Patented Medicine Prices Review Board

1998-99

Estimates
A Report on Plans and Priorities

Approved

Minister of Health Canada

Preface

This document is a report to Parliament to indicate 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 1998-99 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 objective of the Patented Medicine Prices Review Board (PMPRB or Board) is to protect consumer interests and contribute to Canadian health care by ensuring that the prices charged by manufacturers of patented medicines are not excessive.

The mandate of the PMPRB does not cover all prescription drugs. It is limited to the prices charged by manufacturers of patented drugs (prescription and non-prescription), which account for approximately 45% of manufacturers' sales of all drugs.

The issue of rising drug costs in Canada remains a focus of legitimate concern and debate, as reflected by the deliberations and recommendations of the House of Commons Standing Committee on Industry which reviewed the *Patent Act Amendment Act, 1992*, Bill C-91, in 1997. The report of the Standing Committee, issued on April 24, 1997, underscored the concerns of Canadians about the cost of drugs and their impact on the health care system. It also touched on a number of key areas directly affecting the role and mandate of the PMPRB.

Subsequent to the release of this report, the PMPRB carried out a review and published a Discussion Paper in the fall of 1997. This Discussion Paper will form the basis of a formal consultation with Canadians. The purpose of the consultations is to examine the role, function and methods of the PMPRB with a view to obtaining input on issues of concern, that are within the Board's mandate and scope of activities. These consultations represent a response by the Board to a recommendation by the Standing Committee.

The consultations will continue in the first half of 1998 with a report planned for late summer 1998. The report is expected to propose operational changes to the PMPRB and may include proposals for changes to the Guidelines and other policies that would require further consultation before implementation.

Over the next three years, the PMPRB's priorities will continue to be to protect consumer interests by ensuring that the prices of patented drugs do not increase faster than the rate of inflation and by limiting the introductory prices of new patented drugs. The Board will also
focus on ways to more meaningfully engage its stakeholders in the development of its policies and reporting on drug price trends.

Robert G. Elgie
Chairperson

B. Management Representation Statement

MANAGEMENT REPRESENTATION
Report on Plans and Priorities 1998-1999

I submit, for tabling in Parliament, the 1998-99 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 PMPRB is an independent quasi-judicial body created by Parliament in 1987 under the *Patent Act.* The PMPRB protects consumer interests and contributes to Canadian health care by regulating the prices charged by manufacturers of patented medicines to ensure that they are not excessive.

The PMPRB reports to Parliament through the Minister of Health. The PMPRB's Annual Report is tabled in Parliament each year and includes a review of the PMPRB's major activities, analysis of the prices of patented medicines and of the price trends of all drugs, and reports on the R & D expenditures by patent-holding drug manufacturers. The Board is also responsible for inquiring into any matter which may be referred to it by the Minister of Health.

The PMPRB protects consumer interests and contributes to Canadian health care by regulating the prices charged by manufacturers of patented medicines to ensure they are not excessive.

The PMPRB's jurisdiction includes both prescription and non-prescription patented medicines sold in Canada for both 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. This manufacturer's price does not include wholesale or retail markups or dispensing fees.

The sale of patented drugs represents approximately 45% of the sale of all drugs[1]. The Board does not regulate the prices of non-patented drugs, including generic drugs sold under compulsory licences.

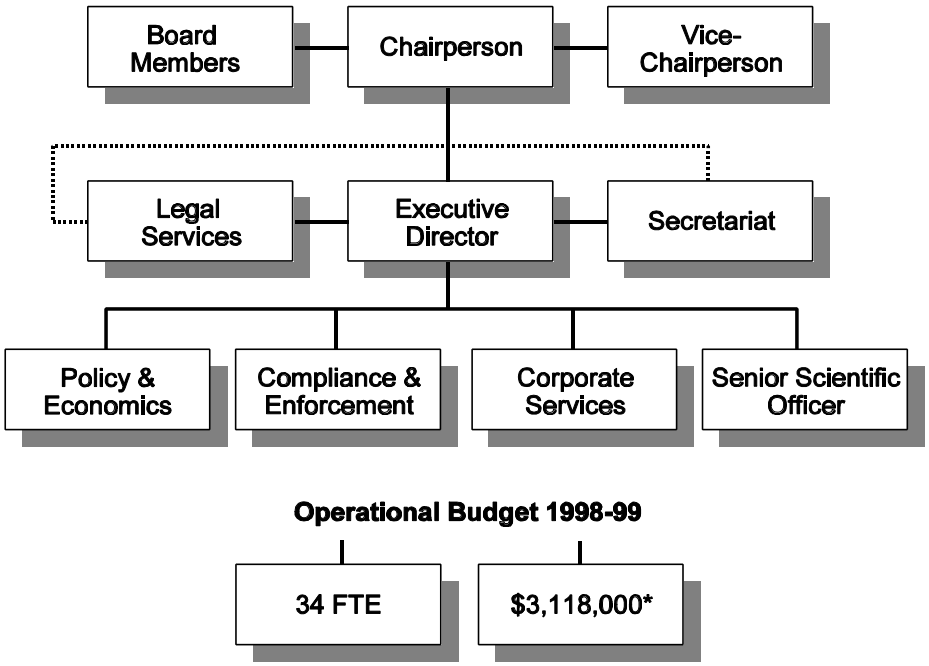
[1] PMPRB Ninth Annual Report for the Year Ended December 31, 1996

B. Program Objective

The objective of the Patented Medicine Price 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.

