Patented Medicine Prices Review Board

1999-2000

Estimates
A Report on Plans and Priorities

Approved

Minister of Health Canada

Preface

This document is a report to Parliament indicating how the resources voted by Parliament will be spent. As such, it is an accountability document that contains several levels of detail to respond to the various needs of its audience.

The Report on Plans and Priorities for 1999-2000 is based on a revised format intended to focus on the higher level, longer term plans of the Board.

The document is divided into four sections:

- *Messages*;
- *Overview;*
- *Plans, Priorities and Strategies; and*
- *Supplementary Information*

It should be noted that, in accordance with the Operating Budget principles, human resource consumption reported in this document will be measured in terms of full-time equivalents (FTEs).

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Section I
Messages

A. Chairperson's Message

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). The revisions increased patent protection for pharmaceutical products. 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 regulating the maximum prices charged by manufacturers of patented medicines to ensure that 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.

The 1998-99 fiscal year proved to be one of the most challenging and important years in the history of the Board with the conclusion of a year-long public consultation on how it fulfils its mandate. The *Road Map for the Next Decade*, released in September, reports on the results of the consultations and sets out an action plan to address the issues raised. In particular, the *Road Map* demonstrates the Board's commitments to continue to find more ways to carry out its responsibilities in a transparent and accountable manner. Also in 1998, the Auditor-General of Canada tabled a report on the PMPRB which made a number of recommendations consistent with the objectives of the *Road Map*.

The implementation of the *Road Map for the Next Decade* and the Auditor General's recommendations will be the key factors in the strategic direction of the Board in coming years.

Robert G. Elgie
Chairperson

B. Management Representation Statement

MANAGEMENT REPRESENTATION

Report on Plans and Priorities 1999-2000

I submit, for tabling in Parliament, the 1999-2000 Report on Plans and Priorities (RPP) for the Patented Medicine Prices Review Board.

To the best of my knowledge the information:

- Accurately portrays the Board's mandate, plans, priorities, strategies and expected key results of the organization.
- Is consistent with the disclosure principles contained in the *Guidelines for Preparing a Report on Plans and Priorities*.
- Is comprehensive and accurate.
- Is based on sound underlying departmental information and management systems.

I am satisfied as to the quality assurance processes and procedures used for the RPP's production.

The planning and reporting structure on which this document is based has been approved by Treasury Board Ministers and is the basis for accountability for the results achieved with the resources and authorities provided.

Name: _____
Wayne D. Critchley
Executive Director

Date: _____

Section II
Overview

A. Mandate, Roles and Responsibilities

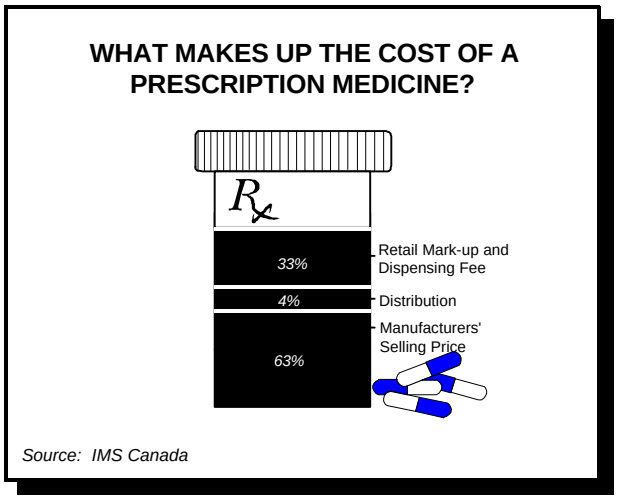
The Patented Medicine Prices Review Board (PMPRB) is an independent quasi-judicial body created by Parliament as a result of revisions to the *Patent Act* in 1987 (Bill C-22) which increased patent protection for pharmaceutical products. The PMPRB represents a strategic component of federal policy to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

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*** ★ ***the ratio of research-and-development expenditures to sales revenues for individual patentees and for all pharmaceutical patentees in Canada.***
Inquiry	***To inquire into any matter which may be referred to it by the Minister of Health.***

