ESTIMATES

# Patented Medicine Prices Review Board Canada

## Performance Report

For the period ending
March 31, 2001

Canada

## Improved Reporting to Parliament
## Pilot Document

Each year, the government prepares Estimates in support of its request to Parliament for authority to spend public monies. This request is formalized through the tabling of appropriation bills in Parliament.

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The Estimates, along with the Minister of Finance's Budget, reflect the government's annual budget planning and resource allocation priorities. In combination with the subsequent reporting of financial results in the Public Accounts and of accomplishments achieved in Departmental Performance Reports, this material helps Parliament hold the government to account for the allocation and management of funds.



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## Foreword

In the spring of 2000 the President of the Treasury Board tabled in Parliament the document "Results for Canadians: A Management Framework for the Government of Canada". This document sets a clear agenda for improving and modernising management practices in federal departments and agencies.

Four key management commitments form the basis for this vision of how the Government will deliver their services and benefits to Canadians in the new millennium. In this vision, departments and agencies recognise that they exist to serve Canadians and that a "citizen focus" shapes all activities, programs and services. This vision commits the government of Canada to manage its business by the highest public service values. Responsible spending means spending wisely on the things that matter to Canadians. And finally, this vision sets a clear focus on results – the impact and effects of programs.

Departmental performance reports play a key role in the cycle of planning, monitoring, evaluating, and reporting of results through ministers to Parliament and citizens. Earlier this year, departments and agencies were encouraged to prepare their reports following certain principles. Based on these principles, an effective report provides a coherent and balanced picture of performance that is brief and to the point. It focuses on results – benefits to Canadians – not on activities. It sets the department's performance in context and associates performance with earlier commitments, explaining any changes. Supporting the need for responsible spending, it clearly links resources to results. Finally the report is credible because it substantiates the performance information with appropriate methodologies and relevant data.

In performance reports, departments strive to respond to the ongoing and evolving information needs of parliamentarians and Canadians. The input of parliamentarians and other readers can do much to improve these reports over time. The reader is encouraged to assess the performance of the organization according to the principles outlined above, and provide comments to the department or agency that will help it in the next cycle of planning and reporting.

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# Patented Medicine
# Prices Review Board

## Performance Report

**For the**
**period ending**
**March 31, 2001**

Minister of Health Canada

# Contents

## Section I Chairperson's Message

I am pleased to present the 2000 - 2001 Performance Report for the Patented Medicine Prices Review Board (PMPRB). Over the past decade, pharmaceuticals have been the fastest-growing component of health care costs in Canada. During this period, expenditures on drugs have grown, on average, at about three times the annual rate of inflation and two times the rate of growth of the other health care components. The Canadian Institute of Health Information (CIHI) has estimated that the share of total health care spending represented by drugs, not including drugs used in hospitals, grew from 11.3% in 1990 to 15.5% in 2000.

In this environment of rapid growth and change, the mandate of the PMPRB, to ensure that prices charged by manufacturers of patented medicines are not excessive, and to report on pharmaceutical price trends, is as relevant as ever. In recent years, the significant growth in expenditures on pharmaceuticals has led Federal/Provincial/Territorial (F/P/T) ministers of health to look at the drug price trends for publicly-funded drug plans and to analyze the cost drivers in those plans. The PMPRB has been tasked with conducting extensive analyses of these issues. Last year, the Government released the initial reports and, as the work proceeds, we trust that it will assist governments to develop appropriate policies in this area.

In the context of the PMPRB's evolving role, transparency becomes more important than ever. Transparency in public institutions supports democracy and accountability which are in turn the cornerstones of good governance. Without a free flow of information, we are unable to make informed decisions about how our governments are performing. Transparency also plays a significant role in the area of pharmaceutical pricing. Increased transparency and openness in the price review process can contribute to fostering an environment that facilitates evidence-based decision-making for stakeholders, researchers and policy-makers.

This focus on transparency builds on the recommendations of the Standing Committee on Industry, on our extensive consultations which led to the Road Map for the Next Decade, and on the report of the Auditor General in 1998.

The PMPRB is adapting and evolving as changes occur in the pharmaceutical sector. This demands that we pursue a dynamic and forward-looking approach, one based on ongoing consultations with stakeholders and a continued commitment to openness and transparency.

The Board's record in fulfilling its mandate is well-known. We have achieved compliance with the *Patent Act* through our ongoing monitoring of the prices of new and existing patented drugs, in obtaining the cooperation of patentees through our Voluntary Compliance Policy, and in using the statutory provisions for public hearings and remedial orders when necessary. The publicly-funded drug plans, which, according to CIHI, account for approximately 33% of total drug expenditures in Canada, have adopted a large number of innovative approaches to help contain costs while still providing for prescription drug coverage. These initiatives by both levels of government have helped to ensure that drug prices in Canada have not increased faster than overall consumer prices as measured by the Consumer Price Index (CPI).

As the Board is renewing itself to take on the challenges of this new decade, it will continue with the implementation of the *Road Map*. In so doing, it is building a more open, transparent and accountable approach to fulfilling its mandate.

Robert G. Elgie

Chairperson

## Section II Performance of the PMPRB

### 1.0 Mandate

The PMPRB is an independent quasi-judicial body, created in 1987 under the *Patent Act* to protect consumer interests in light of increased patent protection for pharmaceuticals. Its mandate is three-fold:

- to ensure that the prices charged by manufacturers of patented medicines in Canada are not excessive;

- to report annually to Parliament on the price trends of all medicines in Canada; and

- to report annually to Parliament on the ratio of research & development expenditures to sales by patentees.

The PMPRB is responsible for regulating the maximum prices that patentees may charge for prescription and non-prescription patented drugs sold in Canada for human and veterinary use. In most cases, that price is the "factory-gate" price at which the manufacturer sells the product to wholesalers, hospitals or pharmacies. The PMPRB's jurisdiction includes patented medicines marketed or distributed under voluntary licences. The Board does not regulate the prices of non-patented drugs, including generic drugs sold under compulsory licences, and has no jurisdiction over prices charged by wholesalers or retailers and pharmacists' fees.

In Canada, Health Canada assesses new medicines to ensure that they conform with the Food and Drugs Act and Regulations. Formal authorization to market or distribute a medicine is granted through a Notice of Compliance (NOC). A medicine may be temporarily distributed with specified restrictions before receiving a NOC, as an Investigational New Drug or under the Special Access Program (SAP). Patented drugs sold as an Investigational New Drug or under the SAP administered by Health Canada are subject to review by the PMPRB.

The PMPRB regulates the price of each patented drug product, including each strength of each dosage form of a patented medicine. This is normally

the level at which Health Canada assigns a Drug Identification Number (DIN) or General Public (GP) number.

## 2.0 Objective

To protect consumer interests and to contribute to Canadian health care by ensuring that prices charged by manufacturers of patented medicines are not excessive.

## 3.0 Business Line Description

***Patented Medicine Prices Review Board***

The PMPRB receives information on the prices charged by manufacturers of patented medicines in Canada, analyzes the data and takes action, when required, to reduce prices which are, in the opinion of the Board, excessive. Price reductions are accomplished through:

- voluntary action taken by the patentee;
- formal Voluntary Compliance Undertakings (VCUs) to lower prices and offset excess revenues; or,
- following a public hearing in which prices are found to be excessive, through the issuance of remedial orders.[1]

The PMPRB relies on voluntary compliance wherever possible since it is more effective, less time consuming and less costly to all parties. Voluntary compliance by patentees is facilitated by published Guidelines intended to assist companies in setting prices that are not excessive.

