ESTIMATES

Patented Medicine Prices Review Board Canada

Performance Report

For the period ending
March 31, 2000

Canada

Improved Reporting to Parliament
Pilot Document

The Estimates of the Government of Canada are structured in several parts. Beginning with an overview of total government spending in Part I, the documents become increasingly more specific. Part II outlines spending according to departments, agencies and programs and contains the proposed wording of the conditions governing spending which Parliament will be asked to approve.

The *Report on Plans and Priorities* provides additional detail on each department and its programs primarily in terms of more strategically oriented planning and results information with a focus on outcomes.

The *Departmental Performance Report* provides a focus on results-based accountability by reporting on accomplishments achieved against the performance expectations and results commitments as set out in the spring *Report on Plans and Priorities.*

Available in Canada through your local bookseller or by mail from

Canadian Government Publishing — PWGSC

Ottawa, Canada K1A 0S9

Catalogue No. BT31-4/64-2000
ISBN 0-660-61377-8

Foreword

On April 24, 1997, the House of Commons passed a motion dividing on a pilot basis the *Part III of the Estimates* document for each department or agency into two separate documents: a *Report on Plans and Priorities* tabled in the spring and a *Departmental Performance Report* tabled in the fall.

This initiative is intended to fulfil the government's commitments to improve the expenditure management information provided to Parliament. This involves sharpening the focus on results, increasing the transparency of information and modernizing its preparation.

The Fall Performance Package is comprised of 83 Departmental Performance Reports and the President's annual report, *Managing for Results 2000*.

This ***Departmental Performance Report,*** covering the period ending March 31, 2000 provides a focus on results-based accountability by reporting on accomplishments achieved against the performance expectations and results commitments as set out in the department's *Report on Plans and Priorities* for 1999-00 tabled in Parliament in the spring of 1999.

Results-based management emphasizes specifying expected program results, developing meaningful indicators to demonstrate performance, perfecting the capacity to generate information and reporting on achievements in a balanced manner. Accounting and managing for results involve sustained work across government.

The government continues to refine its management systems and performance framework. The refinement comes from acquired experience as users make their information needs more precisely known. The performance reports and their use will continue to be monitored to make sure that they respond to Parliament's ongoing and evolving needs.

This report is accessible electronically from the Treasury Board Secretariat Internet site: http://www.tbs-sct.gc.ca/rma/dpr/dpre.asp

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Patented Medicine
Prices Review Board

Performance Report

For the
period ending
March 31, 2000

Minister of Health Canada

Contents

Executive Summary

The Patented Medicine Prices Review Board (PMPRB) is an independent quasi-judicial tribunal created by Parliament as a result of revisions to the *Patent Act* in 1987 (Bill C-22) which strengthened patent protection for pharmaceutical products. It consists of no more than five part-time members appointed by the government for a term of five years. The PMPRB represents a strategic component of federal policy to balance consumer protection and affordable health care with the trade and industrial development objectives of pharmaceutical patent legislation.

The PMPRB protects consumer interests and contributes to Canadian health care by reviewing the prices charged by manufacturers of patented medicines to ensure that, in line with the factors set out in the *Patent Act*, they are not excessive. Among other things, it has the authority to order, following a public hearing, reductions in the prices of patented medicines and measures to offset excess revenues received by patentees. In 1999-2000 the Board approved the following enforcement measures:

- The Chairperson approved a Voluntary Compliance Undertaking submitted by Hoffman-La Roche in the matter of the price of Anaprox.

- The Board agreed to a Variation Order filed by Staff with respect to the July 26, 1997 Board Order in the matter of ICN Canada Ltd. and ICN Pharmaceuticals, Inc. with respect to the price of Virazole.

In addition, in the matter of Hoechst Marion Roussel Canada Inc. (HMRC) and the price of the nicotine patch, Nicoderm, the Hearing Panel heard evidence and argument on a two-part jurisdictional issue. The Board has rendered its decisions.

Total sales by manufacturers of pharmaceuticals for human use in 1999 in Canada are estimated at $8.9 billion, an increase of 16.8% from 1998. Total sales of drugs in Canada, including the sales of veterinary drugs reported by patentees for patented and non-patented drugs were slightly higher at $9.1 billion for 1999.

In 1999, prices of patented drugs rose by an average of 0.2%, as compared to the Consumer Price Index (CPI) which increased by 1.7%. Internationally, prices for patented drugs for human use in Canada remained relatively stable and in line with prices in Europe.

In 1999, patentees reported total factory-gate sales of patented drugs for human use of $5.4 billion, an increase of 27.0% from the sales of patented drugs for human use in 1998. Patented drugs accounted for 61.0% of the total sales of all drugs.

Patentees reported expenditures on pharmaceutical research and development (R&D) of $894.6 million in 1999. For the 78 reporting companies, the R&D-to-sales

ratio was 10.8% in 1999, down from 11.5% in 1998. Patentees reported expenditures of $155.9 million on basic research. Although spending on basic research increased by 6.2% from 1998, its share of total R&D declined from 19.6% in 1998 to 18.4% in 1999.

After more than a year of working to implement the *Road Map for the Next Decade*, there are a number of important achievements. The results flowing from the Working Group provide a case in point. The Board is focussing on building and maintaining effective communications with stakeholders to provide them with better information, increase their awareness of existing information sources, and work with them through continued consultations to refine tools like the toll-free line, the Web site and the NEWSletter. In addition, the Board continues to seek ways to improve the openness and transparency of its operations.

In the coming year, the Board will continue with the implementation of the *Road Map*.

Section I Chairperson's Message

I am pleased to present the 1999-2000 Performance Report for the Patented Medicine Prices Review Board (PMPRB or the Board).

