricing
  - 2 were opened in 2004
  - 4 were opened in 2005
- 59 DINs were subject to investigations due to price increase
  - 2 were opened in 2003
  - 16 were opened in 2005
  - 41 were opened in 2006
- 27 DINs were, or are currently, the subject of hearings under section 83 of the Act (For additional information see Quasi-judicial Activities – Hearings, on page 24)
  - 3 pertaining to Nicoderm (1999)
  - 1 pertaining to Dovobet (2004)
  - 6 pertaining to Adderall XR (2006)
  - 3 pertaining to Risperdal Consta (2006)[8]
  - 1 pertaining to Airomir (2006)[9]
  - 1 pertaining to Copaxone (2006)
  - 4 pertaining to Concerta (2006)
  - 5 pertaining to Strattera (2007)
  - 1 pertaining to Quadracel (2007)
  - 1 pertaining to Pentacel (2007)
  - 1 pertaining to Penlac (2007)
- 17 DINs were still under review.

[7] For the purpose of this report, existing medicines include all patented drug products that were introduced prior to December 1, 2005.

[8] The Hearing in the matter of Janssen-Ortho Inc. and the medicine Risperdal Consta was concluded by the acceptance of a VCU. For additional information see page 24 of this report.

[9] The Hearing in the matter of 3M Canada Company and the medicine Airomir was concluded by the acceptance of a VCU. For additional information see page 23 of this report.

A summary of the review, compliance and investigation status of the new and existing patented drug products for human use in 2006 is provided in Table 1 below.

Table 1

**Patented Drug Products (DINs) for Human Use Sold in 2006 – Status of Price Review as of March 31, 2007**

| | New Drugs Introduced in 2006 | Existing Drugs | Total |
|---|---|---|---|
| Total | 99 | 1,082 | 1,181 |
| Within Guidelines | 68 | 973 | 1,041 |
| Under Review | 20 | 17 | 37 |
| Under Investigation | 11 | 65 | 76 |
| Notice of Hearing | - | 27 | 27 |

**Update of the Review of Existing Patented Medicine Prices reported in the 2005-2006 Departmental Performance Report**

Last year's Performance Report reported that, of the 969 existing patented drug products for human use sold in 2005, the prices of 22 were still under review. The results of those reviews concluded that: six DINs were within the Guidelines; ten DINs were priced at levels that appeared to exceed the Guidelines resulting in initiation of investigations; and six are still under review and included in the total figure of existing drugs under review reported in Table 1.

The PMPRB also reported in the 2005-2006 Departmental Performance Report that 37 DINs were under investigation. Of those, 11 investigations have been concluded; in eight cases the prices were ultimately found to be within the Guidelines. In three cases, VCUs were approved: Eloxatin (2 DINs), Hextend (1 DIN). (See Voluntary Compliance Undertakings on page 22.)

**Patented Drugs for Veterinary Use**

The Board has adopted a policy for the review of patented veterinary medicines that differs somewhat from that for human drugs. Board staff only reviews the introductory prices of new patented veterinary medicines according to the current Guidelines and determines whether or not the price is excessive. In subsequent years, veterinary drug prices are subject to formal review only when a complaint with significant evidence has been received. Thus, patentees are required to maintain price information but only file this with the PMPRB upon request following a complaint. No complaints were received in 2006. Last year we reported that all new drugs for veterinary use had been reviewed and found to be within the Guidelines.

One drug product, Paylean 20, sold by Elanco Animal Health Canada, a division of Eli Lilly and Company, was sold prior to being reported to the PMPRB in 2006. In 2006, in total, six new DINs were reported to the PMPRB and are under review. The 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 its price to conform to the Board's Guidelines and to pay back any excess revenue which was obtained as a result of the medicine being sold at an excessive price.

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 has sold the patented medicine 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 Board Panel struck for the purpose of the Hearing.

In 2006-2007, and up to the date of this report, VCUs were approved for five patented medicines:[10]

### NuvaRing, Organon Canada Ltd.

**NuvaRing**™ is a new medicine for contraception. It is a flexible, soft, transparent, slow release vaginal ring.

On June 20, 2006, the Vice-Chairperson of the Board accepted a VCU for NuvaRing™, submitted by Organon Canada Ltd. (Organon). Organon reduced the average transaction price of NuvaRing™ to a level at or below the 2006 maximum non-excessive (MNE) price of $13.6791. To offset excess revenues, as calculated by Board Staff, during the period January 17 to June 30, 2005, Organon made a payment to the Government of Canada in the amount of $115,584.93. The remaining excess revenues, for the period July 1, 2005, to June 30, 2006, were offset by the reduction of the price of another patented drug, Remeron® 15mg, 30mg and 45mg. The price of NuvaRing™ remains under the PMPRB's jurisdiction until the patent expires in 2018.

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

**Eloxatin, sanofi-aventis Canada Inc.**

**Eloxatin** is used to treat patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed during or within six months of completion of first-line therapy with the combination of bolus 5-FU/LV and irinotecan.

On July 14, 2006, the Chairperson of the Board accepted a VCU for Eloxatin. sanofi-aventis Canada Inc. (sanofi-aventis) agreed that the MNE prices for Eloxatin 50 mg and 100 mg were $430.9208 and $922.6750 at introduction and that they were $490.5901 and $1,030.0175 in 2006. In lieu of a price reduction for the 50 mg vial and in order to avoid a distortion in the pricing relationship between the 50 mg and 100 mg vials, sanofi-aventis agreed to maintain the price of Eloxatin 100 mg vial at $1,000.00 until such time as the MNE price for the 50 mg vial reached $500.00. In order to offset excess revenues received from the sale of Eloxatin, sanofi-aventis made payments totaling $1,767,078.84 to hospitals, cancer clinics and cancer boards that had previously purchased Eloxatin at excessive prices. The individual payments reflected the distribution of purchases of Eloxatin across Canada up to the end of March 31, 2006. The price of Eloxatin is under the PMPRB's jurisdiction at least until the end of the January to June 2019 reporting period.

**Hextend, Hospira Healthcare Corporation**

**Hextend** is indicated for the treatment of hypovolemia when plasma volume expansion is required.

The Chairperson approved a VCU for Hextend on July 14, 2006. Hospira Healthcare Corporation (Hospira) agreed that the 2004 and 2005 MNE prices of Hextend were $0.0858 per mL. It will ensure that the average transaction price of Hextend in all future periods does not exceed the MNE price – where the price in the U.S. in local currency terms remains unchanged or increases, the MNE shall be the lower of the CPI-adjusted price and $0.0858 per mL; and where the price in the U.S. in local currency terms decreases, the MNE shall be calculated using the new U.S. price in conducting the International Price Comparison (IPC) test as set out in the Guidelines. Hospira further agreed to ensure that the average transaction price for 2006 did not exceed the 2006 MNE price. Hospira offset excess revenues accrued between March 15 and December 31, 2004, by making a payment to the government of Canada in the amount of $8,823.60. The price of Hextend remains under the PMPRB's jurisdiction until the patent expires in 2014.

**Airomir, 3M Canada Company**

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

In early 2007, the Board approved a VCU agreed to by 3M Canada Company (3M Canada) and Board Staff, for the payment in full of revenues, in the amount of $485,498.58, alleged by Board Staff to have been excessive, received from January 1, 2004 to December 29, 2006. By order of the Board Hearing Panel, the proceeding that was commenced by the issuance of a Notice of Hearing was concluded. On February 20, 2006, the Board had issued a Notice of Hearing pertaining to the allegations of Board Staff that Airomir had been, and was being, sold by 3M Canada at prices exceeding the Excessive Price Guidelines. The Board held a pre-hearing conference on May 19, 2006, and scheduled the hearing to commence on October 19. At the request of 3M Canada, the hearing was postponed. The Board was subsequently informed that 3M Canada had

sold its marketing rights for Airomir to Graceway Canada (Graceway) on December 29, 2006. On May 9, 2007, the Board received a submission for the approval of a VCU to resolve all issues raised by the Notice of Hearing.