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[1] In addition to lowering the price of a patented medicine to a non-excessive level, the Board may order a patentee to offset excess revenues it has received by:
- ordering a further price reduction on the medicine, one other patented medicine or both; or
- making a payment in the amount of the excess revenues.

If there has been a policy of selling at an excessive price, the Board may order the patentee to offset twice the excess revenues. (For more information see S. 83 of the *Patent Act*)

The Guidelines are not a rigid set of decision-making rules and are not binding on the Board or on patentees. Rather, they are policies which have been approved by the Board and are used by Board Staff to review the prices being charged by patentees for their products. The Guidelines are developed in consultation with stakeholders including provincial and territorial ministers of health, consumer groups, health care associations and the pharmaceutical industry.

Under the *Patent Act*, the Board is required to consider the prices of medicines in other countries, the prices of other medicines in the same therapeutic class, changes in the Consumer Price Index (CPI), and other factors in determining whether or not the price of a medicine is excessive. The *Act* allows the Minister of Health, in consultation with provincial ministers of health and others, to make regulations regarding additional factors the Board shall take into consideration in determining if a price is excessive and to assign additional duties and powers to the PMPRB. Furthermore, it authorizes the Minister of Health to require the Board to conduct inquiries into matters as determined by the Minister.

The PMPRB also reports to Parliament on the price trends of all medicines and on the ratio of pharmaceutical research and development expenditures to sales for the patented pharmaceutical industry and individual patentees in Canada.

## 4.0 Challenges

### 4.1 Increase in Drug Expenditures

In 2000, according to the latest figures published by the CIHI, Canada's total health care expenditures are forecasted to have reached $95.1 billion, of which approximately 71% are public funds.[2] The allocation of that spending has changed over time. Spending on hospitals has declined from 45% in 1975 to 32% in 2000. At the same time, drugs have been taking an increasing share and are now the second largest component, after hospitals, of health care spending.

Again in 2000, total expenditures on drugs, not including drugs used in hospitals, have increased faster than other major components of health care, and reached 15.5% of total health expenditures. Based on filings to the PMPRB by manufacturers, their total sales of drugs, patented and non-

[2] Canadian Institute for Health Information: *National Health Expenditure Trends 1975 - 2000*

patented, in Canada for human use totalled $9.1 billion in 2000. Sales of patented drugs alone increased 16.7% from sales of patented drugs for human use in 1999, to reach a total of $6.3 billion.

## 4.2 Transparency and Accountability

Several reviews in the late 1990's encouraged the Board to increase the information it reports and to find ways to be more transparent in its operations. Building on the recommendations of the Standing Committee on Industry, on our extensive consultations which led to the *Road Map for the Next Decade*, and on the report of the Auditor General in 1998, the Board has continued to focus on increased transparency and openness in its processes. This is intended to contribute to the fostering of an environment that facilitates evidence-based decision-making for stakeholders, researchers and policy-makers.

## 4.3 Federal/Provincial/Territorial (F/P/T) Initiatives

In recent years, the significant growth in expenditures on pharmaceuticals has led Federal/Provincial/Territorial (F/P/T) ministers of health to look at the drug price trends for publicly-funded drug plans and to analyze the cost drivers in those plans. The PMPRB has been tasked with conducting extensive analyses of these issues.

Reports prepared by the PMPRB for the F/P/T ministers of health released last year provided more in-depth information on rates of growth in drug spending and in similarities and differences for six provincial plans. Governments have committed to doing more work on issues related to drug spending in Canada.

## 5.0 Strategic Outcomes

| **Patented Medicine Prices Review Board** | | |
|---|---|---|
| Strategic Outcomes: | Activities: | achievement reported in: |
| assurance that manufacturers' prices for patented medicines sold in Canada are not excessive | review of the manufacturer's prices of 100% of the new and existing patented medicines sold in Canada each year. | See 6.1 |
| | an annual percentage change in the Patented Medicine Price Index (PMPI) that is not greater than the annual percentage change in the Consumer Price Index (CPI). | See 6.3.1<br>6.3.2 |
| | manufacturers' prices for new and existing patented medicines no greater than manufacturers' prices charged in other countries. | See 6.3.3 |
| | level of compliance as shown by the percentage of patented medicines priced within the guidelines. | See 6.1 |
| | the enforcement measures taken in accordance with the *Patent Act* to ensure that prices are not excessive | See 6.2<br>6.2.1<br>6.2.2 |
| information on trends in manufacturers' prices of all medicines in Canada | comprehensive reports on:<br>‣ trends in manufacturers' prices and volume of patented drug products sold;<br>‣ trends in manufacturers' prices of all drug products -- patented and non-patented; and<br>‣ the comparison of Canadian patented drug prices to international prices. | See 6.3<br>6.3.1<br>6.3.2<br>6.3.3 |
| information on the pharmaceutical research-and-development expenditures of patentees in Canada | comprehensive reports of:<br>‣ the ratio of R&D expenditures to sales revenues for each patentee and the industry as a whole based on information supplied by patentees; and<br>‣ R&D expenditure by location and by type of research. | See 6.4<br>6.4.1<br>6.4.2 |
| a more transparent and accountable public agency recognized as adding value to pharmaceutical policy in Canada | ongoing consultations with a representative cross-section of stakeholders | See 6.5.1<br>6.5.2<br>6.5.3 |

## 6.0 Outcomes Achieved

### 6.1 Review of Patented Medicine Prices and Compliance with the Excessive Price Guidelines

Board Staff review the prices of all patented drugs on an ongoing basis to determine if they comply with the Guidelines. Under the Board's policies, when a price appears to exceed the Guidelines, and the circumstances are within the criteria established by the Board, the staff conduct an investigation to determine the facts.[3]

#### 6.1.1 *New Patented Medicines*

In 2000, there were 93 new patented drug products (DINs), representing 61 medicines, that fell under the PMPRB's jurisdiction.[4] Of the 93 new patented DINs, 81 (87.1%) are for human use and 12 (12.9%) for veterinary use. Nineteen (20.4%) of the 93 new patented DINs were being sold in Canada prior to the issuance of the Canadian patent which brought them under the PMPRB's jurisdiction. The time delay between the date of first sale and date of patent grant for these products ranged from 4 months to 6 years with the majority having a delay of about one year.

As of May 31, 2001, the prices of 67 of the 81 new DINs for human use had been reviewed. Of the 67 new patented DINs reviewed, the prices of 49 (73.1%) were considered to be within the Guidelines. Eighteen new patented DINs (27.3%) were priced at levels which appeared to be outside the Guidelines and investigations were commenced. One investigation was subsequently concluded on the basis of additional scientific evidence and the price was found to be within the Guidelines.