Pharmaceuticals, and patented medicines in particular, represent the fastest growing component of health care expenditures. In 1999, total sales by manufacturers of all drugs for human use in Canada increased by 16.8% to $8.9 billion, while sales of patented drug products for human use increased by 27% to $5.4 billion. Patented drugs accounted for 61% of the total sales of all drugs.

In fulfilling its consumer protection role, the PMPRB limits the maximum prices charged by manufacturers for patented drugs to ensure that they are not excessive. In 1999, manufacturers' prices of patented drugs in Canada increased slightly by an average of 0.2%, as compared to the CPI which increased by 1.7%. Since 1987, Canadian prices for patented drugs have declined over 30% compared to foreign prices.

The fact that drug prices have remained relatively stable while sales and expenditures on drugs are increasing rapidly highlights the need to better understand the factors contributing to high drug costs. The Board welcomes the opportunity to conduct analyses, at the request of the Minister of Health, of public drug plan spending.

In the context of our core responsibilities and mandate, the Board's *Road Map for the Next Decade*, 1998 responded to the concerns that had been identified by the Auditor General and our stakeholders. After more than a year of implementation, there are a number of achievements. The Working Group on Price Review Issues has served as a valuable source of feedback and input to the PMPRB. The Board has recently implemented recommendations of the Working Group related to the inclusion of the U.S. Federal Supply Schedule prices in calculating U.S. prices for the purpose of international price comparisons.

In addition, the Board is focussing on providing better information to all stakeholders, increasing their awareness of existing information sources, and working with them to refine tools such as the toll-free line, the Web site and the NEWSletter, in order to better serve their needs.

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

1.0 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.

2.0 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.

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 staff to review and assess 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.

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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 monetary penalty in the amount of the excess revenues.

If there has been a policy of selling at an excessive price, the Board may impose "double damages", i.e., order the offset of twice the excess revenues by an additional price reduction or monetary penalty. (For more information see S. 83 of the *Patent Act*)

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 when assessing 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.

The PMPRB's jurisdiction includes both prescription and non-prescription patented medicines sold in Canada for human and veterinary use as well as patented medicines marketed or distributed under voluntary licenses. In addition, patented drugs that do not have a Notice of Compliance (NOC) but are sold as Investigational New Drugs or under the Special Access Program administered by Health Canada are subject to review by the PMPRB. The Board has no authority over the prices of non-patented drugs, including generic drugs sold under compulsory licenses.

3.0 Strategic Priorities

The PMPRB's strategic direction is set out in its Report on Plans and Priorities for 1999 -2000. The PMPRB's priorities are as follows:

To provide Canadians with:

- *assurance that manufacturers' prices for patented medicines sold in Canada are not excessive;*
- *information on trends in manufacturers' prices of all medicines sold in Canada;*
- *information on pharmaceutical research-and-development expenditures of patentees in Canada; and*
- *a more transparent and accountable public agency recognized as adding value to pharmaceutical policy in Canada*.

4.0 Position within Government

The PMPRB is a quasi-judicial administrative tribunal. It reports to Parliament through the Minister of Health and forms part of the Health portfolio. The PMPRB:

- is consulted by **Health Canada** and **Industry Canada** on matters related to pharmaceutical prices and research and development;
- participates in several federal/provincial/territorial initiatives and working groups related to pharmaceuticals;
- consults with other departments and agencies on matters related to fulfilling its mandate including **Health Canada**, the **Canadian Intellectual Property Office** (CIPO), **Statistics Canada** and **Agriculture and Agri-Food Canada**;
- participates in **groups of federal administrative tribunals** which deal with issues of common interest.

5.0 Challenges

5.1 Increase in Drug Expenditures

Total health care expenditures in Canada have grown to $86 billion in 1999, of which approximately 70% 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 1999. At the same time, drugs have been taking an increasing share and are now the second largest component, after hospitals, of health care spending.

In 1999, according to the latest figures published by the Canadian Institute for Health Information (CIHI), total expenditures on drugs, not including drugs used in hospitals, have increased faster than other major components of health care, and reached 15.2% of total health expenditures. Based on filings to the PMPRB by manufacturers, their total sales of drugs for human use increased almost 17% in 1999 to $8.9 billion. Sales of patented drugs increased 27% to $5.4 billion.

5.2 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. Following up on the *Road Map for the Next Decade*, 1998, the Board has continued to enhance its reporting of information and has asked

[2] Canadian Institute for Health Information: *National Health Expenditure Trends 1975 - 1999*

a working group of stakeholders to recommend how to make the price review process more transparent.

5.3 Federal/Provincial/Territorial (F/P/T) Initiatives

At the invitation of federal and provincial ministers of health, the PMPRB has assisted in the work of several committees and task forces studying pharmaceuticals. The PMPRB has recently entered into a Memorandum of Understanding (MOU) with the federal Minister of Health to continue and expand analysis of price trends and cost drivers for F/P/T public drug plans on behalf of the Working Group on Drug Prices. Under the terms of the MOU, the PMPRB will conduct analyses of the expenditures of public drug plans in Canada including annual price trends, cost-driver studies, comparisons of Canadian and foreign prices of non-patented single-source drugs and inter-provincial drug price comparisons.

5.4 Auditor General's Report on the PMPRB

In 1998, the Auditor General performed a thorough audit of the Board and tabled a report to Parliament on all aspects of its operations. The Board responded positively to the Auditor General's recommendations. Progress has been made on the recommendations and work is ongoing.

5.5 Workload Pressures/Increases

From 1992 to 1999, the number of patented drugs under the PMPRB's jurisdiction has increased by 37%, from 791 to 1,082. In addition to the increased number of patented drugs being reviewed, patentees have become more sophisticated in their approach to the price review process. This has resulted in more creative and complex submissions by patentees in an attempt to justify their prices. These submissions often involve scientific, pharmacoeconomic and jurisdiction issues as seen in the current hearing in the matter of Hoechst Marion Roussel Canada Inc. and the price of Nicoderm.