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 Economics, the Senior Scientific Officer, the Director of Corporate Services, the Secretary to the Board and Senior Counsel.

Figure 1: Organizational Structure of the PMPRB



* inclusive of statutory benefits of $420,000

C. Financial Spending Plan

Figure 2: Patented Medicine Prices Review Board - Financial Spending Plan

(thousands of dollars)	Forecast Spending 1997-98	**Planned Spending 1998-99**	Planned Spending 1999-2000	Planned Spending 2000-01
Patented Medicine Prices Review Board	3,143	**3,118**	3,116	3,111
Net Program Cost	3,143	**3,118**	3,116	3,111
Plus: Cost of Services Provided by other Departments	648	**648**	648	648
Net Cost of the Program	3,791	**3,766**	3,764	3,759

Section III
Plans, Priorities and Strategies

A. Summary of Plans and Priorities

The table below lists the PMPRB's key results commitments which were included in the October 1997 Report by the President of the Treasury Board. In addition, the PMPRB is adding, as a key result commitment for the 1998-99 fiscal year, to undertake and complete formal consultations with Canadians on how it fulfills its mandate.

(Plan) ***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
information on trends in manufacturers' prices of all medicines sold in Canada	• complete and accurate 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
information on pharmaceutical research-and-development expenditures of patentees in Canada	• complete and accurate 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

(Plan) ***to provide Canadians with:***	**(Strategies)** *to be demonstrated by:*
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

B. Details by Program and Business Line

Patented Medicine Prices Review Program

The objective of the Patented Medicine Prices Review Program is to protect consumer interests and contribute to Canadian health care by ensuring that prices of patented medicines are not excessive. This is done through the use of one business line which is the same as its program. 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; 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 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.

Under the *Patent Act*, the Board is required to consider the prices of medicines in other countries, the prices of similar 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 patented medicine is excessive. The *Act* allows 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.

External Factors Influencing the Business Line

The predominant external factor influencing the PMPRB is the continued increase in pharmaceutical costs within the Canadian health care system. Pharmaceuticals continue to be the fastest-growing component of health care expenditures due to several factors including: increased utilization of drugs, shifts by physicians from

prescribing cheaper drugs to more expensive ones and increases and changes in the population.

The growth in pharmaceutical expenditures as a proportion of total health expenditures is expected to continue in the longer term due to the development of important new medicines that replace other forms of medical intervention or new medicines which treat diseases which were previously untreatable.

Other external factors influencing the PMPRB are the recommendations of the Standing Committee on Industry, issued on April 24, 1997. The Committee's report underscored the concerns of Canadians about rising drug costs and touched on a number of key areas directly affecting the role and mandate of the PMPRB. Among other things, the Committee recommended that:

- The "mandate of the [PMPRB] be reviewed and strengthened" [by the Government];

- "To facilitate the public debate on pricing, usage and costs of drugs, as well as on pharmacare, the Committee recommends that the PMPRB consult with consumers, health care professionals, experts and the provinces to assess its current statistical reporting, and find out what other information it could provide to the public."[2]

In response to the latter recommendation, the Board launched an extensive public consultation process with the release of a Discussion Paper in November 1997. The results of the consultations in 1998 will undoubtedly affect the program.

The PMPRB's work is also directly affected by the volume of new drugs introduced to the market each year and the nature and quality of information available concerning their therapeutic and economic benefits. In addition, federal and provincial policies concerning pharmaceuticals, including regulatory approval and reimbursement plans, will impact on the PMPRB's activities.

Key Plans and Strategies

The PMPRB will continue to protect consumer interests by fulfilling its regulatory functions under the *Patent Act*.

In addition, the PMPRB will conduct formal consultations with its stakeholders on how it fulfills its mandate. The PMPRB is particularly interested in determining how it can improve the way it carries out its statutory responsibilities so as to ensure the confidence of Canadians and facilitate informed public debate on the key issues related to the pricing, usage and cost of drugs.

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[2] House of Commons Standing Committee on Industry. *Review of Section 14 of the Patent Act Amendment 1992 (Chapter 2, Statutes of Canada, 1993)*. Ottawa: Canada Communications Group. April 1997.

The PMPRB is committed to a review and renewal of its role, functions and methods within its mandate and scope of activities. The objectives of the review and renewal initiative are to:

- make the Board more relevant and responsive to its stakeholders' needs;
- achieve greater transparency, openness and awareness of the Board's activities; and
- identify opportunities to improve the price review process.