The 12 new patented drug products for veterinary use introduced to the Canadian market in 2000 remained under review as of May 31, 2001 as

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[3] A price is considered to be within the Guidelines if it does not exceed the maximum allowed by the Guidelines by the overall margin contemplated by the criteria for commencing an investigation. For further information on the criteria, refer to the PMPRB' web site: www.pmprb-cepmb.gc.ca, under Legislation, Regulations, Guidelines - *Compendium of Guidelines, Policies & Procedures*, Schedule 5, Criteria for Commencing an Investigation

[4] For purposes of the review of prices by the PMPRB, new patented medicines in 2000 include those introduced on the market in Canada or those previously marketed but first patented between December 1, 1999 and November 30, 2000. Because of the timing of the filing requirements under the *Patented Medicines Regulations* and the manner of calculating benchmark prices, medicines introduced or patented in December are considered to be new patented medicines in the following year.

priority is given to drug products for human use (refer to section 6.1.3 for more information).

### 6.1.2 *Existing Patented Medicines*

A total of 859 existing patented drug products (DINs) for human use were sold during 2000.[5] As of May 31, 2001, the prices of 807 DINs (93.9%) were reviewed and found to be within the Guidelines. Thirty-one existing patented DINs were the subject of investigations commenced as a result of pricing in earlier periods.[6] Eighteen DINs were still under review and three DINs, different strengths of Nicoderm, were the subject of a hearing by the Board under s. 83 of the *Act* (refer to Enforcement Measures Section, page 11 for more information).

A summary of the review, compliance and investigation status of the new and existing patented drug products for human use in 2000 is provided in Table 1.

**TABLE 1** Patented Drug Products for Human Use Sold in 2000 as of May 31, 2001

| | New Drugs introduced in 2000 | Existing Drugs | Total |
|---|---|---|---|
| Total | 81 | 859 | 940 |
| Under review | 14 | 18 | 32 |
| Subject of Investigation | 17 | 31 | 48 |
| Notice of Hearing | 0 | 3 | 3 |
| Within Guidelines | 50 | 807 | 857 |

Source: PMPRB, Annual Report 2000

[5] For the purposes of this report, existing medicines include all patented drug products that were on the market before December 1, 1999. The PMPRB's Guidelines limit the price changes for existing patented drugs to changes in the Consumer Price Index (CPI). In addition, the price of a patented drug cannot exceed the highest price of the same drug product in the countries listed in the *Patented Medicines Regulations*, namely France, Germany, Italy, Sweden, Switzerland, the U.K. and the U.S.

[6] Includes three DINs which became subject to investigation as a result of new information received during the year.

### 6.1.3 *Patented Medicines for Veterinary Use*

In March 1999, the Board implemented, on a three year trial basis, a complaints-driven process as an alternative means of reviewing the prices of patented veterinary medicines.[7]

The Board did not receive any complaints with respect to the prices of any patented veterinary drug products in 2000.

### 6.1.4 *Update of the Review of Patented Medicine Prices in 1999*

In last year's Performance Report, the Board reported that the prices of 36 new patented drug products were still under review. The results of those reviews concluded that the prices of 20 had been within the Guidelines, but 16 DINs were priced at levels that appeared to exceed the Guidelines and therefore investigations were commenced. At the time of this report, two of those investigations have been concluded as a result of additional information. The prices of both of these drug products were within the Guidelines.

At the time of last year's Performance Report, the Board reported that 29 DINs (including three DINs of Nicoderm, which are still the subject of a hearing) were under investigation. Of the 29 investigations ongoing at the time of last year's report, Board Staff have concluded 12 of those investigations; in 11 cases, the prices were ultimately found to be within the Guidelines. One case, Plavix, was concluded as a result of a Voluntary Compliance Undertaking (VCU) (see Enforcement Measures, page 11).

In summary, as of May 31, 2001, as shown in Table 1, the total number of investigations in progress has increased to 51, i.e., 48 DINs which are under investigation and the three DINs of Nicoderm which are still subject of a hearing.

[7] Refer to *Excessive Price Guidelines Special Provisions for Veterinary Patentees* in the PMPRB's Compendium. Under this policy, patentees are not required to report price and sales information to the PMPRB as required by the *Regulations*.

## 6.2 Enforcement Measures

VCUs and Board decisions are available on the Board's web site: http://www.pmprb-cepmb.gc.ca under Publications, VCUs and Hearings & Decisions of the Board respectively.

### 6.2.1 *Voluntary Compliance Undertakings (VCUs)*

Under the Compliance and Enforcement Policy, patentees are given an opportunity to make a VCU when Board Staff conclude, following an investigation, that a price appears to have exceeded the Guidelines. Approval of a VCU by the Chairperson or Board is an alternative to the commencement of formal proceedings through the issuance of a Notice of Hearing.[8]

In 2000, the Chairperson approved one VCU by Bristol Myers Squibb Pharmaceutical Group and Sanofi-Synthélabo Canada Inc. for the patented medicine Plavix, following *Notice and Comment*.

**Plavix - Bristol Myers Squibb Pharmaceutical Group and Sanofi-Synthélabo Canada Inc.**

In its April 2000 NEWSletter, the Board gave notice to ministers of health in the provinces and terrritories and other interested persons of a VCU made by Bristol Myers Squibb Pharmaceutical Group (BMS) and Sanofi-Synthélabo Canada Inc. (Sanofi) regarding the patented medicine Plavix. The Board indicated that it would consider submissions in this matter in determining whether to accept the VCU.

One submission was received, from the Province of Saskatchewan. Having considered that submission and all of the other evidence before it, the Board accepted the VCU.

In compliance with the terms of the VCU, BMS and Sanofi agreed to lower the price of Plavix from $2.47 per tablet to $2.40, and to offset the excess revenues. The patentees made a payment in the amount of $583,065 to offset excess revenues received from the sale of Plavix at prices higher than

[8] The Compliance and Enforcement Policy requires that a VCU ensure that a price will be adjusted to conform with the Guidelines and, where appropriate, include measures to offset excess revenues that may have been received by the patentee.

the maximum non-excessive price (MNE) from October 1998 to February 29, 2000; and submitted copies of credit notes issued to pharmacies, wholesalers, hospitals and other customers for the difference between actual prices paid and the MNE of $2.4015 for the year 2000, to offset excess revenues received from the sale of Plavix from March 1, 2000 to April 9, 2000.

The Board will continue to monitor changes to the product monograph and review this matter again if the circumstances warrant.

**Virazole - ICN Canada Ltd. and ICN Pharrmaceuticals Inc.**

As reported on page 34 of the 1999 Annual Report, on March 30, 2000, following a hearing, the Board issued a Variation Order to its July 26, 1996 Order in the case of ICN and the price of Virazole. ICN made an initial cash payment of $350,000 on April 27, 2000, and has reduced the price of Virazole by at least $200 per vial below the maximum non-excessive price until ICN's full obligation of $1,7ll,957 has been satisfied.

### 6.2.2 *Public Hearings*

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

As reported last year, the Chairperson of the Board issued a Notice of Hearing on April 20, 1999, in the matter of Hoechst Marion Roussel Canada Inc. (HMRC) and the price of the nicotine patch Nicoderm, to determine whether, under the *Patent Act*, Nicoderm was being sold at an excessive price.

By Notice of Motion dated May 25, 1999, HMRC challenged the jurisdiction of the Board to proceed with the matters described in the Notice of Hearing. For procedural purposes, the jurisdiction issue was divided into two parts. The Board heard the argument on the first part of the motion on July 5, 1999 and issued its decision affirming its jurisdiction on August 3, 1999. HMRC filed an application for judicial review of this decision in the Federal Court of Canada.