6.0 Performance Results Expectations and Chart of Key Results Commitments

Patented Medicine Prices Review Board		
to provide Canadians with:	achievement to be demonstrated by:	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 7.1 7.2
	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 7.4.1 7.4.2
	manufacturers' prices for new and existing patented medicines no greater than manufacturers' prices charged in other countries.	See 7.4.3
	level of compliance as show by the percentage of patented medicines priced within the guidelines.	See 7.1 7.2
	the enforcement measures taken in accordance with the *Patent Act* to ensure that prices are not excessive	See 7.3 7.3.1 7.3.2
information on trends in manufacturers' prices of all medicines in Canada	comprehensive reports on: ‣ trends in manufacturers' prices and volume of patented drug products sold; ‣ trends in manufacturers' prices of all drug products -- patented and non-patented; and ‣ the comparison of Canadian patented drug prices to international prices.	See 7.4 7.4.1 7.4.2 7.4.3
information on the pharmaceutical research-and-development expenditures of patentees in Canada	comprehensive reports of: ‣ 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 ‣ R&D expenditure by location and by type of research.	See 7.5 7.5.1 7.5.2
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 7.6.1 7.6.2 7.6.3

7.0 Performance Accomplishments

7.1 Review of Patented Medicine Prices and Compliance with the Guidelines

7.1.1 *New Patented Medicines*[3]

There were 117 new patented drug products (DINs), representing 72 medicines, that fell under the PMPRB's jurisdiction in 1999. Of the 117 DINs, 111 (94.9%) are for human use and six (5.1%) for veterinary use. Twenty-eight (23.9%) of the 117 new patented DINs were being sold in Canada prior to 1999 and the issuance of the Canadian patent which brought them under the PMPRB's jurisdiction.

As of May 31, 2000, the prices of 89, or 76.1% of the 117 new DINs, had been reviewed. The remaining 28 DINs, 22 for human use and six for veterinary use, were still under review. Of the 89 new patented DINs reviewed, 84, or 94.4%, were priced within the Guidelines.[4] Five of the new patented DINs appeared to be priced at levels outside the Guidelines and are the subject of an investigation.

7.1.2 *Existing Patented Medicines*[5]

A total of 840 existing patented drug products (DINs) for human use were sold during 1999. As of May 31, 2000, price reviews for 826 DINs or 98.3% were completed. Of the 826 existing patented DINs reviewed, 802, or 97.1%, were priced within the Guidelines. Of these, 24 or 2.8% are currently the subject of an investigation. Included in this number are the three strengths of Nicoderm which is the subject of a hearing by the Board under s. 83 of the *Act* (refer to pages 10 &11 for more information).

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3 For purposes of the review of prices by the PMPRB, new patented medicines in 1999 include those introduced on the market in Canada or those previously marketed but first patented between December 1, 1998 and November 30, 1999. 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.

4 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. Please refer to Schedule 5 of the *Compendium of Guidelines, Policies and Procedures*.

5 For the purposes of this report, existing medicines include all patented drug products that were on the market before December 1, 1998. 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.

A summary of the review, compliance and investigation status of the new and existing patented drug products for human use in 1999 is provided in Table 1.

Table 1
Patented Drug Products for Human Use Sold in 1999

	New Drugs	Existing Drugs	Total
Total	111	840	951
Under review	22	14	36
Subject of Investigation	5	24	29
Within Guidelines	84	802	886

Source: PMPRB, Annual Report 1999

7.2 Update of the Review of Patented Medicine Prices in 1998

7.2.1 *New Patented Medicines*

In last year's Performance Report, the Board reported that the prices of three new patented drug products in 1998 were still under review. Upon completion of those reviews, it was concluded that the prices of two DINs were within the Guidelines. The price of the third DIN is now the subject of an investigation and is included in the 24 existing drug products reported under investigation in 1999 in Table 1.

In 1998, it was also reported that eight new drug products were the subject of investigation. Of those, the investigations for three DINs were subsequently resolved upon receipt of additional information that showed that the prices were within the Guidelines. The remaining five DINs continue to be under investigation and are included in the 24 existing drug products reported under investigation in 1999 in Table 1.

7.2.2 *Existing Patented Medicines*

In last year's Performance Report, the Board reported that the prices of three existing drug products in 1998 were still under review. Upon completion of those reviews, it was concluded that the prices of two DINs were within the Guidelines. The price of the third DIN continues to be under review and is included in the 14 existing drug products reported as under review in 1999 in Table 1.

In 1998, it was also reported that 23 existing drug products were the subject of investigation. Of those, one investigation, Anaprox, was closed on receipt

of a Voluntary Compliance Undertaking, (see Section 7.3 Enforcement Measures). The investigations for six other DINs were subsequently resolved upon receipt of additional information that showed that the prices were within the Guidelines. The remaining 16 DINs continue to be under investigation and are included in the 24 existing drug products reported as under investigation in 1999 in Table 1.

7.3 Enforcement Measures

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

7.3.1 *Voluntary Compliance Undertakings (VCUs)*

Under the Compliance and Enforcement Policy, patentees are given an opportunity to make a VCU when Board Staff find, 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.[6]

Anaprox - Hoffmann-La Roche Limited

Having been advised that the price of Anaprox may have been excessive under the Board's Guidelines, Hoffmann-La Roche (Roche) made a Voluntary Compliance Undertaking (VCU) to reduce the price of Anaprox and to offset the excess revenues derived from its sale. Roche undertook to ensure that the average price of Anaprox would be within the Board's Guidelines in 1999 and in future years, commencing with the 1999 maximum non-excessive price of $0.5841 per 275 mg tablet, and to make a payment to Her Majesty in right of Canada in the amount of $67,252.55. The Chairperson approved Roche's VCU on August 11, 1999.

