Patented Medicine Prices Review Board

2004-2005

Estimates
A Report on Plans and Priorities

Approved

Minister of Health Canada
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Section I

Chairperson’s Message and Management Representation Statement

The Patented Medicine Prices Review Board (PMPRB) was created by Parliament in 1987 under the Patent Act as an independent, quasi-judicial tribunal. The PMPRB represents a strategic component of the federal government’s 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.

In 2003, the Board concluded a hearing into the price of Remicade by accepting a Voluntary Compliance Undertaking (VCU) agreed to by Board Staff and Schering Canada Inc. This VCU benefited patients with an immediate price reduction of 20%, bringing the price of Remicade within the Board’s Guidelines. In addition, Schering made a payment to the Government of Canada in the amount of $7.8 million to offset excess revenues.

The PMPRB also has a responsibility to inform Canadians about the price trends of patented medicines and of all drugs, and the research and development performance as reported by patent-holding drug manufacturers.

The PMPRB continues to pursue its mandate and the initiatives directed towards enhancing the transparency of the price review process. The PMPRB is also involved in various studies of drug price and utilization trends and it is working collaboratively with governments, agencies and other stakeholders.

A prime example of inter-governmental collaboration is the National Prescription Drug Utilization Information System (NPDUIS). The NPDUIS was created by the federal/provincial/territorial ministers of health as a partnership between the Canadian Institute for Health Information (CIHI) and the PMPRB. The NPDUIS will create the first national database of public drug plans to allow analyses of drug expenditures and utilization. This information will be especially valuable in supporting policy making in Canada.

Another major initiative in inter-governmental collaboration is the Common Drug Review (CDR). Established by federal/provincial/territorial governments and housed at the Canadian Coordinating Office for Health Technology Assessment...
(CCHOTA), the CDR provides a single national review of new drugs, including their cost-effectiveness, to allow public drug plans to make listing decisions. The goal is to reduce duplication, maximize the use of limited resources and expertise and enhance the consistency and quality of drug reviews. The PMPRB through its timelines project is working to better align its price review process with the CDR and to keep pace with improvements to Health Canada’s marketing approval process.

Along with Health Canada’s therapeutic review initiatives, the PMPRB program and the F/P/T initiatives all contribute to a common objective shared by governments, manufacturers, and, above all, patients – to improve timely patient access to necessary medications at non-excessive prices.

The PMPRB is committed to playing its part in supporting this collaborative process based on the goal of serving the health care needs of all Canadians.

Robert G. Elgie
Chairperson
MANAGEMENT REPRESENTATION STATEMENT

I submit, for tabling in Parliament, the 2004-2005 Report on Plans and Priorities (RPP) for the Patented Medicine Prices Review Board.

This document has been prepared based on the reporting principles and disclosure requirements contained in the Guide to the preparation of the 2004-2005 Report on Plans and Priorities:

- It accurately portrays the PMPRB’s plans and priorities.
- The planned spending information in this document is consistent with the directions provided in the Minister of Finance’s Budget and by Treasury Board of Canada Secretariat.
- It is comprehensive and accurate.
- It is based on sound underlying information and management systems.

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: _________________________________
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 pharmaceuticals. The PMPRB represents a strategic component of the federal government’s 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:

- its price review activities;
- the price trends of all medicines;
- the ratio of research-and-development expenditures to sales revenues for individual patentees and for all pharmaceutical patentees in Canada; and
- inquiries conducted at the request of the Minister of Health.
The PMPRB is funded through operating expenditures. The PMPRB is responsible for regulating the prices that patentees charge for prescription and non-prescription patented drugs sold in Canada for human and veterinary use to ensure that they are not excessive. If, after a public hearing, the Board finds that a price is excessive it may order the patentee to reduce the price and take measures to offset any excess revenues the patentee may have received. The PMPRB reviews the "factory gate" price at which the manufacturer sells the product to wholesalers, hospitals and pharmacies. The PMPRB's jurisdiction includes patented medicines marketed or distributed under voluntary licences. The PMPRB has no authority to regulate 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 or over pharmacists' professional fees.

In Canada, Health Canada assesses new medicines to ensure that they conform to the *Food and Drugs Act* and *Regulations*. Formal authorization to market or distribute a medicine is granted through a Notice of Compliance (NOC). A medicine may be temporarily distributed with specified restrictions before receiving a NOC, as an Investigational New Drug or under the Special Access Program (SAP). Patented drugs sold as an Investigational New Drug or under the SAP are subject to review by the PMPRB.

The PMPRB regulates the price of each patented drug product, including each strength of each dosage form of a patented medicine. This is normally the level at which Health Canada assigns a Drug Identification Number (DIN).