For purposes of the application of the Board's Excessive Price Guidelines, Graceway is the Canadian patentee of Airomir as of December 29, 2006. Under the *Patented Medicines Regulations, 1994*, Graceway is required to file pricing and sales information with the PMPRB twice a year, at regular intervals, as well as file its R&D expenditures annually.

**Risperdal Consta, Janssen-Ortho Inc.**

**Risperdal Consta** is used for the management of the manifestations of schizophrenia and related psychotic disorders.

In June 2007, the Board approved a VCU agreed to by Janssen-Ortho Inc. (Janssen-Ortho) and Board Staff. Janssen-Ortho agreed to the MNE prices for Risperdal Consta for 2004, 2005, 2006 and 2007 and to offset cumulative excess revenues by making a payment to Her Majesty in right of Canada in the amount of $4,386,172.99. On January 30, 2006, the Board had issued a Notice of Hearing in the matter of Janssen-Ortho and the medicine Risperdal Consta. The Hearing was held in 2006 and 2007. On July 4, 2007, the Board Hearing Panel accepted the VCU of Janssen-Ortho which concluded the proceeding.

**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.

From January 2006 to March 31, 2007 the Board has issued eight Notices of Hearing, which brought the total number of hearings to ten. [11] This represented a significant increase in the number of Notices of Hearing compared to previous years. Indeed, by way of comparison this number is equal to the total of the Notices of Hearing issued by the Board going back to its inception in 1987 through to 2005. Of those previous eight, one hearing was completed, five were resolved through Voluntary Compliance Undertakings, and two others – Dovobet and Nicoderm – are ongoing as part of the ten hearings referred to above.

The reasons for an increase in hearings may involve such factors as the shift in the drug pipeline away from blockbuster new chemicals to more incremental innovations, and the influence of global pricing goals. It may also relate in part to recent price increases after a period of considerable price stability. The purpose of these hearings is to determine whether, under sections 83 and 85 of the Act, patentees are selling or have sold medicines in any market in Canada at

[11] The total number of hearings was subsequently reduced to eight as a result of the Hearing Panel's acceptance of a VCU to resolve the matter of 3M Canada and the medicine Airomir, and the matter of Janssen-Ortho and the medicine Risperdal Consta. On July 25, 2007, a further Notice of Hearing was issued in the matter of Abbott Laboratories Limited and the price of the medicine Zemplar bring the number of ongoing hearings to nine.

prices that, in the Board's opinion, are, or were, excessive, and if so, what order if any, should be made.

**Adderall XR, Shire BioChem Inc.**

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

On January 18, 2006, the Board issued a Notice of Hearing in the matter of Shire Biochem Inc. (Shire) and the price of the medicine Adderall XR.On December 15, 2006, the Board issued a decision on the issue of pre-patent. Shire had made a motion to the Board for an order that the Board amend its Notice of Hearing to limit the Board's inquiry to the period following the date of issuance of patent 2,348,090, namely April 13, 2004. The Board dismissed Shire's motion. Shire filed an application for judicial review in this matter with the Federal Court of Canada. The matter has not yet been heard.

Closing arguments on the merits were heard on June 18, 2007. The decision of the Board Hearing Panel is pending.

**Airomir, 3M Canada Company**

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

On February 20, 2006, the Board issued a Notice of Hearing in the matter of 3M Canada Company (3M Canada) and the price of the medicine Airomir.

On May 14, 2007, the Board Hearing Panel approved a VCU[12] which resolved all issues raised by the Notice of Hearing.

**Concerta, Janssen-Ortho Inc.**

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

On July 24, 2006, the Board issued a Notice of Hearing in the matter of Janssen-Ortho Inc. (Janssen-Ortho) and the price of the medicine Concerta.

Closing arguments were heard on August 29, 2007. The decision of the Board Hearing Panel is pending.

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

Copaxone 20 mg/1.0 mL syringe is a new formulation of an existing compound (glatiramer acetate) indicated for use in ambulatory patients with Relapsing-Remitting Multiple Sclerosis to reduce the frequency of relapses.

On May 8, 2006, the Board issued a Notice of Hearing in the matter of Teva Neuroscience G.P.-S.E.N.C. (Teva) and the price of the medicine Copaxone.

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[12] Details of this case are provided under Voluntary Compliance Undertakings on page 23.

Closing arguments were heard on August 13, 2007. The decision of the Board Hearing Panel is pending.

**Dovobet, LEO Pharma Inc.**

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

On November 29, 2004, the Board issued a Notice of Hearing in the matter of LEO Pharma Inc. (LEO Pharma) and the price of the medicine Dovobet. The hearing concluded in December 2005. On April 19, 2006, the Hearing Panel issued its decision.

On April 19, 2006, LEO Pharma made an application to the Federal Court of Canada for a judicial review of the Board's decision. A hearing was held on February 12, 2007 and the reasons and judgement of the Court were issued on March 21, 2007. The final order of the Board Hearing Panel is pending.

**Nicoderm, Hoechst Marion Roussel Canada Inc.**

Nicoderm is a transdermal nicotine patch, indicated as an aid for smoking cessation for the partial relief of nicotine withdrawal symptoms.

On April 20, 1999, the Board issued a Notice of Hearing in the matter of Hoechst Marion Roussel Canada Inc. (HMRC) and the price of the medicine Nicoderm. On May 25, 1999, HMRC filed a motion requesting that the Board rescind the Notice of Hearing. The Board Hearing Panel issued decisions on the motion in two parts on August 3, 1999 and August 8, 2000.

On September 3, 1999, HMRC sought a judicial review of the first and later, the second Board decision. The Federal Court issued its decision on November 17, 2005. The resolution of the hearing is pending.

**Penlac Nail Lacquer, sanofi-aventis Canada Inc.**

Penlac is a new formulation of an existing compound (ciclopirox), indicated as part of a comprehensive nail management program in immunocompetent patients with mild to moderate onychomycosis (due to Trichophyton rubrum) of fingernails and toenails without lunula involvement.

On March 26, 2007, the Board issued a Notice of Hearing in the matter of sanofi-aventis Canada Inc. (sanofi-aventis) and the price of the medicine Penlac. A pre-hearing conference was held on June 6, 2007; the hearing is pending.

**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 $7^{th}$ 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).

On March 27, 2007, the Board issued a Notice of Hearing in the matter of sanofi-pasteur Limited (sanofi pasteur) and the prices of the medicines Quadracel and Pentacel.

A pre-hearing conference is scheduled to be held on October 31, 2007 and hearing dates have been set for November 28-30, 2007.

**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 January 30, 2006, the Board issued a Notice of Hearing in the matter of Janssen-Ortho Inc. (Janssen-Ortho) and the price of the medicine Risperdal Consta. The Hearing was held in 2006 and 2007. On July 4, 2007, the Board Hearing Panel accepted the VCU of Janssen-Ortho which concluded the proceeding.

**Strattera, Eli Lilly Canada Inc.**

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

On December 15, 2006, the Board issued a Notice of Hearing in the matter of Eli Lilly Canada Inc. (Eli Lilly) and the price of the medicine Strattera. On February 22, 2007, the Board Hearing Panel held a hearing on a Motion for Adjournment brought by Eli Lilly; a verbal decision to dismiss the motion was issued. The hearing in the matter is pending.