The PMPRB's jurisdiction includes both prescription and non-prescription patented medicines sold in Canada for human and veterinary use. The price reviewed by the PMPRB is the price at which the manufacturer sells the product to wholesalers, hospitals or pharmacies. The manufacturers' selling price represents approximately 63% of the total cost of a prescription medicine (see figure 1). The PMPRB's jurisdiction includes patented medicines marketed or distributed under voluntary licences. The Board has no authority to regulate the price of non-patented drugs, including generic drugs sold under compulsory

FIGURE 1



licences, and does not have jurisdiction over prices charged by wholesalers or retailers nor pharmacists' dispensing fees. The sale of patented drugs represented 52.3% of manufacturers' sales of all drugs in Canada in 1997.[1]

The PMPRB promotes Canadians' access to needed medications by ensuring that prices of patented drugs 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.

B. Program Objective

The objective of the Patented Medicine Prices Review Program is to protect consumer interests and contribute to Canadian health care by ensuring that prices charged by manufacturers of patented medicines are not excessive.

C. Operating Environment

Rising Health Care Costs

Since the 1980's, spending on drugs has grown faster than other major components of the health care system, including physicians and hospitals. As in past years, the pressures of cost containment in health care generally, and for pharmaceuticals specifically, continue to mount. A perception exists that the Board regulates the prices of all drugs. This lack of general public knowledge about the Board leaves a significant expectation gap between what it actually does and what the public expects that it does to regulate the prices of medicines and protect consumers.

Drug Patent Legislation

During the Board's consultations with Canadians in 1998, many expressed dissatisfaction with the government's policy regarding pharmaceutical patent protection. They believe this policy has led to higher prices and costs. As a result, many consumer organizations and others would like to see legislative and regulatory changes in a number of areas.

Echoing a recommendation of the Standing Committee on Industry in 1997, many stakeholders wanted the PMPRB to have a larger role. In addition to controlling the

[1] PMPRB Tenth Annual Report for the Year Ended December 31, 1997, Table 1

prices charged by manufacturers of patented drugs, they would like the Board to have more influence over total drug expenditures in Canada. Many think that the regulation of manufacturers' prices should apply to all drugs, including non-patented single-source drugs and generic drugs.

In addition, many stakeholders have questioned the appropriateness of the current basket of comparator countries,[2] as set out by the government in the *Patented Medicines Regulations*, that are used by the Board for price review purposes. There are concerns about the continued inclusion of the United States (U.S.) In the basket because the U.S. has no regulatory system that affects the pricing of pharmaceuticals. Some of the alternatives suggested include broadening the basket of countries used for comparison purposes to include all OECD countries[3] or including countries based on their similarity in the level of pharmaceutical research and development to that of Canada. The basket of countries used for price review purposes is a matter of government policy. The Board has passed on the concerns of stakeholders on these matters to the government through the *Road Map for the Next Decade*.

Because criticism of the government's patent policy is sometimes expanded to include the program administered by the PMPRB, its mandate and performance will continue to come under scrutiny.

Federal/Provincial/Territorial Initiatives

The federal government has made a commitment to work with the provinces - and others - on pharmaceutical issues. Both levels of governments in Canada have acknowledged the problem of drug costs - and access to drugs - as a national concern. In 1996, at the meeting of the Federal/Provincial/Territorial (F/P/T) Ministers of Health a task force was established to look into the underlying issues, including pricing and the increasing use of drugs within our health care system.

The PMPRB was asked and agreed to participate by providing information and expertise and conducting research for the Federal/Provincial/Territorial Task Force on Pharmaceutical Prices.

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[2] The basket of countries used for international price comparisons by the PMPRB, as set out in the Schedule of the *Patented Medicine Regulations, 1994* are: France, Germany, Italy, Sweden, Switzerland, United Kingdom, and United States.

[3] The OECD is made up of a group of 29 countries from around the world, encompassing wide variations in the type of health care systems used (including the means by which medications reach patients); the level of the population's health; and the levels of pharmaceutical research and development. Canada and the seven countries listed in the *Regulations* are members of the OECD.

