ESTIMATES

Patented Medicine Prices Review Board Canada

2001-2002
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.

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Patented Medicine Prices Review Board

2001-2002

Estimates
A Report on Plans and Priorities

Approved

Minister of Health Canada

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Section I

Message

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.

In its quasi-judicial role, established by legislation, the Board can 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 to consider whether, under sections 83 and 85 of the *Patent Act*, the patented medicine Nicoderm is being, or has been, sold by Hoechst Marion Roussel Canada Inc. (HMRC) in Canada at a price that, in the opinion of the Board, is excessive and if so, what order should be made. The Board heard two motions by HMRC that the Board does not have jurisdiction in this matter. The Board issued its decision on Part I of the motion on August 3, 1999 and its decision on Part II on August 8, 2000. Both matters are now the subject of an application in the Federal Court for judicial review.

In the 2001-02 fiscal year, the PMPRB will continue to implement the *Road Map for the Next Decade*, which was released in September 1998. In so doing, the PMPRB continues to focus on ways in which it can function in a more open and transparent manner. This can be seen by the review of the price review process for new patented medicines being done by the Working Group on Price Review Issues.

In addition, under the terms of a Memorandum of Understanding with the federal Minister of Health, the PMPRB continues to provide reports on drug price trends and cost drivers of publicly funded drug benefit plans in Canada.

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

Management Representation

Report on Plans and Priorities 2001-2002

I submit, for tabling in Parliament, the 2001-2002 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 planned 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 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

2.1 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 licensing. 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. . .

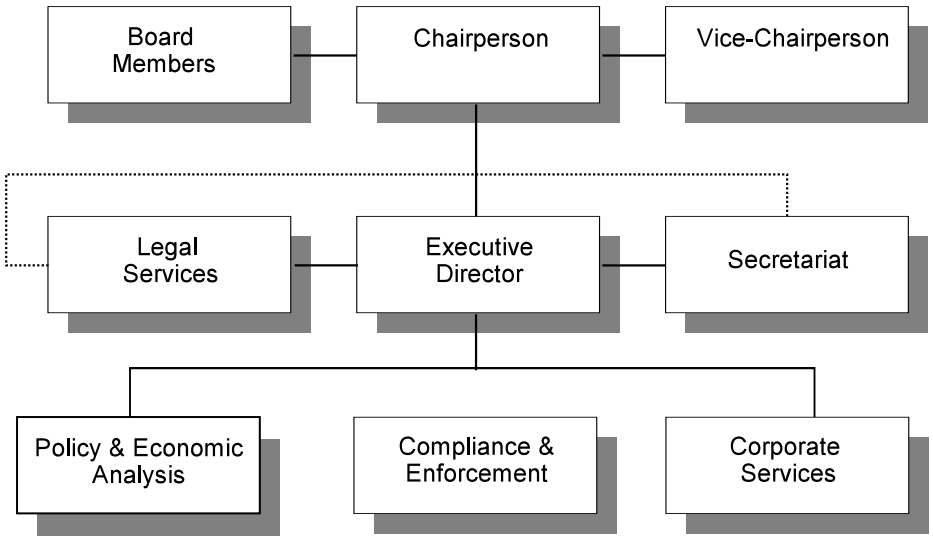
Regulatory	***To protect consumer interests and contribute to Canadian health care by regulating the maximum prices charged by manufacturers of patented medicines to ensure that they are not excessive.***
Reporting	***To report annually to Parliament on:*** ***1. its price review activities*** ***2. 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, pharmacies and other customers. The PMPRB's jurisdiction includes patented medicines marketed or distributed under voluntary licenses. The Board has no authority over the prices of non-patented drugs, including generic drugs sold under compulsory licenses, 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. 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 of the Board and Senior Counsel.