## Consultations

### Amendments to the Patented Medicines Regulations, 1994

On December 31, 2005, proposed regulatory amendments were published in the *Canada Gazette*, Part I. Following publication, numerous submissions were received from stakeholders and were carefully examined by the Board.

As part of the subsequent consideration of revisions to the proposed amendments, Board Staff met with Rx&D in the spring of 2006 and with Rx&D, the Canadian Generic Pharmaceutical Association and BIOTECanada in February and March 2007. Work on the regulatory amendments is ongoing.

**Review of the Board's Excessive Price Guidelines**

In 2005, the Board had released a Discussion Paper on Price Increases and the submissions of stakeholders identified introductory prices as being of greater concern. The release of the *Discussion Guide on the Board's Excessive Price Guidelines* (Guide) in May 2006 marked the first step in the Board's review of its Guidelines, with a focus on introductory price issues. The Guide asked stakeholders to consider three issues: the categorization of new drugs; introductory price tests; and the wording of the Act regarding excessive prices in "any market." The Board received 45 written submissions in response, reflecting the wide-ranging views of the individuals and groups affected by or interested in the Guidelines: patentees; patient and health care provider representatives; private and public insurance plans; members of the PMPRB's Human Drug Advisory Panel; academics; and consultants.

In November 2006, the Board met with close to 140 members of these stakeholder groups at sessions held in Edmonton, Montreal, Toronto, Halifax, and Ottawa. Participants deliberated on the topics of "categories" and "any market", as well as two new subjects: whether and when an introductory price should be "re-benched" (re-evaluated); and potential principles that could guide how the price factors in the Act are operationalized in the price review process. (The Guide and Summary Reports on each stakeholder meeting are available on the PMPRB's Web site: www.pmprb-cepmb.gc.ca, under Consultations, Consultations on the Board's Excessive Price Guidelines, Reference Material.)

The fundamental purpose of the Guidelines is to provide transparency and predictability in the price review process for all stakeholders. The Board recognizes that the pharmaceutical environment has evolved since the last major revision to the Guidelines in 1994, and that it is essential to ensure that the Guidelines remain relevant and appropriate in the current context. At the same time, it must be recognized that the Guidelines have been very effective in promoting voluntary compliance with non-excessive pricing. Currently, there are more than 1,100 patented drug products under the Board's jurisdiction. While a number of Notices of Hearing were issued and several investigations into apparent excessive prices were ongoing in 2006, the overall rate of compliance with the Guidelines for all patented drugs being sold in Canada is extremely high – at over 90%.

The Board is continuing its analysis in 2007. It has noted that the current Guidelines do not encompass all of the factors in the Act that the Board must consider in determining whether prices of patented medicines are excessive. For example, there is no guidance on the review of the second part of paragraph 85(1) (c), "the prices at which …other medicines in the same therapeutic class have been sold in countries other than Canada."

Neither is there direction on subsection 85(2) – "Where, after taking into consideration the factors referred to in subsection (1), the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price, the Board may take into consideration the following factors: (a) the costs of making and marketing the medicine; and (b) such other factors as may be specified in any regulations made for the purposes of this subsection or as are, in the opinion of the Board, relevant in the circumstances." The current Guidelines are silent on guidance as to when a determination of whether prices are excessive based on

subsection 85(1) may not be possible, and on how the costs of making and marketing the medicine should be assessed, if the Board considers it appropriate to do so.

The need to address these gaps has been added to the Board's overall workplan on the review of the current Guidelines. To further advance this work, and as announced in its April 2007 NEWSletter, the Board is holding bilateral consultations with groups representing sectors of the pharmaceutical industry, federal/provincial/territorial governments and consumers beginning in the summer of 2007.

## Priority 2: Report on pharmaceutical trends

**Financial Resources ($ thousands):**

| 2006-2007 | | |
|---|---|---|
| **Planned Spending** | **Authorities** | **Actual Spending** |
| $3,405.0 | $3,464.9 | $1,813.4 |

**Human Resources:**

| 2006-2007 | | |
|---|---|---|
| **Planned** | **Actual** | **Difference** |
| 23 | 13 | 10 |

**Price Trends**

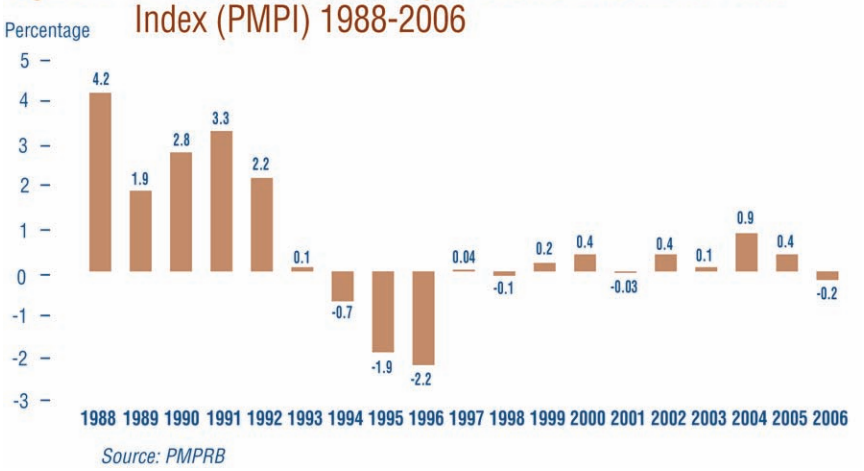
The PMPRB's second priority is to report on pharmaceutical price trends relating to all medicines, and on R&D spending by pharmaceutical patentees. This priority contributes to informed decisions and policy-making among stakeholders.

Section 100 of the Act requires the Board to annually submit to the Minister of Health a report on its activities during the preceding 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 maintains and 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 2006. As measured by the PMPI, prices of patented drugs declined on average by 0.2% from 2005 to 2006. This small decline in the PMPI in 2006 follows two years of slight increases.

**Figure 1** Annual Rates of Change, Patented Medicine Price Index (PMPI) 1988-2006



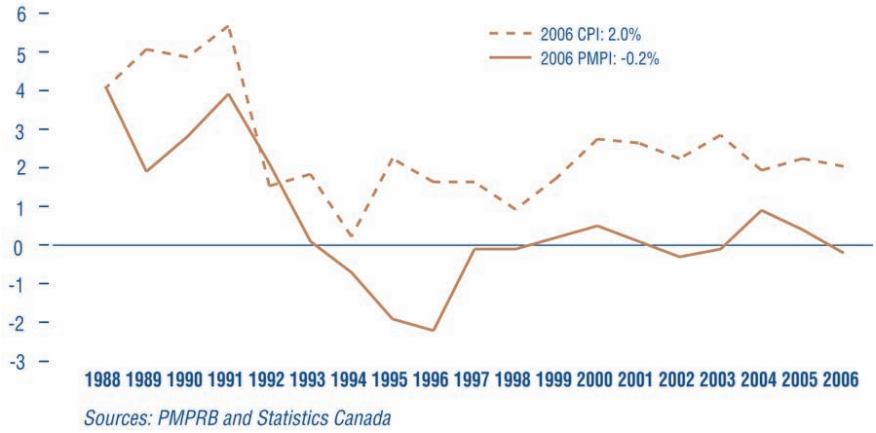

*Source: PMPRB*

**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 in every year since 1988 except 1992 when the forecast rate of CPI inflation (used by patentees to set price increases) significantly exceeded the ultimate actual rate of inflation. This pattern continued in 2006, with the CPI rising by 2.0% while the PMPI declined by 0.2%. 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. Theoretically, the cap could result in the PMPI exceeding CPI inflation, but this has never occurred.)

