ESTIMATES

Patented Medicine Prices Review Board Canada

Performance Report

For the period ending
March 31, 1999

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.*

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Foreword

On April 24, 1997, the House of Commons passed a motion dividing on a pilot basis what was known as the annual *Part III of the Estimates* document for each department or agency into two documents, a *Report on Plans and Priorities* and a *Departmental Performance Report.*

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.

This year, the Fall Performance Package is comprised of 82 Departmental Performance Reports and the government's report *Managing for Results* - Volumes 1 and 2.

This ***Departmental Performance Report,*** covering the period ending March 31, 1999, 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 pilot *Report on Plans and Priorities* for 1998-99. The key result commitments for all departments and agencies are also included in Volume 2 of *Managing for Results.*

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 and develop both managing for and reporting of results. 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/tb/key.html

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Planning, Performance and Reporting Sector
Treasury Board Secretariat
L'Esplanade Laurier
Ottawa, Ontario, Canada
K1A OR5
Tel: (613) 957-7042
Fax (613) 957-7044

Patented Medicine
Prices Review Board

Performance Report

For the
period ending
March 31, 1999

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.

Following an investigation by Board staff during 1998-99, the Chairperson of the Board issued a Notice of Hearing on April 20, 1999, in the matter of Hoechst Marion Roussel Canada Inc. and the price of Nicoderm, a transdermal nicotine patch. The purpose of the hearing is to determine whether, under sections 83 and 85 of the *Patent Act*, Hoechst Marion Roussel is selling or has, while a patentee, sold Nicoderm in any market in Canada at a price that, in the Board's opinion, is or was excessive; and, if so, what order, if any, should be made.

In 1998, prices of patented drugs were virtually unchanged from 1997, falling by an average of 0.1%, as compared to the Consumer Price Index (CPI) which increased by 1.4%. Internationally, prices for patented drugs in Canada still ranked third lowest, just below the United Kingdom.

Total sales by manufacturers of all drugs in Canada increased over 11.4% to $7.8 billion in 1998, while sales of patented drug products increased by over 18.9% to $4.3 billion. Patented drugs accounted for over 55% of the total sales of all drugs. Patentees reported expenditures on pharmaceutical research and development (R&D) of $798.9 million in 1998, an increase of $73.8 million from 1997. For the 74 reporting companies, the R&D-to-sales ratio remained unchanged at 11.5%. Patentees reported expenditures of $146.8 million on basic research. Although spending on basic research increased by 4.6% from 1997, its share of total R&D declined from 20.7% in 1997 to 19.6% in 1998.

On September 14, 1998, the Board honoured its commitment to report on its year-long public consultations by releasing the *Road Map for the Next Decade*. This report sets out a summary of what it heard and an action plan to address the concerns, issues and suggestions identified by its stakeholders.

In September 1998, the Auditor General of Canada tabled a Report on the PMPRB. While confirming that the Board's operations are essentially on track, the Auditor General recommended a number of areas relating to the PMPRB's operations and legislation that merit further review and attention. For its part, the PMPRB is moving forward, in the context of its consultations with stakeholders, to address many of the issues identified by the Auditor General. The Board is continuing to consult on the price review process, to

make it more transparent, and its Guidelines, and appropriate ways to achieve greater openness and transparency in reporting the outcomes of investigations. As well, the Board has brought the Auditor General's concerns with the legislation and regulations to the attention of the Minister of Health.

In February 1999, the Board established the Working Group on Price Review Issues, bringing together representatives of a cross section of stakeholders to examine three issues. In the coming year, the Working Group will begin reporting on the results of its review and analysis of the various issues being considered.

Section I Chairperson's Message

Over the past year, the Board has invested a substantial amount of time and effort to enhance the way it carries out its mandate. The evolution of the Board, as an integral part of Canada's health care system, has been highlighted with the completion of our year-long public consultations, and the release of the *Road Map for the Next Decade* in September 1998. The *Road Map* reflects our commitment to operate in an increasingly transparent, responsive and accessible fashion and sets out an ambitious agenda for action.

The Auditor General's Report on the PMPRB tabled in the fall of 1998 made a number of recommendations that were consistent with the objectives of the *Road Map*. The implementation of the *Road Map for the Next Decade* and the Auditor General's recommendations are the key factors setting the strategic direction for the Board in the 1999 - 2000 fiscal year and subsequent years.

Underlying the various initiatives and activities described in the *Road Map* is one key message: the importance of adapting to a rapidly changing health care environment. Such flexibility and capacity to adapt is critically important if the health care system is to work better in the interests of Canadians. In fulfilling their mandates, organizations such as the Board must demonstrate their ability and readiness to understand stakeholder needs, to make the changes necessary to meet those needs, and thus to be more responsive.

All of which promises to make our second decade every bit as challenging as our first. But in the midst of many challenges and changes that lie ahead, there is one fundamental constant. The Board will continue to make an important contribution to consumers and to health care in Canada by ensuring that the prices of patented medicines are not excessive.

