ESTIMATES

Patented Medicine Prices Review Board Canada

2000-2001
Estimates

Part III – Report on Plans and Priorities

Canada

The Estimates Documents

Each year, the government prepares Estimates in support of its request to Parliament for authority to spend public monies. This request is formalized through the tabling of appropriation bills in Parliament. The Estimates, which are tabled in the House of Commons by the President of the Treasury Board, consist of three parts:

Part I – The Government Expenditure Plan provides an overview of federal spending and summarizes both the relationship of the key elements of the Main Estimates to the Expenditure Plan (as set out in the Budget).

Part II – The Main Estimates directly support the *Appropriation Act*. The Main Estimates identify the spending authorities (votes) and amounts to be included in subsequent appropriation bills. Parliament will be asked to approve these votes to enable the government to proceed with its spending plans. Parts I and II of the Estimates are tabled concurrently on or before 1 March.

Part III – Departmental Expenditure Plans which is divided into two components:

(1) **Reports on Plans and Priorities (RPPs)** are individual expenditure plans for each department and agency (excluding Crown corporations). These reports provide increased levels of detail on a business line basis and contain information on objectives, initiatives and planned results, including links to related resource requirements over a three-year period. The RPPs also provide details on human resource requirements, major capital projects, grants and contributions, and net program costs. They are tabled in Parliament by the President of the Treasury Board on behalf of the ministers who preside over the departments and agencies identified in Schedules I, I.1 and II of the *Financial Administration Act*. These documents are to be tabled on or before 31 March and referred to committees, which then report back to the House of Commons pursuant to Standing Order 81(4).

(2) **Departmental Performance Reports (DPRs)** are individual department and agency accounts of accomplishments achieved against planned performance expectations as set out in respective RPPs. These Performance Reports, which cover the most recently completed fiscal year, are tabled in Parliament in the fall by the President of the Treasury Board on behalf of the ministers who preside over the departments and agencies identified in Schedules I, I.1 and II of the *Financial Administration Act*.

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

Available in Canada through your local bookseller or by mail from
Canadian Government Publishing (PWGSC)
Ottawa, Canada K1A 0S9

Telephone: 1-800-635-7943
Internet site: http://publications.pwgsc.gc.ca

Catalogue No. BT31-2/2001-III-86

ISBN 0-660-61208-9

Patented Medicine Prices Review Board

2000-2001

Estimates
A Report on Plans and Priorities

Approved

Minister of Health Canada

Table of Contents

Section I

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) 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.

The PMPRB has a quasi-judicial role, established by legislation, to hold public hearings and make remedial orders when it finds a patentee has been selling a patented drug at an excessive price. It has been able to fulfil its mandate through an active policy to promote and encourage voluntary compliance with the *Act.*

In 1999, the Board commenced proceedings involving the price at which Hoechst Marion Roussel Canada Inc. (HMRC), has been selling the nicotine patch Nicoderm in Canada. The Board heard two motions by HMRC that the Board does not have jurisdiction in this matter. The Board dismissed the first motion, now the subject of an application in the Federal Court for judicial review; a decision on the second motion was reserved at the time of this report.

In the 2000-01 fiscal year, the PMPRB will continue to implement the *Road Map for the Next Decade*, which was released in September 1998, and the recommendations in the 1998 report of the Auditor General of Canada.

The federal Minister of Health, in collaboration with his provincial and territorial counterparts, has requested the PMPRB to undertake studies of the drug price trends and cost drivers of publicly funded drug benefit plans. Subsequently, the PMPRB entered into a memorandum of understanding with the Minister of Health to provide reports on a regular basis until 2001-2002.

The PMPRB has an important role to play in our health care system to assure Canadians that manufacturers do not charge excessive prices for patented drugs.

Robert G. Elgie
Chairperson

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) further increased patent protection for pharmaceutical products by eliminating compulsory licencing. The amendments also gave the PMPRB increased remedial powers and shifted ministerial responsibility for the PMPRB to the Minister of Health. Prior to that, responsibility for the PMPRB rested with the Minister of Consumer and Corporate Affairs (now the Minister of Industry), who has overall responsibility for the *Act*.