On December 13 to 16, 1999 and June 28 and 29, 2000, the Hearing Panel heard evidence and argument on the second part of HMRC's motion. In its

decision handed down on August 8, 2000, the Board found that it has jurisdiction in this matter because Nicoderm is a medicine and HMRC is a patentee for purposes of the *Act*. On September 8, 2000, HMRC filed an application for judicial review in the Federal Court of Canada with respect to this decision.

As HMRC only named the Attorney-General of Canada as Respondent in its judicial review applications, Board Staff and the Board applied to the Federal Court to participate in the proceedings. On July 13, 2001, a Prothonotary of the court issued a decision denying Board Staff the right to participate and allowing the Board to intervene on a limited basis. Both the Board and Board Staff have filed notices of appeal of this decision.

## 6.3 Trends in Manufacturers' Prices of all Medicines Sold in Canada

### 6.3.1 *Manufacturers' Prices and Volume of Patented Drugs Sold*

The PMPRB maintains the Patented Medicine Price Index (PMPI), an index of manufacturers' prices for patented drugs as reported annually to the PMPRB. The PMPI measures the average change from the previous year in the average transaction prices of patented drug products sold in Canada. The PMPI is derived from the net prices reported by patentees, and, therefore, includes all patented drugs that have been reported to the PMPRB.[9]

Historically, the PMPI has reflected price changes for all patented drugs, whether for human or veterinary use. As of 1999, the PMPI only includes the changes in the prices of patented drug products for human use.

In 2000 patentees reported total factory-gate sales of patented drugs for human use of $6.3 billion. This represents an increase of 16.7% from 1999. Sales of patented drugs as a proportion of total sales of drugs have been increasing from 43.9% in 1995 to 63.0% in 2000. This continued increase in the proportion of total drug sales accounted for by patented drugs may be attributed in part to the long term effects of increased patent protection resulting from Bills C-22 and C-91 in 1987 and 1993.

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[9] See the PMRPB's *A description of the Laspeyres methodology used to construct the Patented Medicine Price Index (PMPI)*, (revised) April 1997. Also, see *A Description of the Major Price Indexes for Pharmaceuticals*, produced by Statistics Canada and the PMPRB, January 2001, for an explanation of the PMPI.

In 2000, manufacturers' prices for patented medicines increased slightly from the previous year. The prices of patented drugs, as measured by the PMPI, rose by 0.4% on average from the level in 1999, while the quantities sold increased by 16.2%.

From 1988 to 2000, the average annual increase in quantities of patented drugs sold was approximately 12.0% as compared to an average annual increase of 0.8% in their prices.

The index for the quantities of patented drugs sold may not be representative of total sales of all pharmaceuticals, because patented drugs have represented between 40.7% and 63.0% of total sales since 1990 (Table 2). Among other things, this analysis does not take into account shifts in utilization between patented drugs and non-patented drugs, nor does it account for changes in patent status. For example, drugs continue to be consumed even though their patents expire and their prices are no longer subject to the PMPRB's jurisdiction.

**TABLE 2** Manufacturers' Sales of All Drugs and Patented Drugs, for Human and Veterinary Use, 1990 - 1998; and for *Human Use, 1999 - 2000*

| Year | Total | | Patented | | Patented Drugs as Percentage of Total |
|---|---|---|---|---|---|
| | Sales ($billions) | Change* (%) | Sales ($billions) | Change* (%) | |
| 2000 | 10.0 | 12.4 | 6.3 | 16.7 | 63.0 |
| 1999 ** | 8.9 | 16.8 | 5.4 | 27.0 | 61.0 |
| 1998 | 7.8 | 11.4 | 4.3 | 18.9 | 55.1 |
| 1997 | 7.0 | 7.0 | 3.7 | 22.6 | 52.3 |
| 1996 | 6.6 | 10.0 | 3.0 | 12.8 | 45.0 |
| 1995 | 6.0 | 1.7 | 2.6 | 10.8 | 43.9 |
| 1994 | 5.9 | 9.3 | 2.4 | -2.1 | 40.7 |
| 1993 | 5.4 | 12.5 | 2.4 | 9.4 | 44.4 |
| 1992 | 4.8 | 9.1 | 2.2 | 14.0 | 43.8 |
| 1991 | 4.4 | 18.9 | 2.0 | 13.1 | 43.2 |
| 1990 | 3.7 | - | 1.7 | - | 43.2 |

Source: PMPRB and IMS Health. Prior to 1996, Statistics Canada information was used.

* Percentage changes reflect exact values and not rounded values.

** The percentage change from 1998 of 16.8% for total drugs and 27.0% for patented drugs represents the change in sales of drugs for human use only.

### 6.3.2 *Manufacturers' Prices of All Drugs -- Patented and Non-Patented*

The *Patent Act* provides that the PMPRB consider changes in the Consumer Price Index (CPI) when determining if the price of a patented medicine is excessive. The PMPRB's Guidelines limit price increases of patented drugs to increases in the CPI. As shown in Figure 1, prices of patented drugs, as measured by the PMPI, have not increased more than the CPI in any year since 1988 with the exception of 1992.[10] In 2000, consumer prices increased

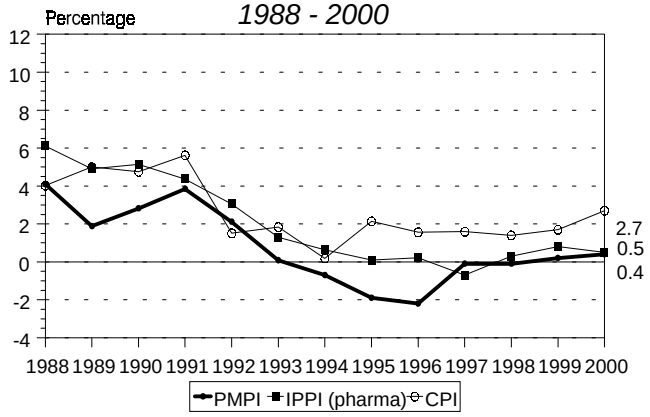
[10] To facilitate and encourage compliance by patentees, the PMPRB's CPI-adjustment methodology uses the forecast rate of CPI inflation published by the Department of Finance. The methodology is self-correcting over time. The forecast CPI inflation rate for 1992 had been 3.2% but the actual rate was 1.5%. For a full explanation of the CPI-adjusted methodology please refer to Schedule 4 of the PMPRB's *Compendium of Guidelines, Policies and Procedures.*

by 2.7% while the prices of patented drug products rose by an average of 0.4%.[11]

**FIGURE 1**

Year-over-Year Changes in PMPI, IPPI (pharma) and CPI

*1988 - 2000*




Sources: Statistics Canada and the PMPRB, Annual Report 2000

It is not unexpected that the overall increases in patented drug prices have been less than the increases in CPI. The PMPRB's Guidelines apply on a product-by-product basis; in other words, no patented drug product can increase in price by more than the CPI. The prices of some will increase by less than the CPI or will decrease, causing the PMPI to be lower than the CPI. In addition, the policies of provincial governments in the administration of their drug plans in recent years have limited the ability of drug manufacturers to increase prices.