Robert G. Elgie
Chairperson

2.1 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.[1]

2.1.1 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.

IMS Canada estimates that, on average, the manufacturer's portion of the final cost of a patented drug is about 63%.

Under the *Act*, the Board reviews the price at which the manufacturer

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

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.

2.1.2 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

2.2 Operating Environment

2.2.1 Position within the 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's Health Protection Branch** (HPB), 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.

2.2.2 Program Objective

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

The *Patent Act* identifies the factors the Board shall take into account in determining if the price of a patented medicine is excessive.[2] They may be summarized as follows:

- changes in the Consumer Price Index (CPI);
- the prices of other drugs used to treat the same disease;
- the prices of drugs in other countries; and
- other factors which may be established by regulation.

The Board used the factors in the *Patent Act* and the *Patented Medicines Regulations (Regulations)* to establish its Excessive Price Guidelines (Guidelines) which, in turn, support the PMPRB's voluntary compliance approach. The Guidelines are not a rigid set of decision-making rules and are not binding on the Board. 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 were developed in consultation with stakeholders including provincial and territorial ministers of health, consumer groups, health care associations and the pharmaceutical industry.

[2] *Patent Act*, R.S., 1985, as amended.

2.2.3 Strategic Priorities

The PMPRB's strategic direction is set out in its Report on Plans and Priorities for 1998 -1999. 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*
- *an opportunity to consult with the Board on how it fulfills its mandate*.

2.2.4 Challenges

i) Increase in Drug Expenditures

Total health care expenditures in Canada have grown to $80 billion in 1998, of which 70% are public funds. The allocation of that spending has changed over time. Spending on hospitals has declined from 45% in 1975 to 33% in 1998[3]; at the same time, drugs have been taking an increasing share.

In 1998, according to the latest figures published by the Canadian Institute for Health Information (CIHI), total expenditures on drugs, not including hospital expenditures, have increased faster than other major components of health care, and reached 14% of total health expenditures. CIHI estimates that overall drug expenditures increased by 5.9% in 1998.

ii) Patent Legislation

In his September 1998 report, the Auditor General expressed concerns with certain aspects of the legislative framework under which the Board operates. Among other things, the Auditor General expressed concerns related to foreign price comparisons and the reliability of the sources for foreign price information. The Board has formally brought these concerns to the attention of the Minister of Health in its *Road Map for the Next Decade* in September 1998 and a report on December 7, 1998.

iii) Transparency and Accountability

It became apparent from the consultation process that the familiarity of stakeholders with the Board's mandate and policies varied considerably. This lack of general knowledge about the Board leaves a significant expectation gap between what the PMPRB actually does and what the public expects that it does to regulate the prices of medicines and protect consumers.

Linked closely with the desire for greater transparency and greater accountability is a push for broader and more frequent consultations. At the meeting of stakeholders in November 1998, the Board heard of stakeholders' support for the

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[3] Canadian Institute for Health Information: *National Health Expenditure Trends 1975 - 1998*

more proactive approach to consultations that it had used in developing the *Road Map*; the Board has committed to continuing a more proactive approach in its new Consultation Policy.

Broader and more frequent consultations have implications on the limited human and financial resources of the PMPRB. The need for ongoing consultations to be successful requires significant expertise, human resources and funding to plan, execute, and properly follow-up the consultations. Non-industry stakeholders have expressed concerns about their ability to participate in consultations on an equal footing with the pharmaceutical industry because of a lack of resources. Their continued involvement in the consultation process depends in large part, on the PMPRB's ability to help defray some of the costs related to their participation. Improved communications and consultations are important to the Board's goal of increasing transparency and accountability of its activities.

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

In September 1998, Ministers of Health approved that all federal/provincial/territorial activities related to pharmaceuticals become the responsibility of the Pharmaceuticals Issues Committee (PIC), a standing committee of the Advisory Committee on Health Services (ACHS). PIC is co-chaired by the federal and provincial/territorial levels of government and supported by a secretariat, provided by Health Canada.

PIC currently has three working groups looking at issues related to pharmaceutical issues and policy (i.e., prices, utilization and system efficiencies). The Working Group on Drug Prices has recommended that new price and cost driver analyses be undertaken by the PMPRB so that all F/P/T drug plans can be provided with information and management tools in support of reimbursement and drug plan policy decisions.

v) Auditor General's Report on the PMPRB

In September, 1998 the Auditor General issued a report on the PMPRB following an audit of all aspects of its operations. In his report the Auditor General stated his support for the direction of the Board's current consultations while identifying a number of concerns and making recommendations for improvements. Among other things, he stated that the scope of the Board's jurisdiction and limitations of its consumer protection role are not widely understood and that its efforts to measure its impact did not adequately reflect other factors that constrain drug prices in Canada. The Auditor General also indicated a need for the Board to more clearly explain the reasons for its decisions, to ensure greater transparency in its operations. Finally, the Auditor General encouraged the Board to find cost-effective means to check the accuracy of price and R&D information, and to improve the reporting of trends in drug prices.