The Road Map for the Next Decade

After a year of extensive consultations on questions related to how it carries out its mandate, the Board released the *Road Map for the Next Decade* in September 1998. The report summarizes the input from stakeholders, and sets out an action plan to address the issues raised.

As evidenced by the stakeholders participation in the consultation process, there is much interest in the role of the Board. The PMPRB will focus on stakeholders' interest in improving the transparency and accountability of the price review process and their desire for broader and more frequent consultations. In addition, the Board will review certain aspects of its guidelines and methodologies. A number of actions were taken with the publication of the *Road Map*. For example, the Board released a new Consultation Policy, published its Research Agenda for consultation for the first time and issued papers on several issues.

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

To facilitate consultation on some of the issues identified in the Research Agenda, the PMPRB is establishing the PMPRB Working Group on Price Review Issues in 1999. The Working Group's mandate, over the next two years, is to review, anlayze and provide reports for the Board's consideration, on the following three issues:

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

Non-industry stakeholders expressed concerns about their ability to be consulted on an equal footing with the pharmaceutical industry because of resources. While increased consultations are critical, the Board does not currently have the resources to cover expenses for non-industry stakeholders. As a result of the *Road Map* and the Auditor General's report, the Board is implementing a more extensive consultation process for the current and future years. This will be a challenge for the Board's financial and human resources.

Audit by the Auditor General

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 PMPRB responded positively to almost all of the recommendations in the report. The Auditor General will do a follow-up on his recommendations in approximately two years time.

In his report the Auditor General noted that the Board exerted a constraining influence on the prices of patented medicines sold in Canada. Moreover, he found that the Board's price guidelines were generally applied rigorously. The Auditor

General also stated that he fully supported the direction of the Board's current consultations. He also encouraged the Board to continue to improve its communications, and where possible, to use other vehicles or stakeholders as part of its communications strategy to enhance public awareness of its work.

The Auditor General also identified a number of concerns and made recommendations for improvement. Among other things, he was concerned that the scope of the Board's jurisdiction and the limitations of its consumer protection role were not well understood. He was concerned that a study in 1997, "The Impact of Federal Regulation of Patented Drug Prices" overstated the Board's impact because it did not quantify the effect of other factors in constraining drug prices in Canada. He identified a small number of instances where he felt the reasons for the Board's decisions were not clear and transparent and he encouraged the Board to find cost-effective ways to check the accuracy of price information and to improve the reporting of trends in drug prices and R&D expenditures. However, the main issue identified by the Auditor General involved aspects of the legislative framework.

The Auditor General observed that some requirements in the legislation and regulations are difficult to apply in practice, and a review of their continued relevance needs to be considered. As he recommended, the Board has brought these concerns to the attention of the Minister of Health and has indicated its readiness to work with the Government in addressing improvements to the legislation.

Most of the Auditor General's other recommendations were addressed through the *Road Map* or are reflected in the Research Agenda.

D. Financial Spending Plan

Patented Medicine Prices Review Board - Financial Spending Plan				
(thousands of dollars)	Forecast Spending 1998-99*	**Planned Spending 1999-2000**	Planned Spending 2000-01	Planned Spending 2001-02
Patented Medicine Prices Review Board	3,399	**3,161**	3,152	3,152
Net Program Cost	3,399	**3,161**	3,152	3,152
Plus: Cost of Services Provided by other Departments	648	**648**	648	648
Net Cost of the Program	4,047	**3,809**	3,800	3,800
Human Resources (FTE)	34	**34**	34	34

* Reflects the best forecast of total planned spending to the end of the fiscal year.

Section III
Plans, Priorities and Strategies

A. Summary of Plans and Priorities

The following table lists the key results commitments included in the October 1998 Report by the President of the Treasury Board. In addition to the commitments published in the President's report, the PMPRB is committing to be a more transparent and accountable public agency through the implementation of the *Road Map for the Next Decade*.