**Figure 2** Annual Rate of Change, Patented Medicine Price Index (PMPI) and Consumer Price Index (CPI), 1988-2006




*Sources: 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 drawn from the World Health Organization's Anatomical Therapeutic Chemical (ATC) Classification System. Results in this table were obtained by applying the PMPI methodology to data segregated by the first level ATC class. The table also lists each therapeutic class' share of total sales of patented drugs, as well as the average percentage price change among the drugs in each class. The last column multiplies the rate of price change in each class by its share of overall sales: this yields an approximation of the contribution of each class to the overall PMPI change.

By this measure, antineoplastics and immunomodulating agents were the largest contributors to overall price change in 2006 with a price decline of 0.3%.

Table 2

Change in the Patented Medicine Price Index (PMPI) by Major Therapeutic Class, 2006

| **Therapeutic Class** | **Share of Sales (%)** | **PMPI Change: 2004 to 2005 (%)** | **Contribution to Overall Change (%)** |
|---|---|---|---|
| A: Alimentary Tract and Metabolism | 13.0 | -0.5 | -0.1 |
| B: Blood and Blood Forming Organs | 6.7 | -1.1 | -0.1 |
| C: Cardiovascular System | 25.6 | 0.2 | 0.0 |
| D: Dermatological | 0.8 | 1.3 | 0.0 |
| G: Genito-urinary System and Sex Hormones | 3.2 | 1.1 | 0.0 |
| H: Systemic Hormonal Preparations | 0.9 | -2.1 | 0.0 |
| J: General Antiinfectives for Systemic Use; and P: Antiparasitic Products[13] | 9.7 | 0.2 | 0.0 |
| L: Antineoplastics and Immunomodulating Agents | 12.8 | -2.4 | -0.3 |
| M: Musculo-skeletal System | 3.9 | 0.5 | 0.0 |
| N: Nervous System | 15.1 | 0.3 | 0.1 |
| R: Respiratory System | 6.7 | 1.0 | 0.1 |
| S: Sensory Organs | 1.2 | 0.4 | 0.0 |
| V: Various | 0.6 | -3.6 | 0.0 |
| Total | 100.0* | | -0.2 |

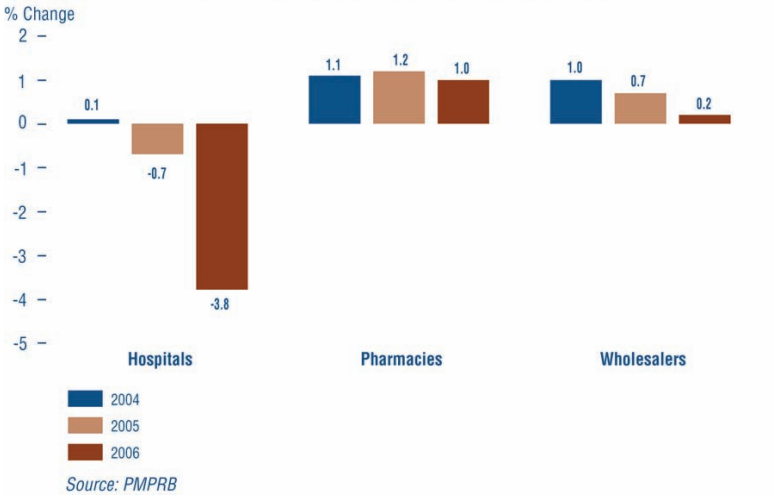
Source: PMPRB
* Values in this column may not add to 100.0 due to rounding.

[13] 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.[14] 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.[15]

**Figure 3** Annual Rate of Change, Patented Medicine Price Index (PMPI), by Class of Customer, 2004-2006



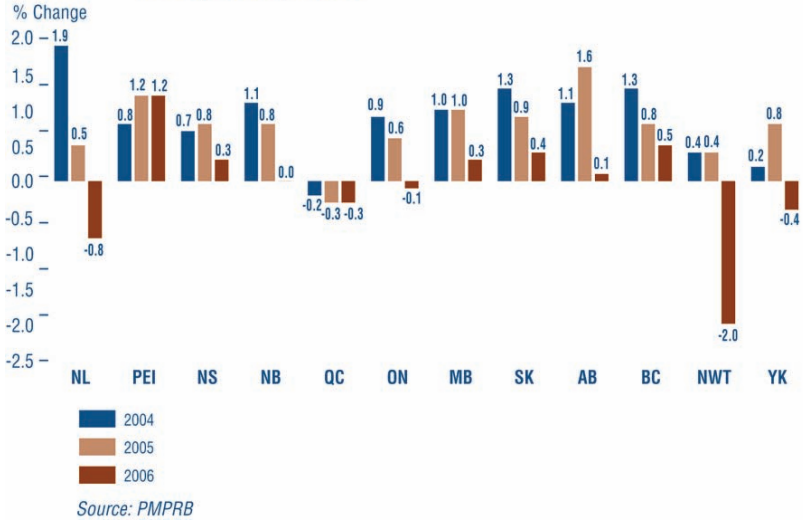

Rates of 2005-to-2006 price change ranged from 1.0% for direct sales to pharmacies to -3.8% for sales to hospitals. Not surprisingly, the rate of price change for sales to wholesalers (which accounts for about three quarters of all sales) is closest to the overall change in the PMPI. Note that in all customer classes, rates of price change were substantially less than CPI-inflation.

It is clear from Figure 3 that the slight decline in the overall PMPI was the result of falling prices paid by hospitals: a PMPI covering just sales to pharmacies and wholesalers would have risen by approximately 0.4% between 2005 and 2006.

## Price Change by Province/Territory

Figure 4 presents average rates of price change by province and territory. These results were obtained by applying the PMPI methodology to data segregated according to the province or territory in which the sale took place. Rates of price change for 2005-to-2006 range from 1.2% in Prince Edward Island to -2.0% in the Northwest Territories. Average price increases in six of

**Figure 4** Annual Rate of Price Change, by Province/Territory: 2004, 2005, 2006




[14] The *Patented Medicines Regulations, 1994*, require patentees to file information according to four customer classes; these classes which are hospitals, pharmacies, wholesalers and other are specified in the Patentees' Guide to Reporting developed by the Board.

[15] 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.

the thirteen provincial/territorial jurisdictions were offset by the modest declines in Ontario and Quebec, resulting in the average national price decrease of 0.2%.

### 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 compare the Canadian prices of patented drugs to those in other countries.

Figure 5 gives annual 2005-to-2006 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 U.S. prices reported by patentees, the second incorporates prices from the U.S. Federal Supply Schedule (FSS) in addition to reported prices. (FSS prices are those negotiated between companies and the U.S. Department of Veteran Affairs.)

**Figure 5** Annual Average Rates of Price Change, Canada and Comparator Countries, 2006


*Source: PMPRB*

Five of the seven comparator countries registered overall price declines in 2006, the exceptions being the U.S. and Sweden. Of these five, Italy saw the largest average decline (-4.9%). In contrast, U.S. prices rose by more than 7% on average.

### Bilateral Comparison of Foreign Prices to Canadian Prices

Table 3 provides detailed statistics comparing the foreign prices of patented drugs to their Canadian prices. The table provides four average price ratios. These are differentiated according to (1) the averaging formula applied and (2) the method by which foreign prices were converted to Canadian dollar equivalents. The table also shows the number of drugs (DINs) and the volume of sales encompassed by each reported statistic.