The Board has responded positively to the Auditor General's recommendations. Many of these recommendations were addressed through the *Road Map* and others are reflected in the Board's Research Agenda.

2.3 Organization and Composition

2.3.1 Business Line Description

The PMPRB has one business line which matches the program, the Patented Medicine Prices Review Program.

The PMPRB gathers information on the prices charged by manufacturers of patented medicines in Canada, analyzes that data and takes action, when required, to reduce prices which are, in the opinion of the Board, excessive.

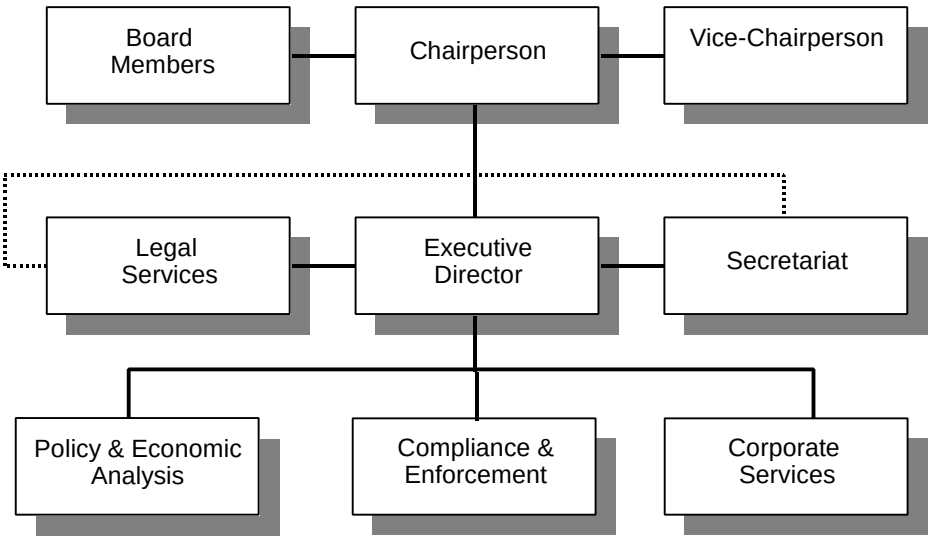
Through the Excessive Price Guidelines and program of advisory assistance, the Board relies on voluntary compliance wherever possible since it is more effective, less time consuming and less costly to all parties. If necessary, price reductions are accomplished through:

- voluntary action by patentees;
- 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.

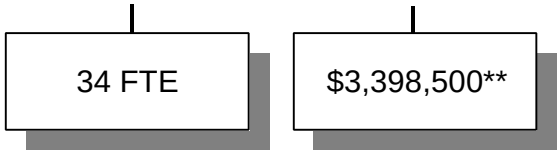
2.3.2 Organization Structure

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 1: Organizational Structure of the PMPRB for 1998-99



Operational Budget 1998-99



** inclusive of statutory benefits of $420,000

3.1 Performance Expectations

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 3.3.1
	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 3.4.1
	manufacturers' prices for new and existing patented medicines no greater than manufacturers' prices charged in other countries.	▸See 3.4.3
	level of compliance as shown by the percentage of patented medicines priced within the guidelines.	▸See 3.3.1
	the enforcement measures taken in accordance with the *Patent Act* to ensure that prices are not excessive	▸See 3.3.1
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 3.4.1 ▸See 3.4.2 ▸See 3.4.3
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 expenditures by location and by type of research.	▸See 3.5.1 ▸See 3.5.1
an opportunity to consult with the Board on how it fulfills its mandate	▸ a report during the fiscal year 1998-99 on the results of its consultations	▸See 3.6

3.2 Presentation of Financial Information

Patented Medicine Prices Review Board

Planned Spending	$3,118,000
Total Authorities	*$3,398,500*
1998-99 Actuals	**$3,037,600**

3.3 Performance Accomplishments

3.3.1 Non-Excessive Prices for Patented Medicines in 1998

i) Price Review of New Patented Drug Products[4]

In 1998, 98 new patented drug products (DINs) were introduced. As of May 31, 1999, the price review for 95 of the 98 DINs had been completed. The review of the remaining three DINs could not be completed by that date due to late filing of data to the Board.

Of the 95 products reviewed, 87, or 91.6%, were priced within the Guidelines. A price is considered to be within the Guidelines if it does not exceed the maximum allowed by the Guidelines and does not meet the criteria established for the commencement of an investigation.[5] Eight of the new patented DINs introduced in 1998 were priced at levels which appear to be outside the Guidelines and are the subject of an investigation.

ii) Price Review of Existing Patented Drug Products[6]

A total of 914 existing patented drug products (DINs) were sold during 1998. A price review was completed on 911 existing patented drug products sold in Canada that year; three DINs are still under review. The review of two DINs was delayed due to late filing of data to the Board; additional information is under review for the third DIN.