7.3.2 *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.

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[6] 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.

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 has filed an application for judicial review of this decision in the Federal Court of Canada. This application is in abeyance.

On December 13 to 16 and June 28 and 29, 2000, the Hearing Panel heard evidence and argument on the second part of HMRC's motion. The decision on this part of the motion was issued on August 8, 2000.

Virazole, ICN Canada Ltd. and ICN Pharmaceuticals, Inc.

In 1996, following a hearing under section 83 of the *Patent Act*, the Board issued an order regarding the price of the medicine Virazole. The details of the Order were reported in the PMPRB's 1996 Annual Report and the Estimates, Part III, 1996-97. Virazole is sold in Canada by ICN Canada Ltd., a wholly-owned subsidiary of ICN Pharmaceuticals, Inc. of the U.S. (hereinafter collectively called "ICN").

The Board found that ICN had been selling Virazole at an excessive price and that it had engaged in a policy of doing so. It ordered ICN to lower the price of Virazole from $1,540 per vial so as not to exceed the maximum non-excessive price of about $400. ICN was also ordered to offset twice the excess revenues it had received by making an immediate payment of $1.2 million to Her Majesty in right of Canada and by further reducing the price of Virazole, by $200 below the maximum non-excessive price. This additional price reduction was to remain in effect until the earlier of December 31, 1999, or the date on which an amount equal to twice the cumulative excess revenues, for a total of $3.5 million, had been offset by the combination of the payment and additional price reductions. In the event the cumulative excess revenues were not offset by this date, ICN was to make a payment or payments to Her Majesty in right of Canada equal to the balance of excess revenues outstanding.

In January 2000, Board Staff asserted that a payment of $1,711,957 remained to be paid while ICN was of the view that no further payments were required. Following discussions with ICN, Board Staff filed a proposed Variation Order which was approved by the Board on consent of the parties, on March 29, 2000. The Variation Order provides that ICN has a continuing obligation to offset over $1.7 million and that it will do so through a combination of payments and reduced prices for Virazole for a further four years.

7.4 Trends in Manufacturers' Prices of all Medicines Sold in Canada

7.4.1 *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.[7]

Historically, the PMPI has reflected price changes for all patented drugs, whether for human or veterinary use. As a result of changes adopted last year, the PMPI will only include the changes in the prices of patented drug products for human use as of 1999.[8]

In 1999 patentees reported total factory-gate sales of patented drugs for human use of $5.4 billion. This represents an increase of 27.0% from 1998. Sales of patented drugs have accounted for an increasing proportion of total sales of drugs, rising to 61.0% in 1999, from 55.1% the previous year.

In 1999, for the first time since 1993, manufacturers' prices for patented medicines increased slightly from the previous year. The prices of patented drugs, as measured by the PMPI, rose by 0.2% on average from the level in 1998, while sales increased by 21.2%.

From 1988 to 1999, the average annual increase in quantities of patented drugs sold was approximately 11.7% 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 61.0% of total sales since 1990. Among other things, this analysis does not take into account shifts in utilization

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[7] See the PMRPB's *A description of the Laspeyres methodology used to construct the Patented Medicine Price Index (PMPI)*, March, 1997, for an explanation of the PMPI.

[8] Following Notice and Comment, in order to better focus on pharmaceuticals for human use, the Board adopted a complaints-driven process for the price regulation of patented veterinary drugs, on a three-year trial basis, effective January 1, 1999. Under this new policy, the PMPRB will continue to review the introductory prices of new patented veterinary medicines, but will not actively monitor and review the annual price changes of existing drugs. It will continue to investigate prices of patented veterinary drugs upon receipt of a substantial complaint. As a result, patentees are no longer required to report price and sales information for patented veterinary drugs. The sales of veterinary drug products in 1997 and 1998 represented 2.9% and 2.3% of total sales of patented drug products respectively.

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.

7.4.2 *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.[9] In 1999, consumer prices increased by 1.7% while the prices of patented drug products rose by an average of 0.2%.

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, or 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.[10] In 1999, the IPPI (pharma) increased by 0.8%.[11] As shown in Figure 1, the IPPI (pharma) has remained virtually unchanged since 1993.

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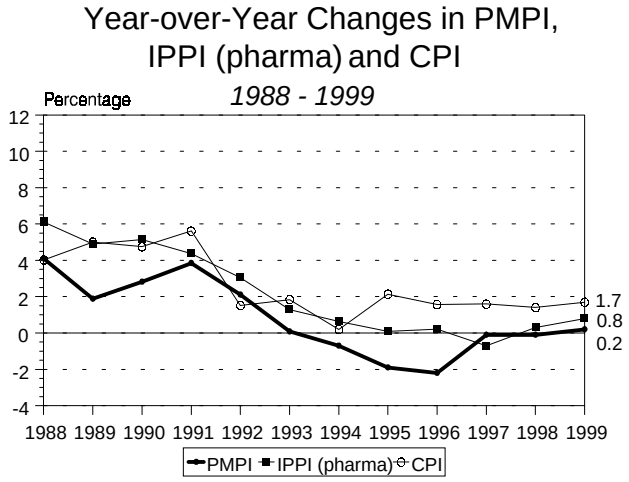
[9] To facilitate and encourage compliance by patentees, the PMPRB's CPI-adjustment methodology uses the forecast rate of CPI inflation published by the Department of Finance. The methodology is self-correcting over time. The forecast CPI inflation rate for 1992 had been 3.2% but the actual rate was 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.*

[10] The PMPRB and Statistics Canada have created a Task Force to review drug prices indices by Statistics Canada and the PMPRB. A report on the Task Force's work is scheduled to be released in the fall of 2000.