Figure 1: Organization Structure of the PMPRB for 2001-02



2.2 PMPRB/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.

2.3 Planning Context

2.3.1 Rising Health Care Costs

Since the early 1990's, drugs have accounted for an increasing proportion of total health spending. Spending on drugs has grown faster than any other major component 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. Many industrialized countries, including Canada, have national systems that regulate drug prices or the profits of drug manufacturers in various ways in an attempt to contain rising health care costs. Globally, there is an interest in not only examining the major components of health care costs (namely, hospital, physician and drug costs), but also in

examining the cost drivers within these groups (such as pricing and utilization, specific classes of drugs, etc.).

As reported in the PMPRB's 1999 Annual Report, total sales by manufacturers of pharmaceuticals for human use in 1999 in Canada were estimated at $8.9 billion, an increase of 16.8% from 1998. The total sales of drugs in Canada, including the sales of veterinary drugs reported by patentees for patented and non-patented drugs, were slightly higher at $9.1 billion for 1999.

In 2000, according to the latest figures published by the Canadian Institute for Health Information (CIHI) total health care expenditures in Canada are forecasted to have grown to $95.1 billion of which approximately 70% are public funds. Total expenditures on drugs, not including hospital expenditures, have increased faster than other major components of health care, and were forecasted to reach 15.5% of total health expenditures in 2000.

2.3.2 Federal/Provincial/Territorial Initiatives

The PMPRB continues to work on fulfilling the terms of its memorandum of understanding (MOU) with the Minister of Health to provide detailed analyses and reports of expenditure trends, price levels and cost drivers facing public drug benefit plans as well as interprovincial price comparison analysis. The MOU is scheduled to terminate on March 31, 2002.

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

After two years of working to implement the *Road Map*, there are a number of important achievements. The results flowing from the Working Group on Price Review Issues[2] provide a case in point. After a thorough review of the issues surrounding the inclusion of the U.S. Department of Veterans Affairs prices in calculating U.S. prices for the international price comparison purposes, the Working Group submitted a series of recommendations to the Board in the fall of 1999.[3]

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[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. The list of members is available on the PMPRB web site: www.pmprb-cepmb.gc.ca, under Working Group on Price Review Issues, Membership

[3] The reports of the Working Group are available on the PMPRB web site: www.pmprb-cepmb.gc.ca, under Working Group on Price Review Issues, Reports

After further public consultation the Board implemented changes to include the U.S. Federal Supply Schedule prices when calculating U.S. prices effective January 1, 2000.

The Working Group has just completed its work on the second issue of its mandate, to review the price review process for new medicines to make it more open and transparent. The Board received the Report of the Working Group on Price Review Issues on the Price Review Process for New Patented Drugs. The Board will review the report, recommendations and options in detail at its meeting scheduled for March 5 & 6, 2001.

In addition, the Working Group has already commenced work on the third issue of its mandate: to review the Guidelines for new drugs in category 3.

2.3.4 Nicoderm, Hoechst Marion Roussel Canada Inc.[4]

On April 20, 1999, the Chairperson of the Board issued a Notice of Hearing to Hoechst Marion Roussel Canada Inc. (HMRC) with respect to the price at which Nicoderm is and has been sold in Canada. By its Notice of Motion dated May 25, 1999, HMRC challenged the jurisdiction of the Board to proceed with the matters described in the Notice of Hearing. For procedural purposes, the jurisdiction motion was divided into two parts, the first concerning allegations of institutional bias and the second challenging the Board's jurisdiction on statutory and constitutional grounds. The Board issued its decision on Part I of the motion on August 3, 1999 and its decision on Part II on August 8, 2000. Both matters are now the subject of an application in the Federal Court for judicial review.

On October 25, 2000 Board Staff filed a motion to intervene in the two applications for judicial review initiated by HMRC. That motion is scheduled to be heard on March 13, 2001.

2.4 Planned Spending

The Planned Spending table summarizes the Main Estimates plus Supplementary Estimates, the Minister of Finance's Budget and other associated adjustments to arrive at the total planned spending requirements for the PMPRB. It also identifies planned full time equivalents (FTE) levels over the planning period.

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[4] All of the Board's decisions and reasons are posted on the PMPRB web site: www.pmprb-cepmb.gc.ca, under Publications, Hearings & Decisions of the Board.