The PMPRB has traditionally reported average Foreign-to-Canadian price ratios constructed as a sales-weighted geometric mean of individual ratios. Such results are included in Table 3 (under the label “Geometric Mean”). The table also provides results obtained using a sales-weighted arithmetic average (under the label “Arithmetic Mean”). These statistics provide an answer to questions of the type: “How much more/less would Canadians have paid for the patented drugs they purchased in 2006 if they had paid Country X prices rather than Canadian prices?”

| Table 3 Average Foreign-to-Canadian Price Ratios, Bilateral Comparisons, 2006 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **(i) At Market Rates** | **Can** | **Fra** | **Ita** | **Ger** | **Swe** | **Swi** | **U.K.** | **U.S.** |
| **Geometric Mean** | 1.00 | 0.87 | 0.77 | 0.99 | 0.92 | 1.06 | 1.00 | 1.68 |
| **Arithmetic Mean** | 1.00 | 0.92 | 0.81 | 1.09 | 1.00 | 1.14 | 1.05 | 1.80 |
| **Number of DINs** | 1,176 | 769 | 746 | 849 | 817 | 813 | 843 | 1,014 |
| **Net Revenues ($M)** | 11,989.2 | 10,004.8 | 9,855.0 | 10,226.2 | 10,122.5 | 10,427.3 | 10,640.6 | 10,898.1 |
| **(ii) At PPPs** | **Can** | **Fra** | **Ita** | **Ger** | **Swe** | **Swi** | **U.K.** | **U.S.** |
| **Geometric Mean** | 1.00 | 0.78 | 0.73 | 0.91 | 0.75 | 0.79 | 0.89 | 1.68 |
| **Arithmetic Mean** | 1.00 | 0.83 | 0.77 | 1.00 | 0.81 | 0.85 | 0.94 | 1.79 |
| **Number of DINs** | 1,176 | 769 | 746 | 849 | 817 | 813 | 843 | 1,014 |
| **Net Revenues ($M)** | 11,989.2 | 10,004.8 | 9,855.0 | 10,226.2 | 10,122.5 | 10,427.3 | 10,640.6 | 10,898.1 |

For example, Table 3 (i) states that the 2006 average French-to-Canadian price ratio obtained using the arithmetic mean is 0.92. This means that Canadians would have paid 8% less for the patented drugs they purchased in 2006 had they been able to buy these products at French prices.

For many years the PMPRB has reported average Foreign-to-Canadian price ratios with foreign prices converted to their Canadian dollar equivalents by means of market exchange rates (or, more exactly, the 36-month moving-averages of market rates the PMPRB normally uses in applying the Guidelines). Last year, the PMPRB began reporting Foreign-to-Canadian price ratios with currency-conversion at purchasing power parity (PPP). The PPP between any two countries measures their relative cost-of-living expressed in their own currencies. In practice, cost-of-living is determined by pricing out a standard set (or "basket") of goods and services at prices prevailing in each country. Because PPPs are designed to represent relative cost-of-living, they offer a simple way to account for differences in national price levels when comparing individual prices, incomes and other monetary values across countries. When applied in calculating average foreign-to-Canadian price ratios, they produce statistics allowing us to answer questions of the form: "How much more/less consumption of other goods and services would Canadians have sacrificed for the patented drugs they purchased in 2006 had they lived in Country X?"

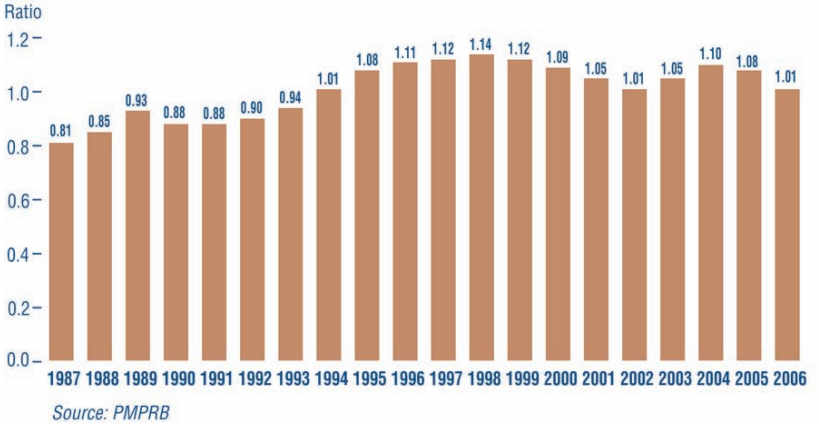
Focusing on the results obtained with currency conversion at market exchange rates (and calculated as a geometric mean), in Table 3 (i), it appears that Canada is in the middle of the pack with regard to the prices of patented drugs. Prices in France and Italy are, on average, appreciably less than Canadian prices, while prices in Switzerland and the U.S. are higher. As in previous years, U.S. prices were substantially higher than prices in Canada or any other comparator country.

However, using PPP and geometric means, Canadians would have sacrificed less consumption of other goods and services for the purchase of patented drugs had they lived in any of the comparator countries except the U.S.

### Multilateral Price Comparisons

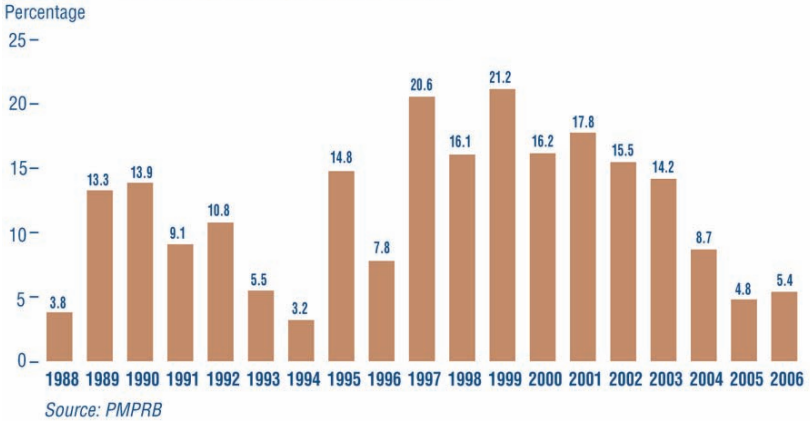
Focusing again on results at market exchange rates (and calculated as a geometric mean), the average Median International Price (MIP)-to-Canadian price ratio stood at 1.01 in 2006, representing a substantial decline from the value of 1.08 reported last year. Figure 6 puts this result in historical perspective. MIPs were on average 19% below Canadian prices in 1987. By 1998, MIPs were on average 14% higher than Canadian prices. The average MIP-to-Canadian price ratio has remained above parity throughout this decade. That is, prices in Canada have been below the MIP.

**Figure 6** Average Ratio of Median International Price (MIP) to Canadian Price, Patented Drugs, 1987-2006[26]




### Utilization of Patented Drugs

**Figure 7** Annual Rate of Change, Patented Medicine Quantity Index (PMQI), 1988-2006

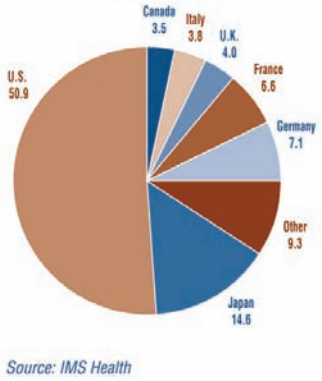



The price and sales data used to calculate the PMPI also allow the PMPRB to examine trends in the quantities of patented drugs sold in Canada. The PMPRB maintains the Patented Medicine Quantity Index (PMQI) for this purpose. Figure 7 displays average rates of utilization growth, as measured by the PMQI, from 1988 through 2006. 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 2006, with utilization of patented drugs growing by 5.4%.