The pharmaceutical component of the Industrial Product Price Index [IPPI (pharma)], published by Statistics Canada, provides an index of manufacturers' prices for all pharmaceuticals produced in Canada for domestic consumption and export. This includes both patented and non-patented drugs. In 2000, the IPPI (pharma) increased by 0.5%.[12] As shown in Figure 1, the IPPI (pharma) has remained virtually unchanged since 1993.

[11] Statistics Canada, CANSIM, Series P100000.

[12] Statistics Canada, CANSIM, Series P3515. The last six months of data is subject to revision by Statistics Canada.

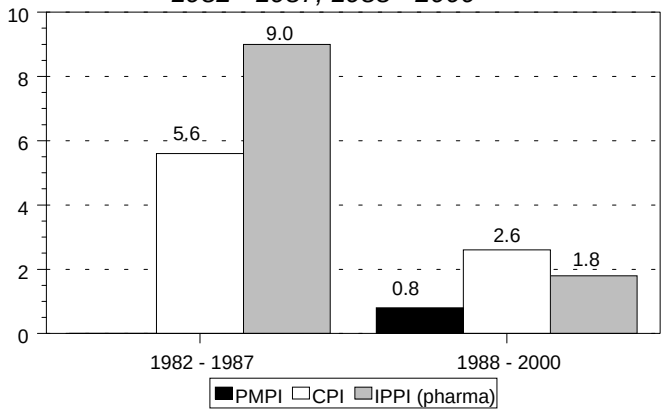
As summarized in Figure 2, from 1988 to 2000, the IPPI (pharma) has increased, on average, by 1.8%, which is less than the average annual increase in the CPI of 2.6%. Prices for patented drugs have increased at a lower rate over that period, growing by an average of 0.8% per year.

Figure 2, also shows information on pharmaceutical price trends prior to the creation of the PMPRB in 1987. From 1982 to 1987, price increases of all drugs, as measured by the IPPI (pharma), averaged 9.0% per year as compared with increases in the CPI of 5.6% per year. The decline in the rate of increase in prices of all drugs relative to the CPI coincided with the introduction of federal price regulation of patented drugs.

Additional information on trends in manufacturers' prices of all medicines sold in Canada is available on the Board's web site: www.pmprb-cepmb.gc.ca, under Publications, Annual Report and Study Series.

**FIGURE 2**

Summary of Price Trends,
Average Annual Percentage Changes
*1982 - 1987; 1988 - 2000*




Sources: Statistics Canada and the PMPRB, Annual Report 2000

### 6.3.3 *Relationship of Canadian Prices to Foreign Prices: Past and Present*

One way of examining drug price trends, taking into account introductory prices and price increases, is to examine the trend in the relationship of prices in Canada to those in other countries.

In accordance with the *Patent Act* and the *Patented Medicines Regulations* (*Regulations*), patentees are required to report all publicly available ex-factory prices for patented drugs in the seven foreign countries, listed in the *Regulations*, in which the drug is sold.[13] This foreign price information is used for two purposes: in the application of the Guidelines, and to compare price levels in Canada with those elsewhere. Following public consultations, the Board adopted a policy effective in January 2000, to include drug prices charged to the U.S. government agencies as listed in the Federal Supply Schedule (FSS), in calculating the average U.S. price of patented drugs.[14]

The next two figures show the relationship between Canadian prices of patented drugs and foreign prices over time.

Figure 3 shows the relationship between Canadian prices of patented medicines and the median prices in the seven countries used for price comparison purposes, as listed in the *Regulations*, over the period from 1987 to 2000.[15] It shows that Canadian prices were, on average, 23% higher than the median international price in 1987. This ratio declined until the mid-1990's and has since remained relatively stable at about 10% below median international prices. The increase in the ratio from 0.89 to 0.92 in 2000 appears to be attributed in part to the inclusion of U.S. FSS prices in calculating the U.S. prices, and in part to a relative decline in prices in the European countries as shown in Figure 4.

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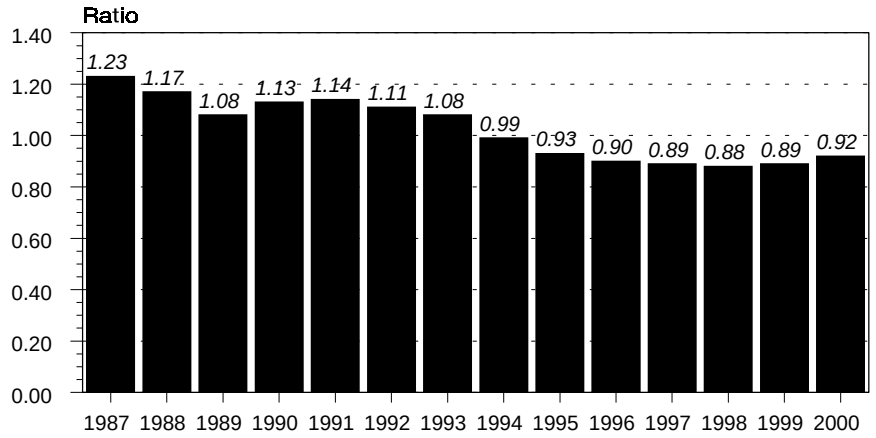
[13] France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States.

[14] For further information on the inclusion of the U.S. FSS prices, please refer to page 12 of the PMPRB's 1999 Annual Report

[15] This calculation is based on a revenue-weighted average of the ratio of the Canadian price to median international price for each patented drug product sold in that year. Foreign prices are converted to Canadian currency by using the simple average of the thirty-six montly average noon spot exchange rates for each country. The methodology used by the Board in conducting foreign price comparisons can be found in the *Compendium of Guidelines, Policies and Procedures*, Schedule 3, and in two papers published with the PMPRB's *Road Map for the Next Decade* in 1998 entitled *Trends in Patented Drug Prices* (S-9811) and *Verification of Foreign Patented Drug Prices* (S-9812).

**FIGURE 3**

Ratio of Canadian Prices of Patented Drugs
to Median International Prices
*1987 - 2000*