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[4] For purposes of the review of prices by the PMPRB, new patented drug products in 1998 include those introduced on the market in Canada or those previously marketed but first patented between December 1, 1997 and November 30, 1998. Because of the timing of the filing requirements under the *Patented Medicine Regulations* and the manner of calculating benchmark prices, drug products introduced or patented in December are considered to be new patented products in the following year.

[5] For a full explanation of the criteria for commencing an investigation please refer to Schedule 5 of the *Compendium of Guidelines, Policies and Procedures*.

[6] For the purposes of this report, existing medicines include all patented drug products that were on the market before December 1, 1997. 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.

Of the 911 existing patented drug products reviewed, 23 are under investigation[7]. The Board has issued a Notice of Hearing in respect of three of these DINs (Nicoderm).

A summary of the review, compliance and investigation status of the new and existing patented drug products in 1998 is provided in Table 1.

TABLE 1 - Patented Drug Products Sold in 1998

Data Year 1998	New Drugs	Existing Drugs	Total
Total	98	914	1012
Under review *	3	3	6
Subject of Investigation	8	23	31
Within Guidelines[7]	87	888	975

* reviews not completed at the time of this publication

Source: PMPRB, Annual Report 1998

iii) Update of 1997 Price Review

In last year's Performance Report, the Board reported that the prices of six new patented drug products in 1997 were still under review. Upon completion of those reviews, it was concluded that the prices of all six were within the Guidelines. It was also reported that the price of two new and 13 existing drug products were the subject of investigation. Of the 15 investigations, five were subsequently resolved upon receipt of additional information that showed that the prices were within the Guidelines. The remaining 10 products continue to be under investigation and are included in the 23 existing drug products under investigation reported in Table 1 above.

[7] The criteria for commencing an investigation represent the standards the Board applies in order to allocate its resources to investigations as efficiently as possible. Their existence should not be construed as indicating that the Board accepts any deviation from the Guidelines. The Board is satisfied that its criteria assure all significant cases of pricing outside the Guidelines will be subject to investigation. In most instances where a price exceeds the maximum allowable price by an amount too small to trigger an investigation in one year, it is offset by a price below that which is permitted by the Guidelines in the following year. The Board expects the prices of all patented medicines to be within the Guidelines and evidence of persistent pricing outside the Guidelines, even by a small amount, may be used as a criterion for commencing an investigation.

iv) Enforcement Activities

Voluntary Compliance Undertakings[8] (VCU)
A VCU represents a form of dispute resolution used by the Board. 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. Since June 1993, the Board has approved 15 voluntary compliance undertakings to reduce prices and offset excess revenues of $12 million. Most of this was offset through payments to the Government of Canada.

Humalog (insulin Lispro), Eli Lilly Canada Inc.

In 1998, the Board approved a Voluntary Compliance Undertaking by Eli Lilly Canada Inc. to reduce the manufacturer's price of Humalog by 23%, from $30 to $23. A detailed report on the Humalog VCU appears in last year's Performance Report.

Pursuant to the VCU, Lilly undertook to make a payment to the Government of Canada to offset excess revenues of $666,824. This amount is included in the $12 million mentioned earlier.

Advance Ruling Certificate (ARC)
Under subsection 98(4) of the *Patent Act*, the Board may, upon application by a patentee, issue an ARC. An ARC is a non-binding certificate stating that the Board is satisfied that the selling or proposed selling price of a patented medicine would not give grounds for an order under the *Act*.

The Board received one application for an ARC in 1998-99, from Pfizer Canada Inc. regarding the price of Viagra. On March 29, 1999 the Board issued an ARC certifying that Pfizer's proposed price for Viagra complied with the *Patent Act* in that it did not exceed the prices of other drugs used to treat the same disorder.

Public Hearings
Following an investigation by Board staff in 1998-99, 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 sold at an excessive price.

[8] Under the Compliance and Enforcement Policy, patentees are given an opportunity to make a Voluntary Compliance Undertaking (VCU) when Board staff conclude, following an investigation, that a price appears to have exceeded the Guidelines. The 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. 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.

3.4 Trends in Manufacturers' Prices of All Medicines

3.4.1 Manufacturers' Prices and Volume of Patented Drugs Sold

> *The principal reason for the increase in claim cost is the replacement of older, lower cost drugs by newer, higher cost drugs. Added to this factor is the impact of larger prescriptions and a shift in the consumption patterns of existing drugs. As a result of these factors, the annualized increase in the cost per prescription is 7.5%,* ***while the actual prices of a representative sample of drugs decreased by 0.8% compounded annually.***
>
> *Analysis of Drug Claim Costs 1993-1997*
> Green Shield

The PMPRB maintains the Patented Medicine Price Index (PMPI)[9], 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. Because the PMPI is derived from the net prices charged by manufacturers, it provides a precise measure of price changes for patented medicines as reported to the PMPRB.

In 1998 patentees reported total factory-gate sales of patented drugs of $4.3 billion. This represents an annual increase of 18.9% from 1997. Sales of patented drugs accounted for over 55% of manufacturers' sales of all drugs, up from 45% in 1996.