## 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 2006, sales amounted to $440.3 billion among major markets.[16] Figure 8 shows how this amount was distributed among these markets. Drug sales in Canada accounted for 3.5% of total major-market sales. The U.S. market is by far the largest, with drug sales exceeding the combined sales of all other major markets.

**Figure 8** Distribution of Drug Sales Among Major Markets, 2006




Source: IMS Health

**Figure 9** Growth in Pharmaceutical Sales: 2005 to 2006, by Major Markets


Source: IMS Health

Figure 9 gives rates of 2005-to-2006 sales growth for individual major markets. Based on IMS data, Canadian sales growth matched that in the U.S. at 7% and exceeded growth observed in all other major markets.

## Analysis of Research and Development Expenditures

With the adoption of the 1987 amendments to the *Patent Act*, Canada's Research-Based Pharmaceutical Companies (Rx&D) made a public commitment that brand name manufacturers would increase their annual research and development (R&D) expenditure to 10% of sales revenue by 1996.[17] 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 total R&D expenditure in Canada

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[16] IMS Health's Retail Drug Monitor, 2006 (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 at ex-manufacturer prices and include all prescription and certain over-the-counter data.

[17] See the Regulatory Impact Assessment Statement (RIAS) of the *Patented Medicines Regulations, 1988*, published in the Canada Gazette Part II, Vol. 122. No. 20 – SOR/DORS/88-474

related to medicines. The Regulations require that R&D data submitted to the PMPRB be accompanied by a certificate affirming the submitted information is "true and correct". The Board does not audit submissions, but it does review submitted data for anomalies and inconsistencies, seeking corrections or clarifications from patentees where these are detected. 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 in the Board's Annual Report. Companies without sales of patented medicines need not report on R&D expenditure. As new patents are granted and existing patents expire, the set of companies required to file R&D data may change from year to year.

For 2006, a total of 72 companies selling drug products for human and veterinary use filed reports on their R&D expenditure. Of these, 28 companies were members of Rx&D.

**Sales Revenue**

For reporting purposes, sales revenue is defined as all revenue from Canadian sales of medicines and from licensing agreements.

As shown in Table 4, patentees reported total revenue of $14.9 billion from Canadian sales of drugs in 2006, an increase of 4.7% over 2005. Sales revenue reported by Rx&D members totaled $11.1 billion, accounting for 75% of the total. Less than 1% of reported sales revenue was generated by licensing agreements.

**R&D Expenditure**

As shown in Table 4, total 2006 R&D expenditure reported by patentees was $1.2 billion, a decrease of 1.9% from 2005. Rx&D members reported R&D expenditure of $949 million in 2006, accounting for 78.4% of all reported expenditure. This represents a decline of 8.7% relative to 2005 Rx&D expenditure.

By comparison, non-Rx&D members reported R&D expenditure of $261 million in 2006, an increase of 34.5% over the corresponding figure for 2005.

**R&D-to-Sales Ratios**

The ratio of R&D expenditure to sales revenue among all patentees was 8.1% in 2006, down from 8.7% in 2005. The ratio for members of Rx&D was 8.5%, down from 8.8% in the previous year. R&D-to-sales ratios have declined markedly in recent years, after reaching a peak in the late 1990s. This is the sixth consecutive year the overall ratio has fallen below 10% and the fourth year in which the Rx&D ratio has failed to achieve this target value.

## Table 4 Total R&D Expenditure and R&D-to-Sales Ratios of Reporting Companies, 1988-2006

| Year | Companies Reporting | Total R&D Expenditure[1] ($M) | Change from Previous Year (%) | Total Sales Revenue[2] ($M) | Change from Previous Year (%) | R&D-to-Sales Ratio | |
|---|---|---|---|---|---|---|---|
| | | | | | | All Patentees[3] (%) | Rx&D Patentees[4] (%) |
| 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*

1 Total R&D expenditure includes scientific research and development expenses – both capital and non-capital – which qualify for an investment tax credit as set out in the *Income Tax Act* and *Income Tax Regulations* as they read on December 1, 1987.

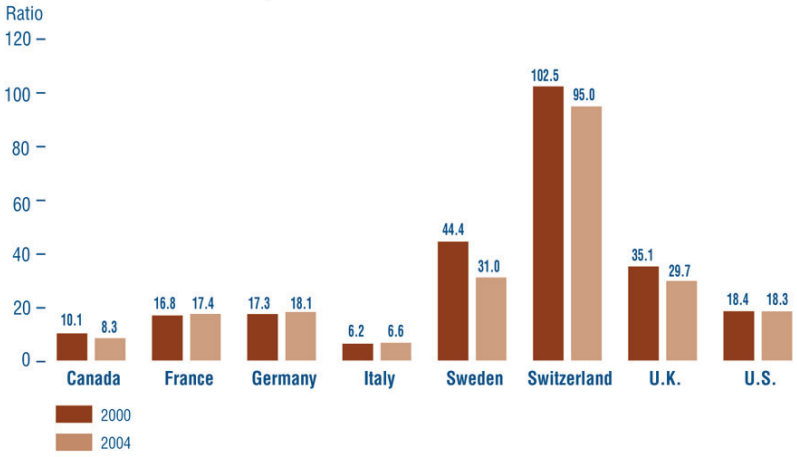
2 Total sales revenue includes sales of patented and non-patented drugs for both human and veterinary use.

3 The R&D-to-sales ratios presented in the above table 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 2006 are 7.9% and 8.3%, respectively.

4 In the past, Rx&D has reported that its members have achieved a higher R&D-to-sales ratio than reported by the PMPRB. Recall, however, that the *Patent Act* requires only companies with Canadian patents pertaining to a medicine sold in Canada to report on R&D expenditure. This means that some Rx&D members do not report their R&D expenditure – for example, biotechnology companies engaged in research but without sales of a patented product in Canada.

## The Global Context

**Figure 10** R&D-to-Sales Ratio, Canada and 7 Comparator Countries, 2000 and 2004




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

Figure 10 compares Canadian R&D-to-sales ratios to those in the seven comparator countries for the years 2000 and 2004. 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 at 35.1%. A very similar pattern emerges in the ratios for 2004. Italy (6.6%) remained at the bottom of the range, with Canada second lowest at 8.3%. Ratios in all other comparator countries were again well above Canada's ratio, but showed declines in Switzerland, Sweden and the U.K.

## 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 so that Canada's health system has more comprehensive and accurate information on how prescription drugs are being used and on sources of cost increases. The Canadian Institute for Health Information (CIHI) and the PMPRB are partners in the NPDUIS. A steering committee, comprised of representatives of participating public drug plans and Health Canada, advises the PMPRB on the development of analytical studies. The NPDUIS initiative involves two major elements:

- development and implementation of a prescription claims level database capable of incorporating drug program data from participating publicly-funded drug plans; and
- production of analytical reports relying on information from this database.

CIHI is responsible for the first of these elements while, as requested by the Minister of Health under section 90 of the *Patent Act*, the PMPRB is principally responsible for the second.

The PMPRB has completed analyses of pharmaceutical trends from 1997-98 to 2004-05 based on aggregated DIN level prescription drug data, provided by eight public drug plans in Canada.

Two other projects have been recently completed to support informed decision-making:

- *Guidelines for Conducting Pharmaceutical Budget Impact Analyses for Submission to Public Drug Plans in Canada* which provide guidance to industry on the methodology and reporting standards to be used when submitting BIAs to the Common Drug Review, administered by Canadian Agency for Drugs and Technologies in Health (CADTH), or to federal, provincial or territorial drug plans that participate in the Common Drug Review (CDR).