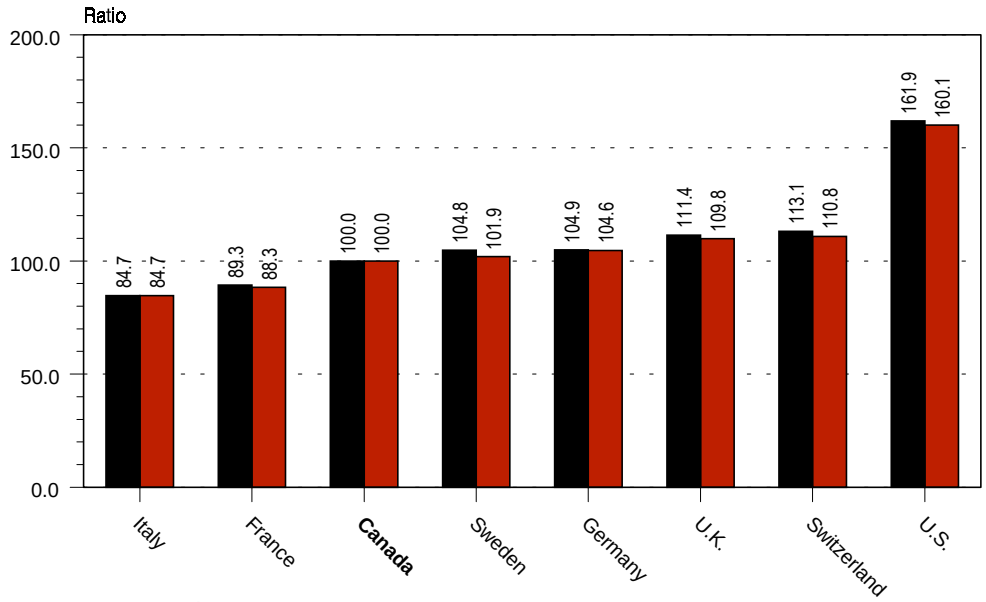

Source: PMPRB, Annual Report 2000

Figure 4 shows the relationship between Canadian prices for patented drug products and prices in each of the countries listed in the *Regulations* in 1999 and 2000. In 1987, Canadian prices were, on average, below those in the U.S., but above the prices in all other countries. By the mid-1990's, the situation had changed dramatically when Canadian prices, in comparison, tended to be in the mid-range of the six European countries. As shown in Figure 4, this relationship continued to remain relatively stable in 2000 as prices of patented drugs for human use in Canada were slightly lower than prices in Sweden, Germany, the United Kingdom, and Switzerland and higher than in France and Italy. In all countries except Italy, however, prices declined slightly in 2000 relative to Canada.

As in previous years, prices in the U.S. appear to be higher than prices in Europe and in Canada. The pharmaceutical industry in the U.S. has argued that the publicly available prices in that country do not reflect actual prices because of confidential discounts and rebates.

**FIGURE 4**

## Average Foreign to Canadian Price Ratios
### *Patented Drug Products 1999 - 2000*




Source: PMPRB, Annual Report 2000
Beginning in the year 1999, the ratio includes prices of patented drugs for human use only. U.S. includes U.S Federal Supply Schedule prices in the calculation of the average U.S. price.

### 6.3.4 *Federal/Provincial/Territorial (F/P/T) Collaboration*

During the year, the Board continued to conduct analyses of price and expenditure trends and cost drivers of publicly-funded drug plans. This work, carried out under a Memorandum of Understanding (MOU) between the Board and the Minister of Health, is coordinated through the F/P/T Working Group on Drug Prices. The reports prepared by the Board under the MOU are submitted to the Minister of Health and provincial/territorial ministries.

In their Action Plan for Health System Renewal of September 11, 2000, Canada's First Ministers agreed to work together on strategies for assessing the cost-effectiveness of prescription drugs in order to ensure that Canadians continue to have access to new, appropriate and cost-effective drugs.

## 6.4 Pharmaceutical Research-and-Development (R&D) Expenditures of Patentees in Canada

With the adoption of the 1987 amendments to the *Patent Act*, Canada 's Research Based Pharmaceutical Companies (Rx&D)[16] made a public commitment that the brand name pharmaceutical industry would increase its annual R&D expenditures as a percentage of sales to 10% by 1996. In 1999, the Conference Board of Canada concluded that Canada maintains the most favourable tax system for R&D of eleven countries it examined.[17]

Under the *Patent Act*, the PMPRB monitors and reports the estimates of R&D spending as filed by pharmaceutical patentees but it has no regulatory authority to influence the type of research or amount of R&D spending by patentees. The *Act* requires each patentee to report its revenues from sales of drugs and the expenditures made by the patentee in Canada on R&D relating to medicine.[18] For individual patentees, this calculation includes all revenues from Canadian sales of medicines, including revenues from licensing agreements.

Only companies with active Canadian patents pertaining to a medicine sold in Canada are required by the *Act* to report on R&D expenditures. As new patents are granted and others expire, the group of companies required to file R&D data may change from year to year.

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16 Formerly the Pharmaceutical Manufacturers Association of Canada (PMAC).

17 Conference Board of Canada, Rating R&D Tax Incentives, November 1999. The Conference Board examined eleven countries including, in addition to Canada, Australia, France, Korea, Mexico, United Kingdom, Japan, Sweden, Italy, Germany, United States.

18 Pursuant to the *Regulations*, patentees report those R&D expenditures that would have been eligible for an Investment Tax Credit for scientific research and experimental development under the provision of the *Income Tax Act* in effect on December 1, 1987. Market research, sales promotions, quality control or routine testing of materials, devices or products and routine data collection are among the expenditures that are not eligible for an Investment Tax Credit and therefore, should not be included in the patentees' filings. Total R&D expenditures include current expenditures, capital equipment costs and allowable depreciation expenses.

The definition of research and development for purposes of the *Regulations* are based on definitions under the *Income Tax Act* in 1987 and differ in some respects from definitions used for tax purposes today. The R&D information filed by patentees with the PMPRB is not necessarily consistent with what may ultimately be allowed by the Canada Customs and Revenue Agency for purposes of the *Income Tax Act*.

The information reported in this section is derived from reports filed with the Board by patentees. Under the *Regulations*, patentees are required to certify that the information reported is true and correct by an officer of the company. The PMPRB does not audit but attempts to reconcile the information and to seek corrections or clarifications from patentees if it finds any discrepancies. Each patentee is also given the opportunity to confirm the R&D-to-sales ratio calculated by the PMPRB for that company before publication of the Annual Report.

Additional information on pharmaceutical R&D expenditures of patentees in Canada is available on the Board's web site: www.pmprb-cepmb.gc.ca, under Publications, Annual Report and Study Series.

### 6.4.1 *Ratio of R&D Expenditures to Sales Revenues*

For 2000, 79 patentees reported total revenues of $9.3 billion from Canadian sales of patented and non-patented drugs, up 12.0% over 1999. Patentees are largely brand name companies that sell patented and non-patented drugs. Of total sales revenues, less than 1% were generated by licensing agreements.

As shown in Table 3, the ratio of R&D expenditures to sales revenues for the patented pharmaceutical industry was 10.1% in 2000, down from 10.8% in 1999. The ratio for the 37 companies that were members of Rx&D was 10.6% in 2000, down from 11.3% in 1999. Although the total R&D expenditures of reporting companies increased by 5.6%, the R&D-to-sales ratios declined because sales for those companies increased even more, by 12.0%. As a result, the R&D-to-sales ratios for all patentees and Rx&D companies were lower in 2000 than in any year since 1992.