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

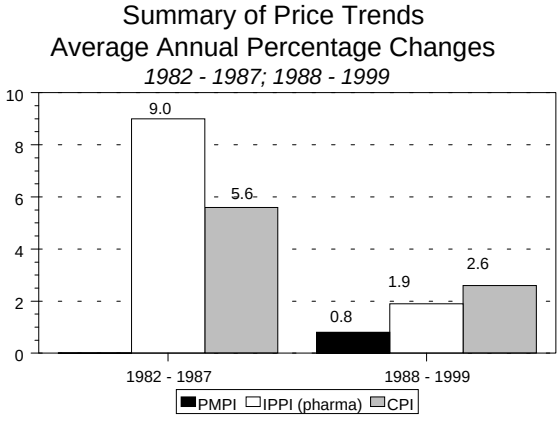
FIGURE 1



Sources: StatisticsCanada and the PMPRB

As summarized in Figure 2, from 1988 to 1999, the IPPI (pharma) has increased, on average, by 1.9%, 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



Sources: Statistics Canada and the PMPRB

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. As shown in Table 2, patented drugs have represented between 40.7% and 61.0% of manufacturers' sales of all drugs since 1988.

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.

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

Year	Total		Patented		Patented Drugs as
	Sales ($billions)	Change* (%)	Sales ($billions)	Change* (%)	Percentage of Total
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.

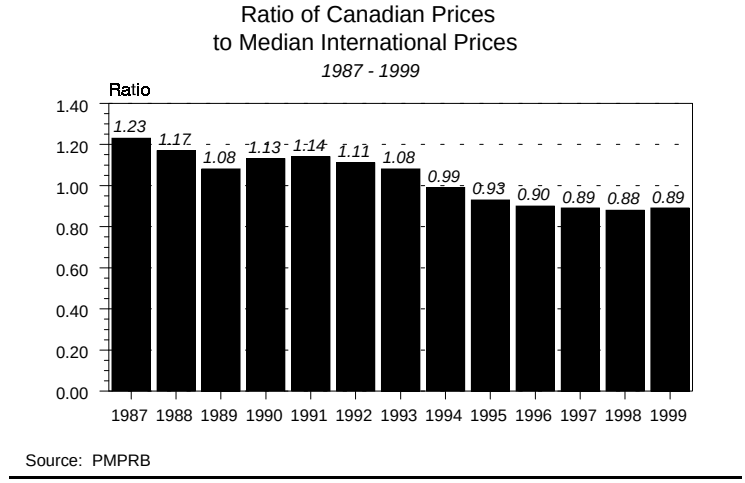
7.4.3 *Relationship of Canadian Prices to Foreign Prices: Past and Present*

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

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.[12] 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.

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 1999.[13] 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 the median international prices.

FIGURE 3



Source: PMPRB

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. 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

12 France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States.

13 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. The methodology used by the Board in conducting foreign price comparisons can be found in the *Compendium of Guidelines, Policies and Procedures* and in two papers published with the PMPRB's *Road Map for the Next Decade* in 1998 entitled, *Trends in Patented Drug Prices* and *Verification of Foreign Patented Drug Prices*.

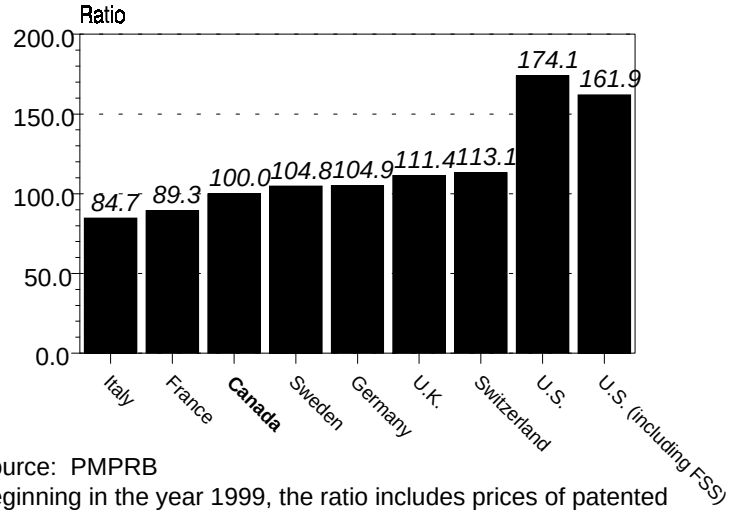
the mid-range of the six European countries. As shown in Figure 4, this relationship remained relatively stable in 1999 as patented drugs for human use in Canada were slightly lower than prices in Sweden, Germany, the United Kingdom, and Switzerland and higher than in France and Italy.

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.

The Board feels it important that it use the best price information available. Following year-long consultations, it has adopted a policy to include the prices in the U.S. Federal Supply Schedule in calculating the average U.S. price of a patented drug. Although this policy came into effect January 2000, Figure 4 shows that the ratio of U.S. prices to Canadian prices would have been reduced if the U.S. FSS prices had been included in 1999.

FIGURE 4

Average Foreign to Canadian Price Ratios
All Patented Drug Products in 1999



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

7.5 Pharmaceutical Research-and-Development (R&D) Expenditures[14] of Patentees in Canada

With the adoption of the 1987 amendments to the *Patent Act*, Canada 's Research Based Pharmaceutical Companies (Rx&D)[15] 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 a recent study, the Conference Board of Canada concluded that Canada maintains the most favourable tax system for R&D of eleven countries it examined.[16]

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. 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.

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.