- *The New Drug Pipeline Monitor* (NDPM) which summarizes information on new drugs that are in the later phases of research and could have a significant impact in terms of therapeutic value. Future editions of the NDPM will track the clinical development of drugs selected for this web-based publication, highlight potential new drugs in the pipeline, and provide market analyses to inform decision-makers of potential cost impacts of the new drugs.

Studies conducted under the NPDUIS are available on the PMPRB Web site, as is the 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 the prices of non-patented prescription drugs. In November 2005, the PMPRB received direction from the federal Minister of Health, to undertake this monitoring and reporting.

In 2006-2007, three reports were released:

- *Canadian and Foreign Price Trends*, which examined domestic and international price and sales trends of non-patented prescription drugs, and was released in July 2006;

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

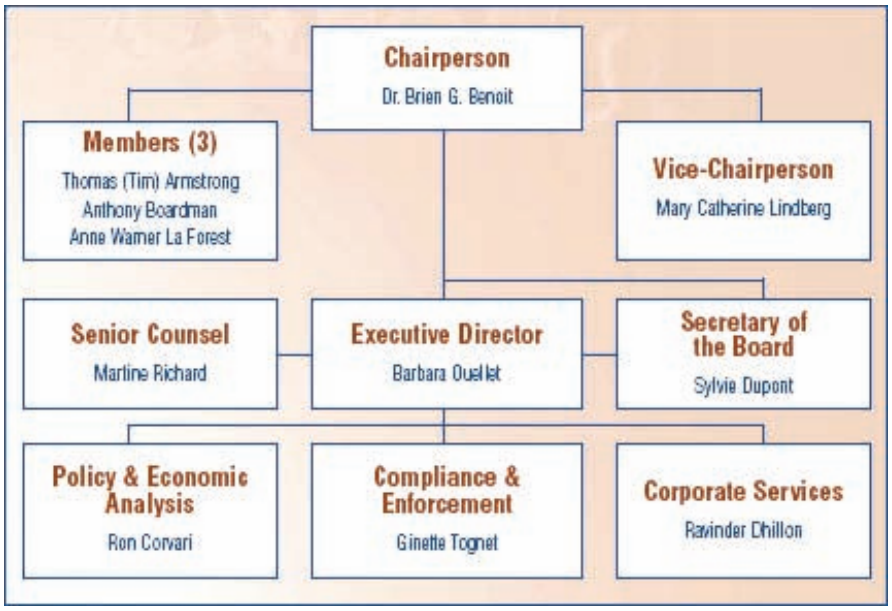
- *Markets for New Off-Patent Drugs* (released in June 2007) which tracked market developments for non-patented drugs in the years immediately following patent expiry.

These reports are available on our Web site under Reporting; Non-Patented Prescription Drug Prices.

Future reports will examine the market for new off-patent drugs and trends in prices of non-patented single-source prescription drugs sold in Canada and abroad.

# SECTION III – SUPPLEMENTARY INFORMATION

## 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 Compliance and Enforcement Policy. The Policy and Economic Analysis Branch is largely responsible for conducting analyses and preparing reports on price trends and other policy and economic studies. The Secretariat, Corporate Services Branch and Senior Counsel provide regulatory, reporting and administrative support.

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

| ($ thousands) | 2004–05 Actual | 2005–06 Actual | 2006–2007 | | | |
|---|---|---|---|---|---|---|
| | | | Main Estimates | Planned Spending | Total Authorities | Total Actuals |
| Patented Medicine Prices Review Board | 4,996.7 | 5,326.5 | 6,512.0 | 6,512.0 | 11,690.0 | 7,365.3 |
| **Total** | **4,996.7** | **5,326.5** | **6,512.0** | **6,512.0** | **11,690.0** | **7,365.3** |
| Less: Non-respendable revenue[(1)] | (3,026.1) | (1,413.3) | - | - | - | (210.0) |
| Plus: Cost of services received without charge | 825.9 | 791.6 | 871.2 | 871.2 | 871.2 | 807.9 |
| **Total Departmental Spending** | **2,796.5** | **4,704.8** | **7,383.2** | **7,383.2** | **12,561.2** | **7,963.2** |
| **Full Time Equivalents** | **42** | **42** | **48** | **48** | **63** | **43** |

(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: Resources by Program Activity

| 2006–2007 | | | | | | |
|---|---|---|---|---|---|---|
| | Budgetary | | | | Plus: Non-Budgetary | Total |
| Program Activity | Operating | Total: Gross Budgetary Expenditures | Less: Respendable Revenue | Total: Net Budgetary Expenditures | Loans, Investments and Advances | |
| **Patented Medicine Prices Review** | | | | | | |
| Main Estimates | 6,512.0 | 6,512.0 | - | 6,512.0 | - | **6,512.0** |
| *Planned Spending* | 6,512.0 | 6,512.0 | - | 6,512.0 | - | **6,512.0** |
| Total Authorities | 11,690.0 | 11,690.0 | - | 11,690.0 | - | **11,690.0** |
| *Actual Spending* | 7,365.3 | 7,365.3 | - | 7,365.3 | - | **7,365.3** |

## Financial Table 3: Voted and Statutory Items

| Vote or Statutory Item | Truncated Vote or Statutory Wording | 2006–2007 | | | |
|---|---|---|---|---|---|
| | | Main Estimates | Planned Spending | Total Authorities | Total Actuals |
| 25 | Operating expenditures | 5,800.0 | 5,800.0 | 10,978.0 | 6,742.5 |
| (S) | Contributions to employee benefit plans | 712.0 | 712.0 | 712.0 | 622.8 |
| | **Total** | **6512.0** | **6,512.0** | **11,690.0** | **7,365.3** |

## Financial Table 4: Services Received Without Charge

| ($ millions) | 2006–2007 Actual Spending |
|---|---|
| Accommodation provided by Public Works and Government Services Canada | 489.9 |
| Contributions covering employers' share of employees' insurance premiums and expenditures paid by the Treasury Board of Canada Secretariat (excluding revolving funds) | 299.7 |
| Salary and associated expenditures of legal services provided by the Department of Justice Canada | 18.3 |
| **Total 2006–2007 Services received without charge** | **807.9** |

## Financial Table 5: Sources of Non-Respendable Revenue

| ($ millions) | Actual 2004-05 | Actual 2005-06 | 2006-2007 | | | |
|---|---|---|---|---|---|---|
| | | | Main Estimates | Planned Revenue | Total Authorities | Actual |
| **Patented Medicine Prices Review Board** | | | | | | |
| *Source of non-respendable revenue*[(1)] | | | | | | |
| Voluntary Compliance Undertakings | 3,026.1 | 1,413.3 | - | - | - | 210.0 |
| **Total Non-Respendable Revenue** | **3,026.1** | **1,413.3** | **-** | **-** | **-** | **210.0** |

(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 6: 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, 2007 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.

| | |
|---|---|
|  |  |
| ***Brien G. Benoit, M.D.***<br>Chairperson<br>Patented Medicine Prices Review Board<br><br>Date: Sept.6 2007 | ***Barbara Ouellet***<br>Executive Director & Senior Financial Officer<br>Patented Medicine Prices Review Board<br><br>Date: Aug. 30 2007 |

