ESTIMATES

Patented Medicine Prices Review Board

2002-2003
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 tabled in the spring 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

2002-2003

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 a recent survey, many of the PMPRB's principal stakeholders commented on the importance of drug price regulation and the value of research and development for new drugs and treatments. The PMPRB must remain mindful of its two fundamental roles in protecting consumers and contributing to Canadian health care, as defined by its mandate: the first is its regulatory role, to ensure that patented drug prices are not excessive; and the second is the analysis and reporting role, to provide information on pharmaceutical trends, including trends in prices and research and development expenditures.

In the October 2001 issue of its NEWSletter (www.pmprb-cepmb.gc.ca, under Publications) the PMPRB announced the implementation of a major transparency initiative with respect to drug price regulation. Following public consultation, the Board is acting on the consensus recommendation of its Working Group on Price Review Issues (Working Group) to make the results of the reviews of new drugs by Board Staff, for purposes of applying the price guidelines, publicly available. This is an important initiative which will provide another valuable source of information about new drugs.

The PMPRB is currently engaged in a major review of the price guidelines for new drugs. The Working Group is now looking at the Guidelines for new drugs in category 3 which includes new medicines that provide moderate, little or no therapeutic advantage over comparable medicines. The Board has also asked it to consider the issue of the use of pharmacoeconomics in the Guidelines. It is anticipated that the Working Group's report will be presented to the Board in fiscal year 2002-03. The Board has committed to further and broader public consultation prior to making any changes to the Guidelines.

The Board has also committed, in its Research Agenda, to a review of the Guidelines with respect new drugs in category 2, i.e., new medicines that provide a breakthrough or substantial improvement, and issues related to international price comparisons.

In addition, the PMPRB has an important role in reporting on pharmaceutical price trends. For the past two and a half years, as a result of a Memorandum of Understanding with the Minister of Health, the PMPRB has conducted detailed analyses and reported on expenditure trends, price levels and cost drivers facing Federal/Provincial/Territorial drug benefit plans. Pending the availability of funding, the PMPRB will accept responsibility, in partnership with the Canadian Institute for Health Information (CIHI), for the new National Prescription Drug Utilization Information System (NPDUIS) which was announced by Federal/Provincial/Territorial Ministers of Health at their annual meeting in September 2001.

The PMPRB is adapting and evolving as changes occur in the pharmaceutical sector. It will continue to pursue a dynamic and forward-looking approach based on ongoing consultations with stakeholders and continued commitment to openness and transparency.

Robert G. Elgie
Chairperson

MANAGEMENT REPRESENTATION STATEMENT

I submit, for tabling in Parliament, the 2002-2003 Report on Plans and Priorities (RPP) for the Patented Medicine Prices Review Board.

To the best of my knowledge the information in this document:

- Accurately portrays the PMPRB's plans and priorities.
- Is consistent with the reporting principles contained in the *Guide to the Preparation of the 2002-2003 Report on Plans and Priorities*.
- Is comprehensive and accurate.
- Is based on sound underlying information and management systems.

I am satisfied as to the quality assurance processes and procedures used for the RPP 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

Raison d'être

2.1 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.***

Section III

Plans and Priorities by Strategic Outcomes

3.1 Strategic Outcomes

The PMPRB's intended strategic outcomes are as follows:

- To provide assurance that manufacturers' prices for patented medicines sold in Canada are not excessive.
- To report on trends in manufacturers' prices of all medicines in Canada.
- To report on the pharmaceutical research and development expenditures of patentees in Canada.
- To continue to be a transparent, dynamic and accountable public agency recognized as adding value to pharmaceutical policy development in Canada.

3.1.1 *To provide assurance that manufacturers' prices for patented medicines are not excessive.*

Under the *Patented Medicines Regulations* (Regulations), patentees are required to report on the introductory prices and sales of new patented medicines within 60 days of the date of first sale and to continue to file detailed information on prices and sales of each patented drug for the first and last six-month period of each year for as long as the drug remains patented. Board staff reviews 100% of the manufacturers' prices of patented medicines sold in Canada to ensure compliance with the PMPRB's Guidelines.[1] The PMPRB receives information on the prices charged by manufacturers of patented medicines in Canada, analyzes the data and takes action, when required, to effect price reductions. Price reductions are accomplished through:

- voluntary action taken by the patentees;

[1] For more information on the Excessive Price Guidelines see the website: (www.pmprb-cepmb.gc.ca under Legislation, Regulations, Guidelines; *Compendium of Guidelines, Policies and Procedures*, Chapter 1)

- formal Voluntary Compliance Undertakings (VCUs) to lower prices and offset excess revenues; or,

- following public hearings in which the Board finds prices 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 patented 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.