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:*** ***1. its price review activities*** ***2. the price trends of all medicines*** ***3. 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. On average, the manufacturers' selling price represents approximately 63% of the total cost of a prescription medicine. The PMPRB's

jurisdiction includes patented medicines marketed or distributed under voluntary licences. The Board has no authority over the prices of non-patented drugs, including generic drugs sold under compulsory licences, and does not have jurisdiction over prices charged by wholesalers or retailers nor pharmacists' professional fees.

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.

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.

B. Program Objective

The objective 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. External Factors Influencing the PMPRB

Increases in Drug Utilization and Expenditures

Health Canada and the Canadian Institute for Health Information (CIHI) have reported that expenditures on pharmaceuticals have increased significantly in Canada over the past decade, faster than the other major components of health spending. These increases are believed to result in part from the increasing numbers of new drugs on the market and increased utilization of drugs. CIHI has estimated that drug expenditures increased 5.1% in 1999.

Sales by manufacturers of patented drugs, which are subject to the PMPRB's jurisdiction, have grown much faster. In 1998, total sales of patented drugs increased 19% to $4.3 billion. There were 1,012 patented drug products under the PMPRB's jurisdiction in 1998, an increase of 32% since 1992. These increases have contributed to the workload pressures on the PMPRB.

The significant increases in drug expenditures, and a desire to control costs, have contributed to the increased concerns of Ministers of Health in Canada and other stakeholders as documented in the *Road Map for the Next Decade*.

Implementation of the Road Map for the Next Decade [1]

The PMPRB published its *Road Map for the Next Decade* in September 1998, following a year of public consultations on how it fulfills its mandate. The *Road Map* summarized stakeholders' concerns and set out a multi-year action plan to deal with them.

The implementation of the *Road Map* was a priority for the PMPRB in 1999-2000 and will continue to be a priority.

In February 1999, the Board created a Working Group on Price Review Issues.[2] The mandate of the Working Group is to review, analyse and provide reports for the Board's consideration on:

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

The Working Group presented its report to the Board on the first issue, the use of U.S. DVA prices, in September. Following further public consultation, the Board has accepted the Working Group's recommendation to include the U.S. Federal Supply Schedule prices when calculating U.S. prices.

In addition, during the span of the PMPRB's planning cycle, 2000-01 to 2002-03, the Board intends to commence a review of the Guidelines with respect to Category 2 drugs. The schedule for this work is yet to be determined.

The Working Group is one example of the commitments made by the Board in its Consultation Policy[3] in 1998. In addition, in response to recommendations from stakeholders and the Auditor General, the Board has taken a number of initiatives to enhance its public communications.

---

1 The *Road Map for the Next Decade* is available on the PMPRB web site: www.pmprb-cepmb.gc.ca, under Publications, or by calling 1-877-861-2350 (toll-free).

2 The Working Group consists of 12 members, representing the provincial ministers of health, consumer groups (including, seniors, health associations, and the medical profession) and the pharmaceutical industry.

3 The Consultation Policy is available on the PMPRB web site: www.pmprb-cepmb.gc.ca, under Publications, *Road Map for the Next Decade*, or by calling 1-877-861-2350 (toll-free).

Federal/Provincial/Territorial Analysis and Reporting Relating to Pharmaceutical Prices

In April 1996, a Federal/Provincial/Territorial (F/P/T) Task Force on Pharmaceutical Prices was established by the Ministers of Health as part of their initiative to examine drug costs. The Task Force was directed to define the scope of drug price issues, and to identify and assess potential initiatives to address concerns.

In 1999, the Task Force completed its examination of price and expenditure trends, price levels, and cost drivers as they relate to prescription drugs reimbursed under six provincial drug plans (British Columbia, Alberta, Saskatchewan, Manitoba, Ontario and Nova Scotia). The PMPRB staff provided expert assistance to this work.

At their meeting in September 1999, F/P/T Ministers of Health approved a recommendation that the Federal Minister of Health, in collaboration with his provincial/territorial counterparts, request the PMPRB to undertake the price and cost driver analysis of drug benefit plans for all provinces and territories.