**TABLE 3** Total R&D Expenditures* and R&D-to-Sales Ratios of Reporting Companies 1988-2000

| Year | Companies Reporting | Total R&D Expenditures* ($M) | Change from Previous Year (%) | Total Sales Revenues ($M) | Change from Previous Year (%) | R&D-to-Sales Ratio | |
|---|---|---|---|---|---|---|---|
| | | | | | | All Patentees (%) | Rx&D Patentees** (%) |
| 2000 | 79 | 944.7 | 5.6 | 9309.6 | 12.0 | 10.1 | 10.6 |
| 1999 | 78 | 894.6 | 12.0 | 8315.5 | 19.2 | 10.8 | 11.3 |
| 1998 | 74 | 798.9 | 10.2 | 6975.2 | 10.9 | 11.5 | 12.7 |
| 1997 | 75 | 725.1 | 9.0 | 6288.4 | 7.4 | 11.5 | 12.9 |
| 1996 | 72 | 665.3 | 6.4 | 5857.4 | 9.9 | 11.4 | 12.3 |
| 1995 | 71 | 625.5 | 11.5 | 5330.2 | 7.5 | 11.7 | 12.5 |
| 1994 | 73 | 561.1 | 11.4 | 4957.4 | 4.4 | 11.3 | 11.6 |
| 1993 | 70 | 503.5 | 22.1 | 4747.6 | 14.0 | 10.6 | 10.7 |
| 1992 | 71 | 412.4 | 9.6 | 4164.4 | 6.9 | 9.9 | 9.8 |
| 1991 | 65 | 376.4 | 23.2 | 3894.8 | 18.1 | 9.7 | 9.6 |
| 1990 | 65 | 305.5 | 24.8 | 3298.8 | 11.0 | 9.3 | 9.2 |
| 1989 | 66 | 211.8 | 47.4 | 2973.0 | 9.4 | 8.2 | 8.1 |
| 1988 | 66 | 165.7 | - | 2718.0 | - | 6.1 | 6.5 |

Source: PMPRB, Annual Report 2000

* Total expenditures include current expenditures, capital equipment expenditures and allowable depreciation expenses. If the expenditures funded by government are excluded, the ratios for all patentees and for the members of the Rx&D are not affected.

** In the past, Rx&D has reported that its members have achieved a higher R&D-to-sales ratio than reported by the PMPRB. Not all members of Rx&D are required to report to the PMPRB each year as, under the Patent Act, only companies with active Canadian patents pertaining to a medicine sold in Canada are required to report on R&D expenditures. For example, some biotechnology companies are engaged in R&D but are not required to report to the PMPRB as they have not made sales of a patented product during this reporting year.

As shown in Table 4, of the 79 reporting companies, 17 companies reported having performed no R&D in 2000. Sales revenues for companies with no R&D totalled $349.5 million in 2000 accounting for 3.8% of total sales revenues for the patented pharmaceutical companies. The 39 companies reporting R&D expenditures with an R&D-to-sales ratio of 10% or less in 2000 was the same as 1999. This group

included companies with total sales of $4.9 billion in 2000 compared to $4.5 billion in 1999. The 23 companies with ratios of more than 10% accounted for a smaller proportion of total sales, 44.0%, or $4.1 billion in 2000.

**TABLE 4** Range of R&D-to-Sales Ratios by Number of Reporting Companies and Total Sales Revenues

| Range of R&D-to-Sales Ratio | 2000 | | | 1999 | | |
|---|---|---|---|---|---|---|
| | Number of Reporting Companies | Total Sales Revenues ($M) | % | Number of Reporting Companies | Total Sales Revenues ($M) | % |
| 0% | 17 | 349.5 | 3.8 | 14 | 273.6 | 3.3 |
| 0% - 10% | 39 | 4,860.5 | 52.2 | 39 | 4,543.5 | 54.6 |
| > 10% | 23 | 4,099.6 | 44.0 | 25 | 3,498.4 | 42.1 |
| Total | 79 | 9,309.6 | 100.0 | 78 | 8,315.5 | 100.0 |

Source: PMPRB, Annual Report 2000

### 6.4.2 *R&D Expenditures by Type of Research and Location*

Table 5 shows how current expenditures on R&D in 2000 were allocated among basic, applied, and other qualifying R&D. Total current expenditures on R&D rose by 5.9% in 2000.

Patentees reported spending on basic research of $159.1 million or 17.8% of the total in 2000. Basic research is defined as work that advances scientific knowledge without a specific application in view. Expenditures on basic research increased by 2.1% in 2000. This is the lowest proportion of total R&D spending on basic research ever reported by patentees since the Board began reporting such information in 1988. The lion's share of R&D spending continued to be on applied research, $549.3 million or 61.3% of the total. Applied research is directed towards some practical application, comprising the manufacturing process, pre-clinical trials and clinical trials. Clinical trials totalled $425.7 million in 2000 and accounted for 77.5% of total applied research expenditures and 47.5% of the total current R&D expenditures. Manufacturing process accounted for $68.2 million, or 7.6% of the total current R&D expenditures, and pre-clinical trials accounted for $55.4 million or 6.2% of the total current R&D expenditures. Other qualifying research, which accounted for 20.9% of total expenditures in 2000, includes

drug regulation submissions, bioavailability studies and Phase IV clinical trials.

**TABLE 5** Current R&D Expenditures* by Type of Research, 1999 and 2000

| Type of Research | 2000 | | 1999 | | % Change in Expenditures 2000 - 1999 |
|---|---|---|---|---|---|
| | $M | % | $M | % | |
| **Basic** | 159.1 | 17.8 | 155.9 | 18.4 | 2.1 |
| • Chemical | 69.3 | 7.7 | 63.5 | 7.5 | 9.1 |
| • Biological | 89.8 | 10.0 | 92.4 | 10.9 | -2.8 |
| **Applied** | 549.3 | 61.3 | 535.2 | 63.3 | 2.6 |
| • Manufacturing Process | 68.2 | 7.6 | 65.2 | 7.7 | 4.6 |
| • Pre Clinical Trial I | 34.1 | 3.8 | 30.1 | 3.6 | 13.3 |
| • Pre Clinical Trial II | 21.3 | 2.4 | 10.9 | 1.3 | 95.4 |
| • Clinical Trial Phase I | 17.8 | 2.0 | 15.3 | 1.8 | 16.3 |
| • Clinical Trial Phase II | 85.8 | 9.6 | 63.6 | 7.5 | 34.9 |
| • Clinical Trial Phase III | 322.1 | 36.0 | 350.1 | 41.4 | -8.0 |
| **Other Qualifying R&D** | 187.0 | 20.9 | 154.7 | 18.3 | 20.9 |
| **Total**** | 895.5 | 100.0** | 845.8 | 100.0** | 5.9 |

Source: PMPRB, Annual Report 2000

* Current expenditures exclude capital equipment and depreciation expenditures.

** Column may not equal totals due to rounding.

In 2000 R&D spending increased in all parts of Canada. There was no significant change in the regional distribution of R&D spending in 2000. As shown in Table 6, more than 85% of total expenditures continued to be made in Ontario and Québec.

**TABLE 6** Current R&D Expenditures* by Location, 1999 and 2000

| Location of R&D | 2000 | | 1999 | | % Change 2000-1999 |
|---|---|---|---|---|---|
| | $M | % | $M | % | |
| Atlantic Provinces | 25.1 | 2.8 | 23.6 | 2.8 | 6.4 |
| Québec | 372.1 | 41.6 | 340.4 | 40.2 | 9.3 |
| Ontario | 396.2 | 44.2 | 381.4 | 45.1 | 3.9 |
| Western Provinces | 102.0 | 11.4 | 100.4 | 11.9 | 1.6 |
| Territories | 0.012 | 0.0 | 0.01 | 0.0 | 20.0 |
| **Total** | 895.5** | 100.0 | 845.8** | 100.0 | 5.9 |

Source: PMPRB, Annual Report 2000

* Current expenditures exclude capital equipment and depreciation expenditures.

** Column may not equal totals due to rounding.

## 6.5 Transparency and Accountability

### 6.5.1 *The Working Group on Price Review Issues*

In 1999 the Board established the Working Group on Price Review Issues, a 12-member consultative group representing its key stakeholders, consumer groups, ministers of health and the pharmaceutical industry, to review, analyse and provide reports for the Board's consideration on three issues.