In the Auditor General's report tabled in Parliament in September 1998, he commented on the verification of price information reported to the PMPRB by patentees.[2] I n 2001-02, the PMPRB completed an evaluation of its foreign and domestic price verification processes. The results of these evaluations indicate that the current processes are appropriate and cost-effective. However, to ensure that the price information provided by patentees continues to be accurate, the PMPRB has committed to conduct further internal reviews of a selected sample of foreign price data and the domestic prices of the 50 top-selling patented drug products from time to time as reported in the Board's Research Agenda.

In addition, the Board has announced that it will make the results of the reviews of new patented medicines by Board Staff, for purposes of applying

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[2] The Auditor General made the following recommendation with respect to price information reported by patentees in order to enhance public confidence in the price review work conducted by the PMPRB:
". . . the PMPRB should, in performing its price review work, identify cost-effective means to check the accuracy of price information submitted by patentees." (*Paragraph 17.90*) www.oag-bvg.gc.ca

the Excessive Price Guidelines, publicly available.[3] For more information on this transparency initiative, see subsection 3.1.4 of this report.

3.1.2 *To report on trends in manufacturers' prices of all medicines in Canada.*

Patentees are also required, under the Regulations, to submit to the PMPRB information on their annual total pharmaceutical sales for both patented and non-patented drugs in Canada. On an annual basis, Board staff conducts analyses of this information and reports the trends in manufacturers' prices and the volume of patented drug products sold in Canada; trends in manufacturers' prices of all drug products - patented and non-patented; as well as a comparison of Canadian patented drug prices to international patented drug prices. The results of these analyses are published in the Board's Annual Report which is available on the website: www.pmprb-cepmb.gc.ca under Publications.

For the past two and a half years, as a result of a Memorandum of Understanding (MOU) with the Minister of Health, the PMPRB has completed detailed analyses and reports on expenditure trends, price levels and cost drivers facing public drug benefit plans as well as interprovincial price comparison analysis. The MOU terminates on March 31, 2002.

Pending the availability of funding, the PMPRB will accept responsibility, in partnership with the Canadian Institute for Health Information (CIHI) for the new National Prescription Drug Utilization Information System which was announced by Federal/Provincial/Territorial Ministers of Health at their annual meeting in September 2001 www.hc-sc.gc.ca under Media Room, *News Releases*). The new drug information system will bring together data from the major public drug plans in Canada and permit more in-depth analyses that can be used to facilitate continuous improvement in pharmaceuticals management.

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[3] For more information on the Excessive Price Guidelines see the website: www.pmprb-cepmb.gc.ca under Legislation, Regulations, Guidelines; *Compendium of Guidelines, Policies and Procedures*, Chapter 1

For additional information on the Board's Decision see the October 2001 issue of the NEWSletter on the website.

3.1.3 *To report on the pharmaceutical research-and-development expenditures of patentees in Canada.*

Under the *Patent Act*, the PMPRB monitors and reports the research and development spending as reported to it by patentees, but it has no regulatory authority to influence the type of research or amount of R&D spending by patentees. The Act requires each patentee to report its revenues from the sales of drugs and the expenditures made by the patentee in Canada relating to medicine. For individual patentees, this calculation includes all revenues from Canadian sales of medicines, including revenues from licensing agreements.

The PMPRB is the only comprehensive source of information on the R&D expenditures by pharmaceutical patentees in Canada, including the R&D-to-sales ratios for individual patent holding companies. An annual report on this analysis can be found in the Board's Annual Report which is available on the website: www.pmprb-cepmb.gc.ca under Publications.

During fiscal year 2002-2003, the PMPRB will conduct and report on a comparison of pharmaceutical research and development spending in Canada and seven other countries; the last report was published in 1997.

3.1.4 *To continue to be a transparent, dynamic and accountable public agency recognized as adding value to pharmaceutical policy development in Canada.*

The PMPRB's focus on transparency builds on the recommendations of the Standing Committee on Industry in 1997, on the PMPRB's extensive consultations which led to the *Road Map for the Next Decade* in 1998, and the report of the Auditor General in 1998. During the consultative process, the Board received valuable feedback from stakeholders, all pointing to the need to increase transparency in the price review policies and procedures.

The PMPRB has just announced the implementation of a major transparency initiative with respect to drug price regulation. Following public consultation, it will act on the consensus recommendation of the Working Group to make results of the reviews of new drugs by Board Staff, for purposes of applying the Guidelines, publicly available. This is an important initiative in providing another valuable source of information about new drugs to both practitioners and consumers. Among other things, these reviews will offer information on the economic and therapeutic assessment of new drugs in comparison with existing drugs already available to treat the same medical conditions. They

will also provide useful cost comparisons to facilitate the cost-effective utilization of pharmaceuticals.

This change also reflects the Board's commitment to increase transparency in how it fulfils its mandate and is consistent with other initiatives to enhance its consultation and communications efforts.