7.5.1 *Ratio of R&D Expenditures to Sales Revenues*

For 1999, 78 patentees reported total revenues of $8.3 billion from Canadian sales of patented and non-patented drugs, up 19.2% over 1998. Patentees are largely brand name companies that sell patented and non-patented

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[14] 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.

[15] Formerly the Pharmaceutical Manufacturers Association of Canada.

[16] 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.

drugs. Of total sales revenues, less than 1% were generated by licensing agreements.

The ratio of R&D expenditures to sales revenues for the patented pharmaceutical industry was 10.8% in 1999, down from 11.5% in 1998. The ratio for the 38 companies that were members of Rx&D was 11.3% in 1999, down from 12.7% in 1998. Although the total R&D expenditures of reporting companies increased by 12.0%, the R&D-to-sales ratios declined because sales for those companies increased even more, by 19.2%. As a result, the R&D-to-sales ratios for all patentees and Rx&D companies were lower in 1999 than in any year since 1993.

As shown in Table 3, of the 78 reporting companies, 14 companies reported no R&D in 1999. Sales revenues for companies with no R&D totalled $273.6 million in 1999 accounting for 3.3% of total sales revenues for the patented pharmaceutical companies. There was a small increase in the number of companies reporting R&D expenditures with an R&D-to-sales ratio of 10% or less in 1999. However, this same group had a significant increase in total sales revenues. Total sales revenues for this group accounted for 54.6% of total sales revenues, up from 35.1% in 1998. There are 39 companies included in this group with total sales of $4.5 billion in 1999 as compared to 34 companies with total sales of $2.4 billion in 1998. The 25 companies with ratios of more than 10% accounted for a smaller proportion of total sales, 42.1% or $3.5 billion in 1999.

TABLE 3
Range of R&D-to-Sales Ratios by Number of Reporting Companies and Total Sales Revenues

Range of R&D-to-Sales Ratio	1999			1998		
	Number of Reporting Companies	Total Sales Revenues ($M)	%	Number of Reporting Companies	Total Sales Revenues ($M)	%
0%	14	273.6	3.3	14	274.6[r]	3.9
0% - 10%	39	4,543.5	54.6	34	2,449.3	35.1
> 10%	25	3,498.4	42.1	26	4,251.3	60.9
Total	**78**	**8,315.5**	**100.0**	**74**	**6,975.2[r]**	**100.0***

Source: PMPRB
[r] Revised
* The percentage does not equal to 100% due to rounding.

7.5.2 *R&D Expenditures by Type of Research and Location*

Table 4 shows how current expenditures on R&D in 1999 were allocated among basic, applied, and other qualifying R&D. Total current expenditures on R&D rose by 12.8% in 1999.

TABLE 4
Current R&D Expenditures* by Type of Research, 1999 and 1998

Type of Research	1999		1998		Change in Expenditures
	$M	**%**	**$M**	**%**	1999 /1998 %
Basic	155.9	18.4	146.8	19.6	6.2
Applied	535.2	63.3	458.0	61.1	16.9
Other Qualifying	154.7	18.3	145.3	19.4	6.5
Total	**845.8**	**100.0****	**750.1**	**100.0****	**12.8**

Source: PMPRB
* Current expenditures exclude capital equipment and depreciation expenditures.
** The percentage does not equal to 100% due to roundings.

Patentees reported spending on basic research of $155.9 million or 18.4% of the total in 1999. Basic research is defined as work that advances scientific knowledge without a specific application in view. Expenditures on basic research increased by 6.2% in 1999 but its share of total R&D continued to decline from 19.6% in 1998 to18.4 % in 1999. 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, $535.2 million or 63.3% of the total. Applied research is directed towards some practical application, comprising the manufacturing process, pre-clinical trials and clinical trials. Clinical trials accounted for 80.2% of total applied research expenditures, $429.0 million, while manufacturing process accounted for $65.2 million, or 12.2% of the total, and pre-clinical trials accounted for $41.0 million or 7.7% of the total. Other qualifying research, which accounted for 18.3% of total expenditures in 1999, includes drug regulation submissions, bioavailability studies and Phase IV clinical trials.

TABLE 5
Current R&D Expenditures* by Location, 1998 and 1999

Location of R&D	1999		1998		Change in Expenditures
	$M	**%**	**$M**	**%**	1999/1998 %
Atlantic Provinces	23.6	2.8	19.0	2.5	24.2
Québec	340.4	40.2	319.2	42.6	6.6
Ontario	381.4	45.1	329.7	44.0	15.7
Western Provinces	100.4	11.9	82.2	11.0	22.1
Territories	0.01	0.0	0.02	0.0	-50.0
Total	**845.8**	**100.0**	**750.1**	**100.0****	**12.8**

Source: PMPRB
* Current expenditures exclude capital equipment and depreciation expenditures.
** The percentage does not equal to 100% due to roundings.

In 1999 R&D spending increased in all parts of Canada with the exception of the Territories. There was no significant change in the regional distribution of R&D spending in 1999. As shown in Table 5, more than 85% of total expenditures continued to be made in Ontario and Québec.

7.6 Continued Implementation of the *Road Map for the Next Decade*

7.6.1 *The Working Group on Price Review Issues*

The Board established the Working Group on Price Review Issues early in 1999. It is composed of 12 members representing the provinces, consumers, seniors, health associations and the pharmaceutical industry. The Working Group was requested to review, analyse and provide reports for the Board's consideration on three issues:

- the first involved the review of the drug prices as set out in the U.S. Federal Supply Schedule (FSS), which are negotiated by the United States Department of Veterans Affairs for federal departments and agencies in that country, and recommended an appropriate use for that information in calculating U.S. prices for purposes of the Board's responsibilities to carry out international drug price comparisons;

- the second deals with examining the process and the methodology used to review the prices of new patented medicines for purposes of the Guidelines, to make the review process more open and transparent; and

- the third involves the Guidelines for the large majority of new drugs that are not breakthroughs or do not provide substantial improvement over existing products.