**Statement of Operations (unaudited)**

| for the year ended March 31 | 2007 | 2006 |
|---|---|---|
| (in dollars) | | |
| | | |
| **Expenses** | | |
| Salaries and employee benefits | **4,815,847** | 4,084,405 |
| Professional and special services | **1,951,204** | 871,998 |
| Accommodation | **489,894** | 582,600 |
| Utilities, material and supplies | **484,531** | 247,009 |
| Travel and relocation | **181,186** | 85,756 |
| Purchased repair and maintenance | **124,330** | 70,340 |
| Information | **122,086** | 55,496 |
| Communication | **83,510** | 76,516 |
| Rentals | **16,014** | 10,133 |
| Amortization | **3,101** | 3,383 |
| Other | **55,634** | 118,942 |
| | **8,327,337** | **6,206,578** |
| | | |
| **Revenues** | | |
| Voluntary compliance undertakings | **210,043** | **1,413,415** |
| **Net cost of operations** | **8,117,294** | **4,793,163** |
| **The accompanying notes form an integral part of the financial statements** | | |

**Statement of Financial Position (unaudited)**

| As at March 31 | 2007 | 2006 |
|---|---|---|
| (in dollars) | | |
| | | |
| **Assets** | | |
| **Financial assets** | | |
| Accounts receivable and advances (Note 4) | **108,595** | 35,819 |
| | **108,595** | 35,819 |
| **Non-financial assets** | | |
| Tangible capital assets (Note 5) | **-** | 3,101 |
| | **-** | 3,101 |
| | **108,595** | **38,920** |
| | | |
| **Liabilities and Equity of Canada** | | |
| **Liabilities** | | |
| Accounts payable and accrued liabilities | **784,600** | 453,184 |
| Vacation pay and compensatory leave (Note 6) | **266,437** | 200,419 |
| Employee severance benefits (Note 7) | **733,660** | 645,076 |
| | **1,784,697** | 1,298,679 |
| | | |
| **Equity of Canada** | **(1,676,102)** | (1,259,759) |
| | **108,595** | **38,920** |
| **The accompanying notes form an integral part of the financial statements** | | |

**Statement of Equity (unaudited)**

| As at March 31 | 2007 | 2006 |
|---|---|---|
| (in dollars) | | |
| | | |
| **Equity of Canada, beginning of year** | **(1,259,759)** | (680,523) |
| Net cost of operations | **(8,117,294)** | (4,793,163) |
| Current year appropriations used (Note 3) | **7,365,303** | 5,326,472 |
| Revenues not available for spending | **(218,605)** | (1,413,557) |
| Change in net position in the Consolidated Revenue Fund (Note 3) | **(253,685)** | (490,541) |
| Services received without charge by other government departments (Note 8) | **807,938** | 791,553 |
| **Equity of Canada, end of year** | **(1,676,102)** | **(1,259,759)** |
| **The accompanying notes form an integral part of the financial statements** | | |

**Statement of Cash Flow (unaudited)**

| For the year ended March 31 | 2007 | 2006 |
|---|---|---|
| (in dollars) | | |
| | | |
| **Operating activities** | | |
| **Net cost of operations** | **8,117,294** | 4,793,163 |
| | | |
| **Non-cash items:** | | |
| Amortization of capital assets (Note 5) | **(3,101)** | (3,383) |
| Services provided without charge by other government departments (Note 8) | **(807,938)** | (791,553) |
| **Variations in Statement of Financial Position:** | | |
| Increase (decrease) in accounts receivable and advances | **72,776** | (589,360) |
| Decrease (increase) in liabilities | (**486,018)** | 13,507 |
| **Cash used for operating activities** | **6,893,013** | **3,422,374** |
| | | |
| **Financing activities** | | |
| Net cash provided by Government of Canada | **(6,893,013)** | (3,422,374) |
| | | |
| **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.

Reporting - The PMPRB reports annually to Parliament through the Minister of Health. The Annual Report, which covers each calendar year, includes a review of the PMPRB´s major activities, analyses of the prices of patented medicines and of the price trends of all drugs, and reports on the R&D expenditures as reported by pharmaceutical patentees.

### 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 plan 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 government 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:** | **2007** | 2006 |
|---|---|---|
| (in dollars) | | |
| Net cost of operations | 8,117,294 | 4,793,163 |
| | | |
| ***Adjustments for items affecting net cost of operations but not affecting appropriations:*** | | |
| ***Add (Less):*** | | |
| Revenues not available for spending | **218,605** | 1,413,557 |
| Services provided without charge by other government departments | **(807,938)** | (791,553) |
| Amortization | **(3,101)** | (3,383) |
| Justice Canada legal fees | **(4,979)** | (7,595) |
| Allowance for vacation pay accrual | **(54,429)** | (1,370) |
| Allowance for time-off in lieu accrual | **(11,589)** | 2,315 |
| Allowance for severance benefits | **(88,586)** | (78,669) |
| Other expenses not charged to Appropriations | **26** | 7 |
| | **(751,991)** | 553,309 |
| | | |
| **Current year appropriations used** | **7,365,303** | 5,326,472 |

| **(b) Appropriations provided and used:** | **2007** | 2006 |
|---|---|---|
| (in dollars) | | |
| Operating expenditures- Vote 25 | **10,978,025** | 5,081,000 |
| Statutory Amounts | **622,760** | 543,344 |
| Less: | | |
| Lapsed appropriations | **(4,235,482)** | (297,872) |
| **Current year appropriations used** | **7,365,303** | 5,326,472 |

| **(c) Reconciliation of net cash provided by Government to current year appropriations used** | **2007** | 2006 |
|---|---|---|
| (in dollars) | | |
| Net cash provided by Government | **6,893,013** | 3,422,374 |
| Revenue not available for spending | **218,605** | 1,413,557 |
| Change in net position in the Consolidated Revenue Fund | | |
| Variation in accounts receivable and advances | **(72,776)** | 589,361 |
| Variation in accounts payable and accrued liabilities | **331,414** | (91,232) |
| Other Adjustments | **(4,953)** | (7,588) |
| | **253,685** | 490,541 |
| **Current year appropriations used** | **7,365,303** | **5,326,472** |

## 4. Accounts receivable and advances

| (in dollars) | **2007** | 2006 |
|---|---|---|
| Receivables from other Federal Government departments and agencies | **108,095** | 35,319 |
| Employee advances | **500** | 500 |
| | **108,595** | 35,819 |

## 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 | 88,141 | 3,101 | - | **91,242** |
| | 88,141 | 3,101 | - | **91,242** |
| | | | | |
| **Net book value** | 3,101 | - | - | - |

Amortization expense for the year ended March 31, 2007 is $3,101 (2006 - $3,383)

## 6. Vacation pay and compensatory leave

| (in dollars) | **2007** | 2006 |
|---|---|---|
| Allowance for vacation | **253,100** | 198,671 |
| Allowance for compensatory leave | **13,337** | 1,748 |
| | **266,437** | 200,419 |

## 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 current and previous year expenses, which represent approximately 2.2 times (2.6 in 2005-06) the contributions by employees, amount to:

| (in dollars) | **2007** | 2006 |
|---|---|---|
| Expense for the year | **458,955** | 402,069 |
| | **458,955** | 402,069 |

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) | **2007** | 2006 |
|---|---|---|
| Accrued benefit obligation, beginning of year | **645,076** | 566,407 |
| Expense for the year | **147,991** | 150,455 |
| Benefits paid during the year | **(59,407)** | (71,786) |
| Accrued benefit obligation, end of year | **733,660** | 645,076 |

## 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) | **2007** | 2006 |
|---|---|---|
| Accommodation | **489,894** | 582,600 |
| Employer's contribution to the health and dental insurance plans | **299,709** | 197,000 |
| Justice Canada | **18,335** | 11,953 |
| | **807,938** | 791,553 |

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) | **2007** | 2006 |
|---|---|---|
| Accounts payable to other government departments and agencies | **32,043** | 36,304 |