Subsequently, the PMPRB entered into a memorandum of understanding with the Minister of Health to provide a detailed analysis and report of expenditure trends, price levels and cost drivers facing public drug benefit plans as well as interprovincial price comparison analysis. The PMPRB was allocated 5 FTEs and $1.5 million over a 2½ year period ending March 31, 2002 to complete this project.

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 Board responded positively to the Auditor General's recommendations. Progress has been made on the recommendations and the Board will continue this work over the next few years.

D. Planned Spending

The Planned Spending table summarizes the Main Estimates, Budget and other associated adjustments to arrive at the total planned spending requirements for the PMPRB. It also identifies planned FTE levels over the planning period.

Table 2.1 Patented Medicine Prices Review Board - Planned Spending

(thousands of dollars)	Forecast** Spending 1999-2000	**Planned** Spending 2000-2001**	Planned** Spending 2001-2002	Planned Spending 2002-2003
Budgetary Main Estimates (gross)	3,161.0	**3,711.0**	3,711.0	3,198.0
Non-budgetary Main Estimates (gross)	-	**-**	-	-
Less: Respendable revenue	-	**-**	-	-
Total Main Estimates	3,161.0	**3,711.0**	3,711.0	3,198.0
Adjustments	599.6	**-**	-	-
Net Planned Spending	*3,760.6	**3,711.0**	3,711.0	3,198.0
Less: Non-respendable revenue[4]	67.3	**-**	-	-
Plus: Cost of services received without charge	648.0	**636.1**	636.1	621.0
Net Cost of Program	4,341.3	**4,347.1**	4,347.1	3,819.0
Full Time Equivalents	36.5	**39.0**	39.0	34.0

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

** Includes funding allocated in the MOU with the Minister of Health - see p. 6

E. Workload Pressures/Increases

Since 1992, the number of patented drugs under the PMPRB's jurisdiction has increased by 32%, from 765 to 1,012. In addition to the increased number of patented drugs being reviewed, patentees have become more sophisticated in their approach to the price review process. This has resulted in more creative and

[4] The money reported as non-respendable revenue (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.

complex submissions by patentees in an attempt to justify their prices. These submissions often involve scientific, pharmacoeconomic and jurisdiction issues as seen in the current hearing in the matter of Hoechst Marion Roussel Canada Inc. and the price of Nicoderm. These trends are expected to continue to challenge the PMPRB's limited resources.

To maintain its program integrity, the Board must be able to continue to respond to changes in the environment and to make the changes necessary. It is essential to the integrity of the price review program that the Board continue the implementation of the *Road Map* and the recommendations of the Auditor General. The PMPRB intends to follow through with the ongoing process of building a more open, transparent and accountable approach to the price review process in 2000 and beyond through increased consultations. The success of this process is largely dependent on stakeholder participation and on the PMPRB's ability to help defray costs. The PMPRB is seeking ways and means to address these pressures to ensure the continued success of its program in future years.

Section III

Plans, Results and Resources

A. Net Planned Spending and Full Time Equivalents (FTE)

The following table displays resources and FTEs for the current financial year, the estimates year, plus two subsequent years.

Table 3.1 Net Planned Spending ($ thousands) and Full Time Equivalents (FTE)

Forecast Spending 1999-2000	**Planned Spending 2000-2001**	Planned Spending 2001-2002	Planned Spending 2002-2003
3,760.6*	**3,711.0**	3,711.0	3,198.0
36.5	**39.0**	39.0	34.0

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

B. Business Line Objective

The PMPRB has one business line which matches its program. The business line objective is to protect consumer interests and to contribute to Canadian health care by ensuring that the prices charged by manufacturers of patented medicines are not excessive.

C. Business Line Description

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

- voluntary action taken by the patentees;
- formal Voluntary Compliance Undertakings (VCUs) to lower prices and offset excess revenues; or,
- following public hearings 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. The Guidelines, which are based on the legislation and regulations, were developed in consultation with stakeholders including the provincial and territorial ministers of health, consumer groups, various associations of health professionals and the pharmaceutical industry.