The information gathered through the consultations will provider greater insight into the needs of the PMPRB's stakeholders making it easier to identify solutions which will be more responsive and transparent to its stakeholders.

In the first quarter of 1998, Board members will travel across the country to hold public sessions with various stakeholders and other interested parties. Stakeholders will also have an opportunity to provide written submissions to the Board up to March 31, 1998. The Board will hear oral submissions at a public hearing on April 30, 1998.

The Board will evaluate the input from these consultations, analyze the issues, and prepare appropriate policy options. A report is planned for late summer 1998.

The report is expected to propose operational changes to the PMPRB and may include proposals for changes to the Guidelines and other policies that would require further consultation before implementation. The PMPRB and its staff will work toward positioning itself to implement necessary changes.

The Board is firmly committed to this process. While the outcome of the consultation process has yet to be determined, what remains clear and unchanging is the fundamental purpose of the PMPRB which is to protect the interests of Canadian consumers.

Expected Results

Over the planning period the PMPRB expects to:

- complete the review of introductory prices of all new patented drugs introduced for sale in 1998 to ensure compliance with the Guidelines;
- review prices of all existing patented drugs sold in Canada in 1998 to ensure compliance with the Guidelines;
- commence investigations in cases where prices are not compliant;
- obtain VCUs or commence hearings, when necessary;
- submit an annual report to the Minister by June 1998, on the Board's activities in 1997 including the price trends of all medicines sold in Canada and on the ratio of pharmaceutical R&D expenditures to sales for the pharmaceutical industry and individual patentees in Canada;

- provide pre-market advisory assistance to manufacturers of patented drug products to facilitate compliance with the Board's Guidelines; and
- provide a report on the results of its consultations.

Section IV
Supplementary Information

A. Profile of Program Resources

1. Spending Authorities

Figure 3: Spending Authorities - Ministry Summary Part II of the Estimates

Vote	(thousands of dollars)	**1998-99 Main Estimates**	1997-98 Main Estimates
	Patented Medicine Prices Review Board		
	Patented Medicine Prices Review Program		
25	Program expenditures	2,698	2,478
(S)	Contributions to employee benefits plan	420	339
	Total Agency	3,118	2,817

2. Financial Requirements by Object

Figure 4: Details of Financial Requirements by Object

(thousands of dollars)	Forecast Spending 1997-98	**Planned Spending 1998-99**	Planned Spending 1999-00	Planned Spending 2000-01
Personnel				
Salaries and wages	1,770	**1,999**	2,008	2,008
Contributions to employee benefit plans	339	**420**	422	422
	2,109	**2,419**	2,430	2,430
Goods and services				
Transportation and communications	190	**115**	110	110
Information	55	**50**	48	48
Professional and special services	389	**334**	329	324
Rentals	40	**5**	5	5
Purchased repair and upkeep	20	**10**	10	10
Utilities, materials and supplies	135	**95**	94	94
Other subsidies and payments	155	**90**	90	90
	984	**699**	686	681
Capital				
Minor capital*	50	**0**	0	0
Total Expenditures	3,143	**3,118**	3,116	3,111

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

3. Personnel Requirements

A profile of the Program personnel requirements is provided in Figure 5.

Figure 5: Details of Personnel Requirements (FTEs) [1]

	Forecast 1997-98	Planned 1998-99	Planned 1999-00	Planned 2000-01
Executive [2]	1	1	1	1
Scientific and Professional	9	9	9	9
Administrative and Foreign Services	17	17	17	17
Technical	4	4	4	4
Administrative Support	4	3	3	3
TOTAL	35	34	34	34

[1] Full-time equivalents (FTE) is a measure of human resource consumption based on average levels of employment. FTE factors out the length of time that an employee works during each week by calculating the rate of assigned hours of work over scheduled hours of work. FTEs are not subject to Treasury Board control but are disclosed in Part III of the Estimates in support of personnel expenditure requirements specified in the Estimates.

[2] Includes all employees in the EX-01 to EX-05 range.

4. Net Cost of Program

The Estimates of the Program include only expenditures to be charged to its voted and statutory authorities. Figure 6 provides details of other cost items which need to be taken into account to arrive at the estimated total cost of the Program.

Figure 6: Total Estimated Cost of the Program for 1998-99

(thousands of dollars)	Patented Medicine Prices Review Program
Gross Planned Spending	3,118
Plus: Services Received without Charge Accommodation provided by Public Works and Government Services Canada (PWGSC)	513
Employee benefits covering the employer's share of insurance premiums and costs paid by the Treasury Board Secretariat	135
Total Cost of Program	3,766
1997-98 Estimated Net Program Cost	3,791

B. Other Information

1. 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 December 31, 1997 the Board members were:

Chairperson:

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

Vice-Chairperson:

Réal Sureau, FCA

Members:

Judith L. Glennie, Pharm.,D.
Ysolde Gendreau, B.C.L., LL.B., LL.M., Ph.D.