Mandate: Regulatory ***to provide Canadians with:***	**(Strategies)** *to be demonstrated by:*
assurance that manufacturers' prices for patented medicines sold in Canada are not excessive	• review of the manufacturers' price of 100% of the patented medicines sold in Canada each year • favourable comparison of the annual percentage change in the Patented Medicine Price Index (PMPI) to the Consumer Price Index (CPI) • manufacturers' price for new and existing patented medicines no greater than manufacturers' prices charged in other countries • percentage of patented medicines priced within the Guidelines
Mandate: Reporting ***to provide Canadians with:***	**(Strategies)** *to be demonstrated by:*
information on trends in manufacturers' prices of all medicines sold 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

Mandate: Reporting ***to provide Canadians with:***	**(Strategies)** *to be demonstrated by:*
information on pharmaceutical research-and-development expenditures of patentees in Canada	• comprehensive publication in the annual report of: - the ratio of R&D expenditures to sales revenues for each patentee and the industry as a whole - R&D expenditure by location and by type of research
Transparency & Accountability ***to provide Canadians with:***	**(Strategies)** *to be demonstrated by:*
a more transparent and accountable public agency recognized as adding value to pharmaceutical policy in Canada	• implementing the *Road Map* for the Next Decade • responding to the Auditor General's recommendations

B. Details by Program and Business Line

Patented Medicine Prices Review Program

The *Patent Act* identifies the factors the Board shall take into account in determining if the price of a patented medicine is excessive.[4] 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.

These factors have been interpreted by the PMPRB in detailed guidelines which have been developed in consultation with the PMPRB's stakeholders including ministers of health and representatives of consumers and the pharmaceutical industry.

The PMPRB gathers information on the prices charged by manufacturers for their patented medicines sold in Canada, analyzes that data and takes action, when required, to reduce prices which are, in the opinion of the Board, excessive. Price reductions are accomplished as follows: through voluntary action by patentees;

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

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.

The PMPRB relies on voluntary compliance wherever possible since it is 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 PMPRB expects to find a large percentage of the prices for new and existing patented medicines will be priced within the Guidelines. In those cases where the manufacturers' price exceeds the Guideline, the PMPRB will initiate enforcement activities as required.

The PMPRB also reports annually 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.

Under the *Regulations*, patentees are required to file information showing the manufacturers' prices, net of discounts, rebates and other price concessions for all patented medicines. The PMPRB maintains the Patented Medicine Price Index (PMPI), an index of manufacturers' prices for patented drugs as reported to the PMPRB by patentees. The index measures the average change from the previous year in the manufacturers' prices of patented drugs sold in Canada.[5] Because of the limits established by the guidelines, the PMPRB expects to find a favourable comparison of the annual percentage change in PMPI to the annual change in the CPI.

In an environment where the operations and mandate of the Board have taken on a level of importance and visibility beyond what it has known in the past, the Board recognizes the need to make changes to the way it conducts its business. As a first step, the Board has increased its dialogue with its stakeholders through increased consultations.

This year, the PMPRB will continue to focus on being a more transparent and accountable public agency recognized as adding value to pharmaceutical policy in Canada. To this end, one of the initiatives this year is the establishment of a Working Group on Price Review Issues to review, analyze and provide reports on a number of issues within the Board's mandate.

It is expected that the mandate of the Working Group will continue for up to two years. The success of the Working Group is largely dependent on stakeholder participation. Some stakeholders have stated that without funding for travel

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

expenses they will be unable to participate. The Board is seeking ways and means to address this pressure to ensure the continued success of consultations and stakeholder participation in the current year and in future years.

In the planning period, the Board will make every effort to ensure that Canadians are kept informed of the main aspects of the Board's activities and the trends in the prices of patented drugs. In this context, the Board is increasing its communications efforts and is following up on the interest expressed by a number of stakeholders during the consultation process to create partnerships for the dissemination of information.