In 1998, the manufacturers' prices for patented medicines which were on the market the previous year, as measured by the PMPI, declined by 0.1%, on average. At the same time, however, the quantities of patented drugs sold increased by about 16%. In other words, while total sales of patented drugs increased by 18.9% in 1998, 85% of that increase was attributable to an increase in the quantity of drugs sold over the previous year. About 15% of the increase in patented drug expenditures was attributable to the introduction of new drugs.[10]

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 41% and 55% of total sales since 1990. 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.

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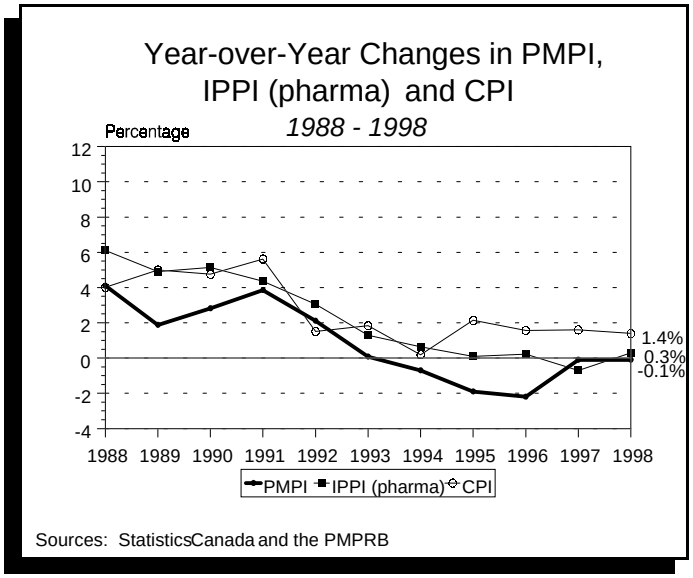
[9] See the PMRPB's *A description of the Laspeyres methodology used to construct the Patented Medicine Price Index (PMPI)*, April, 1997, for an explanation of the PMPI.

[10] PMPRB, *Annual Report 1998*

3.4.2 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. Figure 1 shows that prices of patented drugs, as measured by the PMPI, have not increased more than the CPI in every year since 1988 with the exception of 1992.[11] In 1998, consumer prices increased by 1.4% while the prices of patented drug products fell by an average of 0.1%.

FIGURE 1



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, market forces and the policies of provincial governments and private insurers 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, including both patented and non-patented drugs. In 1998, the IPPI (pharma) decreased by 0.3%.

As summarized in Figure 2, on the next page, from 1988 to 1998, the IPPI (pharma) has increased on average by 2.0% 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 0.9% per year.

[11] 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.*

Figure 2 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 the prices of all drugs relative to the CPI coincided with the introduction of federal price regulation of patented drugs. Patented drugs have represented 43.2% and 45.0% of manufacturers' sales of all drugs from 1990 to 1996 but rose sharply in 1997 and 1998 to 52.3% and 55.1% respectively.[12]

FIGURE 2

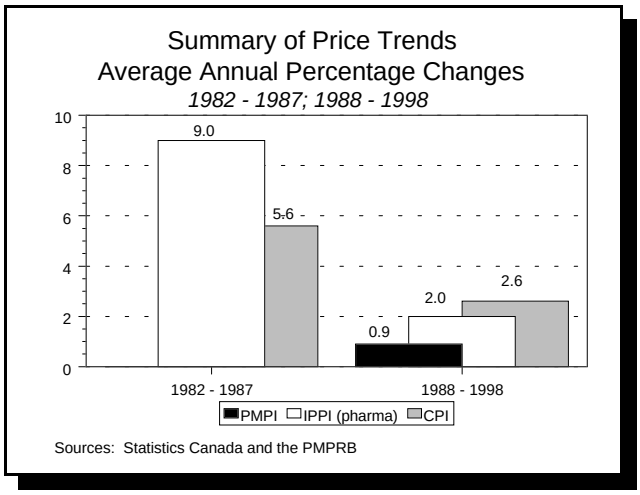


TABLE 2 - Manufacturers' Sales of All Drugs and Patented Drugs, 1990 - 1998

Year	Total		Patented		Patented Drugs as
	Sales ($billions)	Change* (%)	Sales ($billions)	Change* (%)	Percentage of Total
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, Statistics Canada and IMS Canada

* Percentage changes reflect exact values and not rounded values.

[12] PMPRB, *Annual Report 1998*

3.4.3 Relationship of Canadian Prices to Foreign Prices: Past and Present

One way of examining the trends in price levels of drugs, 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 three figures show the relationship between Canadian prices of patented drugs and foreign prices over time.