The use of the FSS prices in calculating U.S. prices for purposes of international drug price comparisons was the first issue to be reviewed by the Working Group. Although the pharmaceutical industry, in general, disagreed with the Board's interpretation of the legal requirement to report these prices, it nevertheless participated constructively in the Working Group. Following several months of study, the Working Group developed a consensus recommendation and presented it to the Board in September. In line with the Board's new consultation policy, the Board invited submissions from stakeholders and the public on the proposal to implement the Working Group's recommendations. The major effect of these changes should be to ensure that the U.S. prices used for international comparisons are better estimates of the average factory-gate prices in that country. (For more information, see the PMPRB NEWSletter, January 2000 or the PMPRB Web site: www.pmprb-cepmb.gc.ca, under Publications, NEWSletter.)

Work on the second project for the Working Group began in 1999 and is ongoing. A report for the Board's consideration is expected in December 2000.

The Working Group will begin work on its third project in October 2000.

The Working Group has served as a valuable source of feedback and input to the PMPRB, helping the Board take into account stakeholders views as it develops its priorities.

7.6.2 *Research Agenda 2000-2003*

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 2000-2003 was first published in the January 2000 issue of the NEWSletter and is also available on the Web site: www.pmprb-cepmb.gc.ca, under Publications, Research Agenda.

7.6.3 *Communications*

The Board is seeking to be more innovative not only in terms of its operations but also in its 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.

In the past year the Board:

- expanded and enhanced its Web site to include more user-friendly features and more timely information;
- increased the frequency of the publication of its NEWSletter to four issues a year;
- published the Minutes of the quarterly Board meetings;
- published the Research Agenda for 2000-2003; and,
- produced and distributed an information brochure on the role and activities of the PMPRB, *Controlling the Prices of Patented Medicines in Canada.*

These initiatives reflect the Board's commitment to foster more effective, two-way communications with its stakeholders and the public.

7.7 Presentation of Financial Information

Patented Medicine Prices Review Board

Planned Spending	$3,161,000
Total Authorities	*$3,823,600*
1999-2000 Actuals	**$3,667,600**

1.0 Financial Performance Overview

The tables are presented in the following order:

1. Summary of Voted Appropriations
2. Comparison of Total Planned Spending to Actual Spending
3. Historical Comparison of Total Planned Spending to Actual Spending
4. Non-respendable Revenues

The variance between total authorities and actual spending for 1999-2000 is primarily due to delays in staffing positions during the course of the year.

Financial Table 1:

Financial Requirements by Authority ($ thousands)				
			1999-00	
Vote		**Planned Spending**	**Total Authorities**	**Actual**
	Patented Medicine Prices Review Board			
25	Operating Expenditures	2,750.0	3,349.6	3,193.6
25	Capital Expenditures			
	Grants and Contributions			
(S)	Contributions to employee benefit plans	411.0	474.0	474.0
	Total Department	**3,161.0**	**3,823.6**	**3,667.6**

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

Financial Table 2:

Planned versus Actual Spending ($ thousands)			
	1999-00		
Patented Medicine Prices Review Board	**Planned**	**Total Authorities**	**Actual**
FTEs	34	39	**32**
Operating	3,161.0	3,823.6	**3,667.6**
Capital	-	-	-
Grants & Contributions	-	-	-
Total Gross Expenditures	**3,161.0**	**3,823.6**	**3,667.6**
Less:			
Respendable Revenues[1]	-	-	-
Total Net Expenditures	**3,161.0**	**3,823.6**	**3,667.6**
Other Revenues and Expenditures			
Non-respendable Revenues[2]	-	-	67.3
Cost of services provided by other departments	648.0	648.0	610.2
Net Cost of the Program	**3,809.0**	**4,471.6**	**4,345.1**

[1] Formerly "Revenue Credited to the Vote"
[2] Formerly "Revenue Credited to General Government Revenues (GGR)"

Financial Table 3:

Historical Comparison of Planned versus Actual Spending ($ thousands)					
			1999-00		
Business Line	**Actual 1997-98**	**Actual 1998-99**	**Planned Spending**	**Total Authorities**	**Actual**
Patented Medicine Prices Review Board	2,899.0	3,037.6	3,161.0	3,823.6	3,667.6
Total	**2,889.0**	**3,037.6**	**3,161.0**	**3,823.6**	**3,667.6**
Total Authorities are main estimates plus supplementary estimates plus other authorities.					

Financial Table 4:

Non-Respendable Revenues*($ thousands)					
			1999-00		
Business Line	**Actual 1997-98**	**Actual 1998-99**	**Planned Revenues**	**Total Authorities**	**Actual**
Patented Medicine Prices Review Board	-	-	-	-	-
Subtotal	-	-	-	-	-
Unplanned	1,200.0	666.8			67.3
Total Non-respendable Revenues[1]	**1,200.0**	**666.8**	**-**	**-**	**67.3**

* Formerly "Revenues Credited to the General Government Revenues (GGR)

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.

1.0 Mandate, Mission and Values

The Patented Medicine Prices Review Board (PMPRB) is an independent quasi-judicial body created by Parliament as a result of revisions to the *Patent Act* in 1987 (Bill C-22) which strengthened patent protection for pharmaceutical products. The PMPRB represents the consumer protection component of federal policy aimed at balancing several objectives including intellectual property, trade policy, research and development and affordable health care.