The first issue considered by the Working Group relates to the challenges in comparing international prices of pharmaceuticals. Early in 2000, the Board implemented recommendations of the Working Group to take into account the prices charged to the U.S. government, published on the FSS, in calculating U.S. prices for comparison purposes.

This policy was effective as of the pricing period commencing January 1, 2000, and subject to a two-year transitional period. This issue was reported in the 1999 Annual Report available on the PMPRB web site: www.pmprb-cepmb.gc.ca.

In December 2000, the Working Group reported on the Board's price review process for new patented medicines. At its meeting on March 5, 2001, the

Board agreed with the Working Group's recommendations and decided to consult more boardly on the implementation of those recommendations that may have a wider effect.

In the April 2001 issue of the NEWSletter, the Board published a text for *Notice and Comment*, which set out specific proposals to implement the Working Group's recommendations to make the price review process more open and transparent. A number of submissions have been received and are being reviewed.

The Working Group has now turned its attention to the current price Guidelines for category 3 drug products. Category 3 drug products are new patented drugs that are not breakthroughs or substantial improvements over existing therapies. The Working Group's review of the issues regarding the Guidelines for category 3 drug products is expected to continue into 2002.

### 6.5.2 *Research Agenda 2001-2004*

In keeping with its commitment in the *Road Map*, the Board now publishes its Research Agenda and invites stakeholders to comment on it. The Research Agenda for 2001-2004 was published in the January 2001 issue of the NEWSletter and is also available on the web site: www.pmprb-cepmb.gc.ca, under Publications, Research Agenda.

### 6.5.3 *Communications*

The PMPRB has focussed on providing better information to all stakeholders, increasing their awareness of existing information, and working with them to refine existing tools and processes, in order to better serve their needs.

## 6.6 Presentation of Financial Information

Patented Medicine Prices Review Board

| | |
|---|---|
| Planned Spending | $3,711,000 |
| *Total Authorities* | *$4,113,300* |
| **2000-2001 Actuals** | **$3,997,600** |

The variance between total authorities and actual spending for 2000-2001 is primarily due to delays in staffing positions during the course of the year.

## 1.0 Financial Performance Overview

The tables are presented in the following order:

1. Summary of Voted Appropriations
2. Comparison of Total Planned to Actual Spending
3. Historical Comparison of Total Planned Spending to Actual Spending
4. Revenue

The variance between total authorities and actual spending for 2000-2001 is primarily due to delays in staffing positions during the course of the year.

**Financial Table 1: Summary of Voted Appropriations**

| Financial Requirements by Authority ($ thousands) | | | | |
|---|---|---|---|---|
| **Vote** | | **Planned Spending** | **2000-2001 Total Authorities** | **Actual** |
| | **Patented Medicine Prices Review Board** | | | |
| 25 | Operating Expenditures | 3,250.0 | 3,652.3 | 3,480.6 |
| (S) | Contributions to employee benefit plans | 461.0 | 517.0 | 517.0 |
| | **Total Department** | **3,711.0** | **4,113.3** | **3,997.6** |
| Total Authorities are main estimates plus supplementary estimates plus other authorities. | | | | |

## Financial Table 2: Comparison of Total Planned to Actual Spending

| Planned versus Actual Spending ($ thousands) | | | |
|---|---|---|---|
| | 2000-2001 | | |
| Patented Medicine Prices Review Board | Planned | Total Authorities | Actual |
| FTEs | 39.0 | 39.0 | **38.0** |
| Operating | 3,711.0 | 4,113.3 | **3,997.6** |
| **Total Gross Expenditures** | **3,711.0** | **4,113.3** | **3,997.6** |
| Less: Respendable Revenues[1] | - | - | - |
| **Total Net Expenditures** | **3,711.0** | **4,113.3** | **3,997.6** |
| **Other Revenues and Expenditures** | | | |
| Non-respendable Revenues[2] | - | - | (933.1) |
| Cost of services provided by other departments | 636.1 | 636.1 | 639.6 |
| **Net Cost of the Program** | **4,347.1** | **4,749.4** | **3,704.1** |

[1] Formerly "Revenue Credited to the Vote"

[2] Formerly "Revenue Credited to General Government Revenues (GGR)" - see Financial Table 4

## Financial Table 3: Historical Comparison of Total Planned Spending to Actual Spending

| Historical Comparison of Planned versus Actual Spending ($ thousands) | | | | | |
|---|---|---|---|---|---|
| | | | 2000-2001 | | |
| Business Line | Actual 1998-99 | Actual 1999-2000 | Planned Spending | Total Authorities | Actual |
| Patented Medicine Prices Review Board | 3,037.6 | 3,667.6 | 3,711.0 | 4,113.3 | 3,997.6 |
| **Total** | **3,037.6** | **3,667.6** | **3,711.0** | **4,113.3** | **3,997.6** |

Total Authorities are main estimates plus supplementary estimates plus other authorities.

## Financial Table 4: Revenue

**Non-Respendable Revenues ($ thousands)**

| | | | 2000-2001 | | |
|---|---|---|---|---|---|
| | **Actual 1998-99** | **Actual 1999-2000** | **Planned Revenues** | **Total Authorities** | **Actual** |
| Patented Medicine Prices Review Board | | | | | |
| Unplanned | 666.8 | 67.3 | - | - | 933.1 |
| **Total Non-respendable Revenues[1]** | **666.8** | **67.3** | **-** | **-** | **933.1** |
| **Total Revenues** | **666.8** | **67.3** | **-** | **-** | **933.1** |

[1] The money deposited to the NRR does not represent revenues generated by the PMPRB. This money includes 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.

## 1.0 Contacts for Further Information and the PMPRB Web Site

Toll-Free Number: 1-877-861-2350

If you have any questions or comments, please contact:

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TTY: (613) 957-4373
Fax: (613) 952-7626
E-mail: pmprb@pmprb-cepmb.gc.ca
WEBSITE: http://www.pmprb-cepmb.gc.ca

## 2.0 Legislation Administered and Associated Regulations

- *Patent Act* R.S. 1985, c. P-4, as amended by R.S. 1985, c. 33 (3rd supp.), and as further amended by S.C. 1993, c. 2
- *Patented Medicines Regulations*, 1994

## 3.0 Guidelines

- Compendium of Guidelines, Policies and Procedures
- Patentees' Guide to Reporting (1995)
- (Proposed) Rules of Practice and Procedure (April 1999)

## 4.0 Statutory Annual Reports and Other PMPRB Reports

**ANNUAL REPORT Series** *(1989 to 2000)*

**NEWSletter Series** *(1997 to 2000)*

**BULLETIN Series** *(1988 to 1996)*

**MOST RECENT PUBLICATIONS**

- *Examining the Role, Function and Methods of the PMPRB*, November 1997
- *Road Map for the Next Decade*, Report on the PMPRB's Public Consultations, September 1998
- S-9811: Trends in Patented Drug Prices
- S-9812: Verification of Foreign Patented Drug Prices
- S-9813: Purchasing Power Parities and International Comparisons of Patented Medicine Prices
- S-9914: Top Selling Non-Patented Single Source Drug Products, 1996: International Price Comparison
- Corporate Brochure - *Controlling the Prices of Patented Medicines in Canada*