FIGURE 3

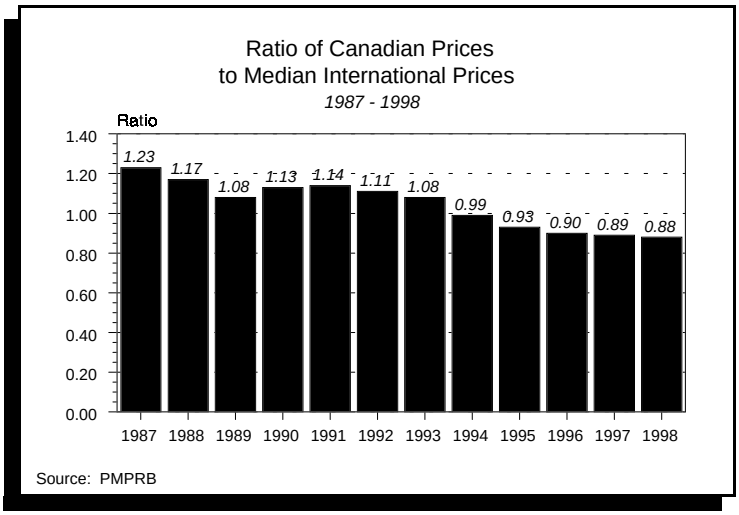


Figure 3 shows the relationship between the prices of patented medicines in Canada and the prices in the seven countries used for price comparison purposes, as listed in the *Patented Medicines Regulations*, over the period from 1987 to 1998. It shows that the average ratio of Canadian prices to median foreign prices has declined from 1.23 in 1987 to 0.88 in 1998. In other words, Canadian prices for patented drugs have declined from 23% above the median of foreign prices to approximately 12% below. This calculation is based on a revenue-weighted average of the ratio of the Canadian price to the median international price for each patented drug product sold in the year.

FIGURE 4

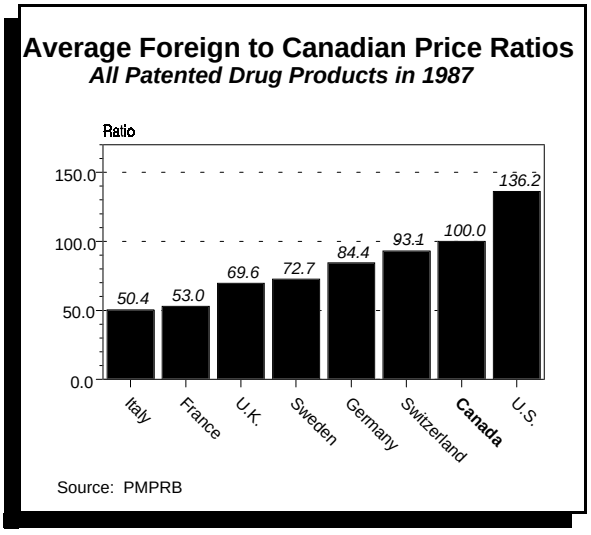
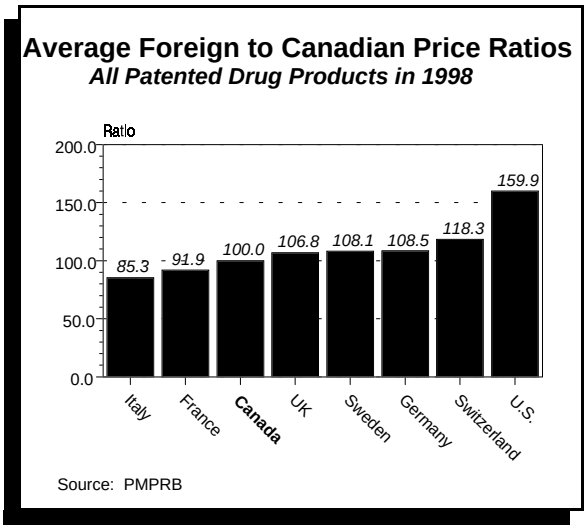


FIGURE 5



In 1987, Canadian prices were, on average, below those in the U.S. but above the prices in all other countries. As shown in Figure 4, Canadian prices were, on average, 36% below those in the U.S., but they were almost twice as high as prices in Italy and France. Eleven years later there has been a dramatic change. As shown in Figure 5, by 1998 Canada is ranked third lowest. Prices in the U.S., Switzerland, Sweden, Germany and the U.K. were higher, on average, while those in Italy and France were lower. With the exception of the U.S., the data appear to show an increased trend towards a convergence of prices for patented drugs in this group of countries.

In his report, the Auditor General of Canada noted practical constraints in performing international price comparisons and said, ". . . in approximately 20 percent of the cases, the only foreign country selling the same drug was the United States, which has the highest drug prices overall." The Board is currently consulting with stakeholders on how to use prices listed in the U.S. Department of Veteran Affairs formulary in future international price comparisons.

The Board has formally brought the legislative and regulatory concerns of the Auditor General and stakeholders to the attention of the Minister of Health in its *Road Map for the Next Decade* in September 1998 and a report on December 7, 1998.

In a letter dated March 3, 1999, the Minister of Health stated that the F/P/T Task Force on Pharmaceutical Prices would continue its comprehensive examination of drug price issues including the countries the Board is directed to use for international price comparisons.