Subsequent revisions to the *Patent Act* in 1993 (Bill C-91) shifted ministerial responsibility for the PMPRB to the Minister of Health and also gave it increased remedial powers. The shift in ministerial responsibility from Consumer and Corporate Affairs (Industry Canada, which has overall responsibility for the *Act*), to Health Canada recognized the PMPRB's role as a social program that supports the government's commitment to maintain universal access to a comprehensive package of publicly funded health services and to basic social services.[17]

1.1 PMPRB's Mandate

Regulatory	***To protect consumer interests and contribute to Canadian health care by regulating the maximum prices charged by manufacturers of patented medicines to ensure that they are not excessive***
Reporting	***To report annually to Parliament on:*** • ***its price review activities;*** • ***the price trends of all medicines; and*** • ***its estimate of research-and-development spending in relation to sales revenues for individual patentees and for all pharmaceutical patentees in Canada. . . and***
Inquiry	***To inquire into any matter which may be referred to it by the Minister of Health.***

The PMPRB reviews the price of each patented drug product. A patented drug product may have different strengths and dosage forms. Normally Health Canada assigns a Drug Identification Number (DIN) to each strength of each dosage form. The PMPRB regulates the price of each DIN.

[17] Treasury Board. President of the Treasury Board, *Getting Government Right: A Progress Report,* Ottawa, 1996, p. 12

Under the *Act*, the Board reviews the price at which the manufacturer sells the medicine whether to wholesalers or directly to hospitals, pharmacies or other institutions. In addition to the manufacturer's price, the retail cost of a prescription to a consumer includes mark-ups and the pharmacist's dispensing fee which are not subject to review by the Board.

The PMPRB's jurisdiction includes both prescription and non-prescription patented medicines sold in Canada for human and veterinary use as well as patented medicines marketed or distributed under voluntary licences. In addition, patented drugs that do not have a Notice of Compliance (NOC) but are sold as Investigational New Drugs or under the Special Access Program administered by Health Canada are subject to review by the PMPRB. The Board has no authority to regulate the prices of non-patented drugs, including generic drugs sold under compulsory licenses.

1.2 Mission and Values of the PMPRB

The mission of the PMPRB is to contribute to Canadian health care by ensuring that prices of patented medicines are not excessive. The PMPRB achieves this by:

- promoting voluntary compliance with Guidelines established by the Board
- reviewing prices and taking remedial action when necessary
- analysing and reporting to Canadians on price trends of all medicines and on research and development conducted by patentees
- consulting with interested parties on Guidelines and other matters of policy
- fostering awareness of the Board's mandate, activities and achievements through communication, dissemination of information and public education.

In fulfilling its mission the PMPRB is committed to innovative leadership based on the following values:

- effectiveness and efficiency
- fairness
- integrity
- mutual respect

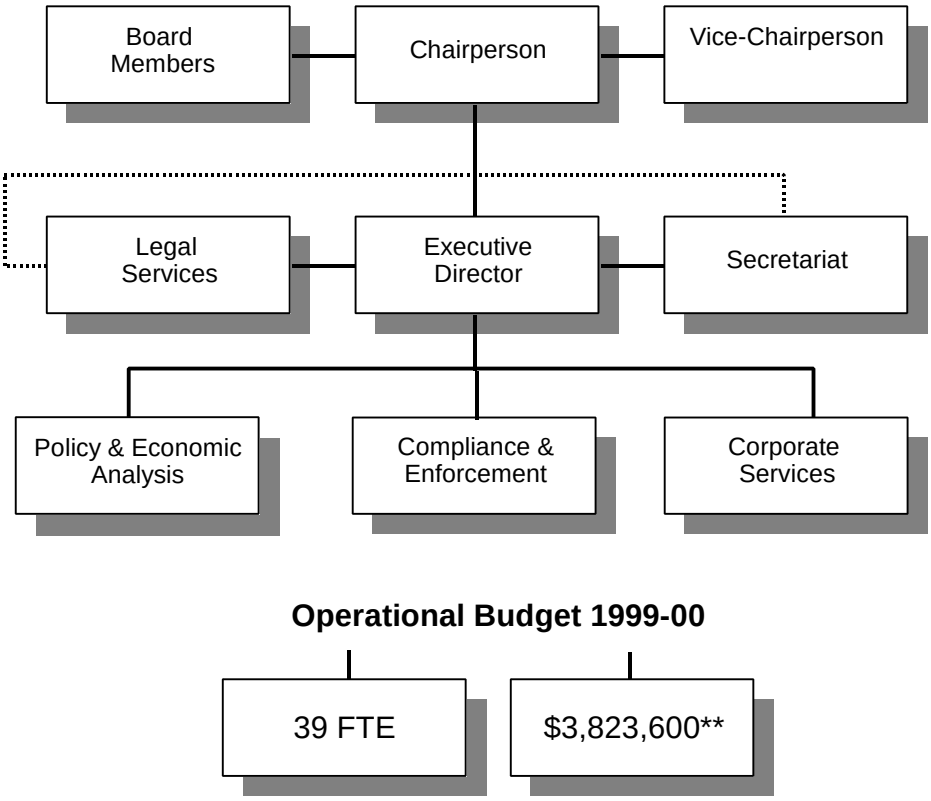
- transparency of process
- a supportive and challenging work environment

2.0 Organization and Composition

2.1 Organization Structure

The PMPRB reports to Parliament through the Minister of Health. The Board consists of not more than five part-time members appointed by the Governor-in-Council for a term of five years. The Board members include 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 to the Board and Senior Counsel.

Figure 6: Organizational Structure of the PMPRB for 1999-00



Operational Budget 1999-00

39 FTE	$3,823,600**

** inclusive of statutory benefits of $474,000

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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Fax: (613) 952-7626
E-mail: pmprb@pmprb-cepmb.gc.ca
WEBSITE: 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 1999)*

NEWSletter Series *(1997 to 1999)*

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*