Table 2.1 Patented Medicine Prices Review Board - Planned Spending

(thousands of dollars)	Forecast* Spending 2000-2001	**Planned Spending 2001-2002**	Planned Spending 2002-2003	Planned Spending 2003-2004
Budgetary Main Estimates (gross)	3,711.0	**4,085.0**	3,572.0	3,577.0
Non-budgetary Main Estimates (gross)	-	**-**	-	-
Less: Respendable revenue	-	**-**	-	-
Total Main Estimates	3,711.0	**4,085.0**	3,572.0	3,577.0
Adjustments**	385.0	**-**	-	-
Net Planned Spending	4,096.0	**4,085.0**	3,572.0	3,577.0
Less: Non-respendable revenue[5]	933.1	**-**	-	-
Plus: Cost of services received without charge	682.1	**690.1**	669.9	669.9
Net Cost of Program	3,845.0	**4,775.1**	4,241.9	4,246.9

Full Time Equivalents	38.0	39.0	34.0	34.0

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

** Adjustments are to accommodate approvals obtained since the Main Estimates and include Budget initiatives, Supplementary Estimates etc.

[5] 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.

Section III

Plans, Results, Activities and Resources

3.1 Business Line Details

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

Objective
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.

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.

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 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.

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 2000-2001	**Planned Spending 2001-2002**	Planned Spending 2002-2003	Planned Spending 2003-2004
4,096.0	**4,085.0**	3,572.0	3,577.0
38.0	**39.0**	34.0	34.0

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

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)	▸ review 100% of the manufacturers' prices of patented medicines sold in Canada	$4,085.0
	▸ enforcement measures taken in accordance with the *Patent Act* when prices appear to be excessive	▸ report on enforcement measures (VCUs and Hearings) taken by the PMPRB	
	▸ 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 ($ thousands)
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 patented drug prices	▸ 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 patented drug prices	
	▸ a detailed report of expenditure trends, price levels and cost drivers facing public drug benefit plans[6]	▸ an analysis of expenditure trends, price levels and cost drivers facing public drug benefit plans	
	▸ a detailed report of interprovincial price comparison analysis[7]	▸ a comparison of provincial drug prices	

[6] As per the terms of the MOU between the Minister of Health and the PMPRB.

[7] As per the terms of the MOU between the Minister of Health and the PMPRB.

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*	▸ ongoing consultations with a representative cross-section of stakeholders	

Section IV

Financial Information

Table 4.1 Source of Non-respendable Revenue				
(thousands of dollars)	Forecast Revenue 2000-2001	**Planned Revenue 2001-2002**	Planned Revenue 2002-2003	Planned Revenue 2003-2004
Patented Medicine Prices Review Board	-	**-**	-	-
Source of non-respendable revenue:				
Voluntary Compliance Undertaking	933.1	**-**	-	-
Total Non-respendable Revenue	933.1	**-**	-	-

Table 4.2 Net Cost of Program for the Estimates Year		
(thousands of dollars)		**TOTAL**
Net Planned Spending (Gross Budgetary and Non-budgetary Main Estimates plus Adjustments)		4,085.0
Plus: Services Received without Charge		
Accommodation provided by Public Works and Government Services Canada (PWGSC)		509.8
Contributions covering employees' share of employees' insurance premiums and expenditures paid by the TBS		180.3
		4,775.1
Less: Non-respendable Revenue		**-**
2001-2002 Net cost of Program		4,775.1

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 January 31, 2001 the Board members were:

Chairperson:

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

Vice-Chairperson:

Réal Sureau, FCA

Members:

Anthony Boardman B.A.(hons.), Ph.D.
Ingrid S. Sketris, BSc (Phm), Pharm.D., MPA(HSA)

Statutory Annual Reports and Other PMPRB Reports

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* SOR/94 - 688, as amended by SOR/95 - 172

Guidelines

- Compendium of Guidelines, Policies and Procedures
- Patentees' Guide to Reporting (1995)
- (Proposed) Rules of Practice and Procedure (April 1999)

ANNUAL REPORT Series *(1989 to 1999)*

NEWSletter Series *(1997 to 2001)*

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*