3.5 Pharmaceutical Research-and-Development (R&D) Expenditures[13] of Patentees in Canada

With the adoption of the 1987 amendments to the *Patent Act*, the Pharmaceutical Manufacturers Association of Canada (PMAC)[14] 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.

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.

3.5.1 R&D-to-Sales Ratio

Total sales by manufacturers of all drugs in Canada increased over 11.4% to $7.8 billion in 1998, while sales of patented drug products increased by over 18.9% to $4.3 billion. The 74 patentees reported total revenues of $7.0 billion from Canadian sales of patented and non-patented drugs in 1998, up 10.9% over 1997. 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.

The ratio of R&D expenditures to sales revenues for the patented pharmaceutical industry was 11.5% in 1998, unchanged from 1997. The ratio for the 36 companies that were members of the PMAC was 12.7% in 1998, down from 12.9% in 1997.

As shown in Table 3, of the 74 reporting companies, 14 companies reported no R&D in 1998 compared to 18 in 1997. Sales revenues for companies with no R&D totalled $273.1 million in 1998 accounting for 3.9% of total sales revenue for the

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[13] 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.

[14] As of May 1, 1999, the Pharmaceutical Manufacturers Association of Canada changed its name to Canada's Research-Based Pharmaceutical Companies.

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; 34 companies in 1998 as compared to 32 in 1997. Total sales revenues for this group were $2,449.3 million in 1998 up from $1,879.8 million in 1997. The sales revenues for companies with ratios of 10% or more increased by 4.4% from $4,073.4 million in 1997 to $4,251.3 million in 1998.

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	1998			1997		
	Number of Reporting Companies	Total Sales Revenues ($M)	%	Number of Reporting Companies	Total Sales Revenues ($M)	%
0%	14	273.1	3.9	18	335.2	5.3
0% - 10%	34	2449.3	35.1	32	1879.8	29.9
> 10%	26	4251.3	61.0	25	4073.4	64.8
Total	**74**	**6973.7***	**100.0**	**75**	**6288.4***	**100.0**

Source: PMPRB
* These sales revenues do not include generic sales.

Table 4 shows how current expenditures on R&D in 1998 were allocated among basic, applied, and other qualifying R&D. Total current expenditures on R&D rose by 10.4% in 1998.

Spending on basic research was $146.8 million or 19.6% of the total. Basic research is defined as work that advances scientific knowledge without a specific application in view. The lion's share of R&D spending continued to be on applied research, $458.0 million or 61.1% 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 79.3% of total applied research expenditures, $363.3 million, while manufacturing process accounted for $63.4 million, or 13.9% of the total, and pre-clinical trials accounted for $31.3 million or 6.8% of the total. Other qualifying research, which accounted for 19.4% of total expenditures in 1998, includes drug regulation submissions, bioavailability studies and Phase IV clinical trials.

TABLE 4 – Current R&D Expenditures* by Type of Research, 1998 and 1997

Type of Research	1998		1997		Change in Expenditures
	$M	**%**	**$M**	**%**	1998 / 1997 %
Basic	146.8	19.6	140.4	20.7	4.6
Applied	458.0	61.1	421.3	62.0	8.7
Other Qualifying	145.3	19.4	117.5	17.3	23.7
Total	**750.1**	**100.0**[1]	**679.2**	**100.0**	**10.4**

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

In 1998, R&D spending increased in all parts of Canada with the exception of the Yukon and the Northwest Territories. There was no significant change in the regional distribution of R&D spending in 1998. As shown in Table 5, more than 86% of total expenditures continued to be made in Ontario and Québec.

TABLE 5 – Current R&D Expenditures* by Location, 1997 and 1998

Location of R&D	1998		1997		Change in Expenditures
	$M	**%**	**$M**	**%**	1998 / 1997 %
Atlantic Provinces	19.0	2.5	16.0	2.4	18.8
Quebec	319.2	42.6	290.6	42.8	9.8
Ontario	329.7	44.0	296.6	43.7	11.2
Western Provinces	82.2	11.0	76.0	11.2	8.2
Yukon and N.W.T.	0.02	0.0	0.17	0.0	-88.2
Total	**750.1**[1]	**100.0**[1]	**679.2**[1]	**100.0**[1]	**10.4**[1]

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

3.6 Report on the Consultations: *Road Map for the Next Decade*

On September 14, 1998, the Board honoured its commitment to report on its year-long consultations by releasing the *Road Map for the Next Decade*. Among other things, it reflects the Board's commitment to respond to stakeholders' suggestions that it adapt its processes and methodologies to be more publicly accountable and transparent and to provide more opportunities for stakeholder input. In his report the same month, the Auditor General said, "We are fully supportive of this initiative."