Section IV
Supplementary Information

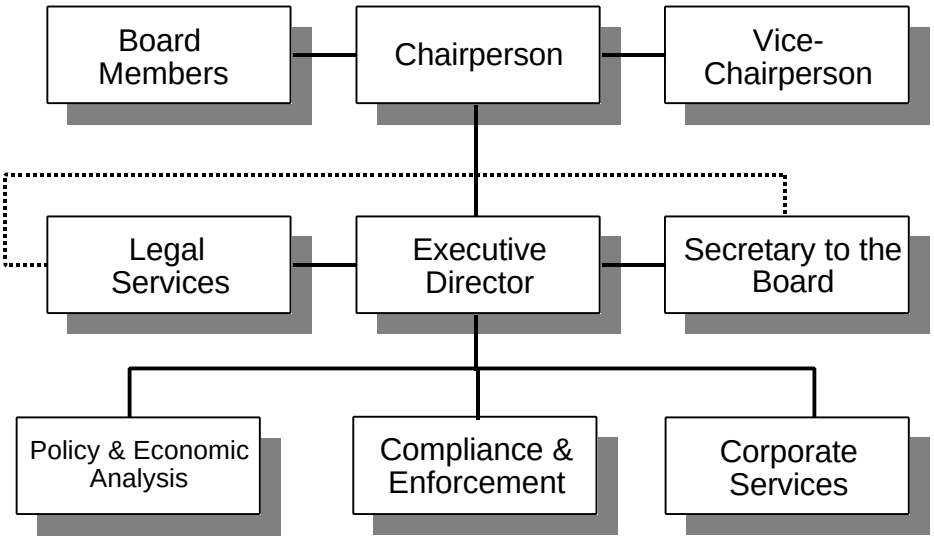
Table 1: Spending Authorities - Ministry Summary Part II of the Estimates

Vote	(thousands of dollars)	**1999-2000 Main Estimates**	1998-99 Main Estimates
	Patented Medicine Prices Review Board		
	Patented Medicine Prices Review Program		
25	Program expenditures	2,750	2,698
(S)	Contributions to employee benefit plans	411	420
	Total Agency	3,161	3,118

Personnel Information

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

Figure 2: Organizational Structure of the PMPRB



Additional Financial Information

Table 2: Details of Financial Requirements by Object				
(thousands of dollars)	Forecast Spending 1998-99	**Planned Spending 1999-2000**	Planned Spending 2000-01	Planned Spending 2001-02
Personnel				
Salaries and wages	1,832	**2,054**	2,051	2,051
Contributions to employee benefit plans	420	**411**	410	410
	2,252	**2,465**	2,461	2,461
Goods and services				
Transportation and communications	222	**110**	110	110
Information	74	**48**	48	48
Professional and special services	501	**339**	334	334
Rentals	40	**5**	5	5
Purchased repair and upkeep	20	**10**	10	10
Utilities, materials and supplies	135	**94**	94	94
Other subsidies and payments	155	**90**	90	90
	1,147	**696**	691	691
Capital				
Minor capital*	0	**0**	0	0
Total Expenditures	3,399	**3,161**	3,152	3,152

* In accordance with the Operating Budget principles, minor capital is interchangeable with Personnel and Goods and Services expenditures.

Table 3: Net Cost of Program for the Estimates Year

(thousands of dollars)	Patented Medicine Prices Review Program
Gross Planned Spending	3,161
Plus:	
Services Received without Charge	
Accommodation provided by Public Works and Government Services Canada (PWGSC)	512
Employee benefits covering the employer's share of insurance premiums and costs paid by the Treasury Board Secretariat	136
Total Cost of Program	3,809
Less:	
Revenue Credited to the Vote	-
Revenue Credited to the CRF	-
Total Revenue	-
1999-2000 Estimated Net Program Cost	3,809

The Estimates of the Program include only expenditures to be charged to its voted and statutory authorities. Table 3 provides details of other cost items which need to be taken into account to arrive at the estimated total cost of the Program.

Other Information

Listing of Board Members

The Patented Medicine Prices Review Board consists of no more than five part-time members appointed by the Governor-in-Council. As of February 15, 1999 the Board members were:

Chairperson:

Robert G. Elgie, LL.B., M.D., F.R.S.C.(C)

Vice-Chairperson:

Réal Sureau, FCA

Members:

Ysolde Gendreau, B.C.L., LL.B., LL.M., Ph.D.

Anthony Boardman B.A.(hons.), Ph.D.