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

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

Key Results Commitments	Planned Results	Related Activities	Resources ($ thousands)
assurance that manufacturers' prices for patented medicines sold in Canada are not excessive	▸ manufacturers' prices for new and existing patented medicines sold in Canada are set within the limits established by the Excessive Price Guidelines (Guidelines) ▸ enforcement measures taken in accordance with the *Patent Act* when prices appear to be excessive	▸ review 100% of the manufacturers' prices of patented medicines sold in Canada	$3,711.0
	▸ 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)	▸ compare the annual percentage change in the PMPI to the annual percentage change in the CPI	
	▸ manufacturers' prices for new and existing patented medicines that are no greater than manufacturers' prices charged in other countries	▸ compare the manufacturers' prices for new and existing patented medicines sold in Canada to manufacturers' prices in other countries	

Key Results Commitments	Planned Results	Related Activities	Resources
information on trends in manufacturers' prices of all medicines in Canada	▸ a comprehensive report on: - trends in manufacturers' prices and volume of patented drug products sold - trends in manufacturers' prices of all drug products- patented and non-patented - the comparison of Canadian patented drug prices to international prices ▸ a detailed report of expenditure trends, price levels and cost drivers facing public drug benefit plans[5] ▸ a detailed report of interprovincial price comparison analysis[6]	▸ an analysis of: - trends in manufacturers' prices and volume of patented drug products sold - trends in manufacturers' prices of all drug products- patented and non-patented - the comparison of Canadian patented drug prices to international prices ▸ an analysis of expenditure trends, price levels and cost drivers facing public drug benefit plans ▸ a comparison of provincial drug prices	

[5] As per the terms of the MOU the PMPRB entered into with the federal Minister of Health.

[6] As per the terms of the MOU the PMPRB entered into with the federal Minister of Health.

Key Results Commitments	Planned Results	Related Activities	Resources ($ thousands)
information on the pharmaceutical research-and-development expenditures of patentees in Canada	▸ a comprehensive report on: - the ratio of R&D expenditures to sales revenues for each patentee and the industry as a whole based on information supplied by patentees - R&D expenditures by location and by type of research	▸ an analysis of: - R&D expenditures to sales revenues for each patentee and the industry as a whole based on information supplied by patentees - R&D expenditures by location and by type of research	
a more transparent and accountable public agency recognized as adding value to pharmaceutical policy in Canada	▸ continue to implement the *Road Map for the Next Decade*[7]	▸ ongoing consultations with a representative cross-section of stakeholders ▸ respond to the recommendations of the Auditor General	

[7] The *Road Map for the Next Decade* is available on the PMPRB web site: www.pmprb-cepmb.gc.ca, under Publications, or by calling 1-877-861-2350 (toll-free).

Section IV

Financial Information

Table 4.1 Source of Non-respendable Revenue				
(thousands of dollars)	Forecast Revenue 1999-2000	**Planned Revenue 2000-2001**	Planned Revenue 2001-2002	Planned Revenue 2002-2003
Patented Medicine Prices Review Board	-	-	-	-
Source of non-respendable revenue:				
Voluntary Compliance Undertaking	67.3	-	-	-
Total Non-respendable Revenue	67.3	-	-	-

Table 4.2: Net Cost of Program for the Estimates Year	
(thousands of dollars)	**TOTAL**
Net Planned Spending	**3,711.0**
Plus: Services Received without Charge	
Accommodation provided by Public Works and Government Services Canada (PWGSC)	**503.5**
Contributions covering employee's share of employees' insurance premiums and expenditures paid by the TBS	**132.6**
	4,347.1
Less: Non-respendable Revenue	**-**
2000-2001 Net Cost of Program	**4,347.1**

Section V

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, 2000 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.
Ingrid S. Sketris, Bsc (Phm), Pharm.D., MPA(HSA)

Statutory Annual Reports and Other PMPRB Reports

ANNUAL REPORT Series *(1989 to 1998)*

NEWSletter Series *(1997 to 2000)*

BULLETIN Series *(1988 to 1996)*

MOST RECENT PUBLICATIONS

- *Road Map for the Next Decade*, Report on the PMPRB's Public Consultations, September 1998

- S-9811: Trends in Patented Drug Prices
- S-9812: Verification of Foreign Patented Drug Prices
- S-9813: Purchasing Power Parities and International Comparisons of Patented Medicine Prices
- S-9914: Top Selling Non-patented Single Source Drug Products, 1996: International Price Comparison

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