A number of actions were taken with the publication of the *Road Map*: The Board released its first Research Agenda, a new consultation policy, a comprehensive report on drug price trends, a detailed report on the verification of foreign price information for European countries, and it announced an alternative approach to regulating prices of veterinary drugs. In addition, the Board announced its first Stakeholders Meeting which took place on November 20, 1998. The purpose of the meeting was to obtain feedback from the stakeholders on the *Road Map*, the Report of the Auditor General and the Research Agenda. At the Stakeholders' meeting in November 1998, stakeholders agreed the Board was on the right track.

The Research Agenda outlines those areas where the Board has or will consult with stakeholders on matters that may result in adjustments to its policies and procedures. The Research Agenda will form part of the PMPRB's annual planning process and will report its areas of priority for the coming year.

The Board is fully committed to implementing the initiatives in the *Road Map*. The *Road Map* also announced further consultations on specific issues as well as the research agenda. In February, the Board established a Working Group on Price Review Issues to review, analyze and provide reports for the Board's consideration on:

- the use of the U.S. Department of Veteran Affairs (DVA) formulary prices in the international price comparison;
- the price review process for new patented drug products; and
- the guidelines for category 3 drug prices[15].

The Working Group consists of 12 members representing the provinces, consumers, seniors, health associations, the medical profession and the pharmaceutical industry. Stakeholders will be consulted on any proposed changes to the Guidelines or policies before the Board adopts the changes.

[15] For definition of category 3, see Chapter 3, subsection 3 of the *Compendium of Guidelines, Policies and Procedures*

Section IV Consolidated Reporting

4.1 Year 2000 Readiness

The PMPRB does not have a government-wide mission critical system. The system which is critical to the PMPRB's mandate is Year 2000 compliant. The PMPRB has also completed its Year 2000 Business Continuity Plan.

Section V Financial Performance

The tables in this section provide a financial overview of the Patented Medicine Prices Review Board's (PMPRB) performance. Tables 1 and 2 address PMPRB's initial spending plans, total financial authorities and actual expenditures. Table 3 - Historical Comparison of Total Planned Spending to Actual Spending provides an historical perspective on the way resources are used by the Board. Table 7 - Non-Respendable Revenues identifies revenues that the Board receives which are non-respendable.

Financial Table 1:

Financial Requirements by Authority ($ thousands)				
		1998-99		
Vote		**Planned Spending**	**Total Authorities**	**Actual**
	Patented Medicine Prices Review Board			
25	Program Expenditures	2698.0	2978.5	**2617.6**
(S)	Contributions to employee benefit plans	420.0	420.0	**420.0**
	Total Department	**3118.0**	**3398.5**	**3037.6**

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

Financial Table 2:

Departmental Planned versus Actual Spending ($ thousands)			
	1998-99		
Patented Medicine Prices Review Board	**Planned**	**Total Authorities**	**Actual**
FTEs	34	34	**30**
Operating	3118.0	3398.5	**3037.6**
Capital	-	-	**-**
Voted Grants & Contributions	-	-	**-**
Subtotal: Gross Voted Expenditures	-	-	**-**
Statutory Grants and Contributions	-	-	**-**
Total Gross Expenditures	**3118.0**	**3398.5**	**3037.6**
Less:			
Respendable Revenues[1]	-	-	**-**
Total Net Expenditure	**3118.0**	**3398.5**	**3037.6**
Other Revenues and Expenditures			
Non-respendable Revenues[2]	-	-	**666.8**
Cost of services provided by other Departments	648.0	648.0	**648.0**
Net Cost of the Program	**3766.0**	**4046.5**	**3018.8**

[1] These revenues were formerly called “Revenue Credited to the Vote”
[2] These revenues were formerly called “Revenue Credited to General Government Revenues”

Financial Table 3:

Historical Comparison of Departmental Planned versus Actual Spending ($ thousands)					
			1998-99		
	Actual 1996-97	Actual 1997-98	Planned Spending	Total Authorities	Actual
Patented Medicine Prices Review Board	3101.0	2899.0	3118.0	3398.5	**3037.6**
Total	**3101.0**	**2899.0**	**3118.0**	**3398.5**	**3037.6**

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

Financial Table 7:

Revenues Credited to the Non-Respendable Revenues ($ thousands)					
			1998-99		
	Actual 1996-97	Actual 1997-98	Planned Revenues	Total Authorities	Actual
Patented Medicine Prices Review Board	-	-	-	-	-
Sub total	-	-	-	-	-
Unplanned	-	1200.0	-	-	**666.8**
Total Non-respendable Revenues[1]	-	**1200.0**	-	-	**666.8**

[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.

Section VI Other Information

6.1 Contacts for Further Information and/or PMPRB Web Site

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

If you have any questions or comments, please contact:
Sylvie Dupont
Box L40
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
K1P 1C1

Tel: (613) 954-8299
E-mail: sdupont@pmprb-cepmb.gc.ca

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

6.2 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

6.3 Statutory Annual Reports and Other PMPRB Reports

ANNUAL REPORT Series *(1989 to 1998)*

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

- Corporate Brochure - *Controlling the Prices of Patented Medicines in Canada*