The importance of the PMPRB's transparency initiatives was confirmed by a survey of its major stakeholders conducted in August and September 2001. The results of this survey showed that stakeholders want greater transparency during and after the price review process in order to increase consumers' confidence in the process.[4]

[4] A summary of the results of the interviews conducted as part of the Environmental Scan and Performance Evaluation for PMPRB can be found in the January 2002 issue of the NEWSletter available on the website: www.pmprb-cepmb.gc.ca under Publications.

Section IV

Organization

4.1 Strategic Outcomes and Business Line

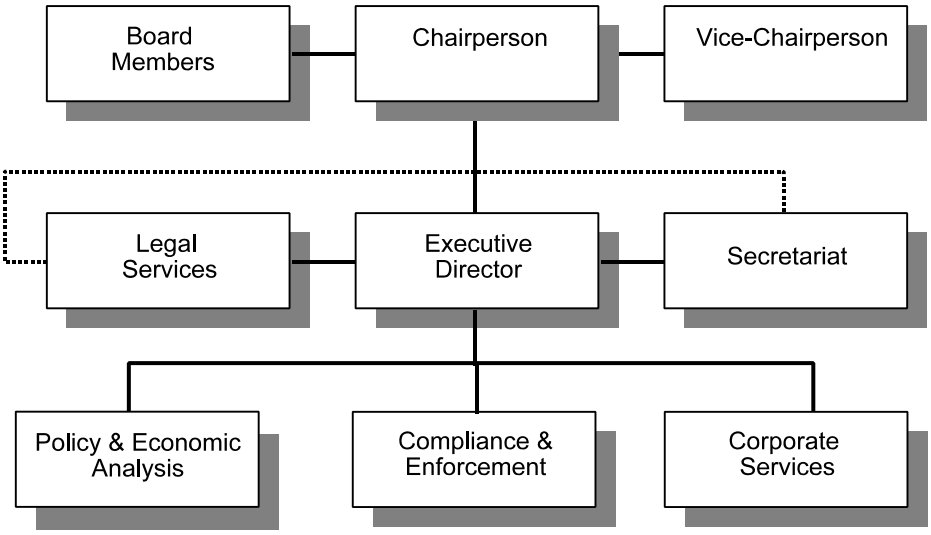
Business Line	Strategic Outcomes				Total (000's)
PMPRB	Assurance that manufacturers' prices for patented medicines sold in Canada are not excessive	Report on trends in manufacturers' prices for all medicines in Canada	Report on the pharmaceutical R&D expenditures of patentees in Canada	To continue to be a transparent, dynamic and accountable public agency recognized as adding value to pharmaceutical policy development in Canada	$ 3,681.0

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

4.2 Accountability

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



4.3 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.

Table 4.1 Patented Medicine Prices Review Board - Planned Spending

(thousands of dollars)	Forecast* Spending 2001-2002	**Planned*** Spending 2002-2003**	Planned Spending 2003-2004	Planned Spending 2004-2005
Budgetary Main Estimates (gross)	4,085.0	**3,681.0**	3,690.0	3,690.0
Non-budgetary Main Estimates (gross)	-	**-**	-	-
Less: Respendable revenue	-	**-**	-	-
Total Main Estimates	4,085.0	**3,681.0**	3,690.0	3,690.0
Adjustments**	114.0	**-**	-	-
Net Planned Spending	4,199.0	**3,681.0**	3,690.0	3,690.0
Less: Non-respendable revenue	62.6	**-**	-	-
Plus: Cost of services received without charge	676.6	**662.6**	662.8	662.8
Net Cost of Program	4,813.0	**4,343.6**	4,352.8	4,352.8

Full Time Equivalents	38.0	**34.0**	34.0	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.

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

*** Does not include funding for the National Prescription Drug Utilization Information System.

Section V

Financial Information

Table 5.1 Source of Non-respendable Revenue[5]				
(thousands of dollars)	Forecast Revenue 2001-2002	**Planned Revenue 2002-2003**	Planned Revenue 2003-2004	Planned Revenue 2004-2005
Patented Medicine Prices Review Board	-	**-**	-	-
Source of non-respendable revenue:				
Voluntary Compliance Undertaking	62.6	**-**	-	-
Total Non-respendable Revenue	62.6	**-**	-	-

[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. The Minister may enter into agreements with any province respecting the distribution to that province of amounts received by the Receiver General, less any costs incurred in relation to the collection and distribution of those amounts.

Table 5.2 Net Cost of Program for the Estimates Year	
(thousands of dollars)	**TOTAL**
Net Planned Spending (Gross Budgetary and Non-budgetary Main Estimates plus Adjustments)	3,681.0
Plus: Services Received without Charge	
Accommodation provided by Public Works and Government Services Canada (PWGSC)	496.3
Contributions covering employees' share of employees' insurance premiums and expenditures paid by the TBS	166.3
	4,343.6
Less: Non-respendable Revenue	-
2002-2003 Net cost of Program	4,343.6

Section VI

General 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 (June 2001)

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NEWSletter Series *(1997 to 2002)*