In addition, the PMPRB is required by legislation to report annually on price trends of patented and non-patented drug products and on research and development (R&D) spending by the patented pharmaceutical industry in Canada. These reports provide Parliamentarians with the information necessary to develop informed pharmaceutical policy and all stakeholders with an understanding of trends in patented drug prices and R&D spending.

Over the past several years, the PMPRB has conducted various studies of drug price and utilization trends under a Memorandum of Understanding (MOU) with the Minister of Health. In 2001, Federal/Provincial/Territorial Ministers of Health announced the establishment of the National Prescription Drug Utilization Information System (NPDUIS) based on a Business Case prepared by the PMPRB and the Canadian Institute for Health Information (CIHI). The NPDUIS is a natural evolution of the work conducted under the MOU.
The NPDUIS will create the first national database of public drug plans. It will provide accurate and timely national prescription drug utilization information to support public drug programs in the establishment of sound pharmaceutical policies and the effective management of Canada’s public drug benefit programs.

Rising health care costs

Spending on health care is outpacing economic growth in most industrialized countries, particularly in Canada, the United States and Finland according to the Organization for Economic Co-operation and Development (OECD). This increase in health care spending has forced all governments to find new funds or to pass a larger share of the costs onto individuals.\(^1\) Globally, there is an interest in examining the major components of health care costs (namely, hospital, physician and drug costs), as well as in examining the cost drivers within these groups (such as pricing and utilization, specific classes of drugs, etc.).

Governments throughout the world have found it necessary to intervene in the pharmaceutical market because of the imperfections that exist in this market. Drugs are so important to health care that most countries seek policies to facilitate access by citizens to medically necessary medications. Most industrialized countries, including Canada, have systems that regulate drug prices or the profits of drug manufacturers in various ways in an attempt to contain rising drug costs.

In December 2003, the Canadian Institute for Health Information (CIHI) released its annual statistical report on health care expenditure in Canada. According to its latest figures, CIHI has forecasted that total health care expenditures in Canada increased to $121.4 billion in 2003, up from $113.4 billion for 2002. This implies year-over-year growth of 7.1%, which compares to estimated annual growth rates of 7.0% for 2002 and 8.5% for 2001.\(^2\)

CIHI estimates that expenditures on drugs have increased from 8.4% of total health care expenditure in the late 1970s to 15.7% in 2001. Spending on drugs is forecast to have continued to increase more rapidly than other major components of health expenditure, increasing by 8.8% in 2002 to $18.1 billion and by 8.1% in 2003 to $19.6 billion, bringing drugs to 16.2% of total health care spending.\(^3\)

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\(^2\) Consult the Canadian Institute for Health Information website: [www.cihi.ca](http://www.cihi.ca), to obtain *The National Health Expenditure Trends, 1975 – 2003*.

\(^3\) Canadian Institute for Health Information, *National Health Expenditure Trends, 1975 – 2003*, December 2003. For CIHI’s purposes, drug spending includes public and private expenditures at the retail level on prescription and non-prescription drugs but does not include spending by hospitals and other institutions.
Patented Medicines: Trends in Sales and Prices

The PMPRB has estimated that total sales of drugs in Canada by manufacturers were $13.1 billion in 2002, up 13.9% from 2001. Patentees reported total factory-gate sales of patented drugs for human use of $8.8 billion. This represented an increase of 17.3% over sales in 2001. Sales of patented drugs as a proportion of total sales have increased from 45% in 1996 to 67.4% in 2002. The annual increases in sales of patented drugs have been greater than increases in the sales of all drugs since 1995.

The manufacturers’ prices of patented drugs, as measured by the Patented Medicine Price Index (PMPI) fell by 1.2% in 2002. This result continues the pattern of declines and near-negligible increases in the PMPI that began in 1993.

In 2002, a change occurred in the relationship of Canadian to foreign prices for patented drugs. For the first time since 1994, Canadian prices were, on average, about 1% higher than median foreign prices. There are several factors that could explain this change. As a result the PMPRB is currently examining the impact of changes in the exchange rate, as well as examining the differences in price trends in domestic currencies from one country to another. In addition, the PMPRB will investigate whether changes have occurred in the relationship of the prices of new drugs at the time of introduction over the past few years.

In the latter half of 2003, there were reports of price increases for some patented drugs. Consequently, the PMPRB has received enquiries regarding the application of its Guidelines with respect to price increases. Consistent with section 85 of the Patent Act, the Guidelines limit increases in the prices of patented medicines to increases in the Consumer Price Index (CPI).

There is no requirement for a manufacturer to seek the approval of the PMPRB before implementing a price increase. In the event of an increase, the PMPRB expects that manufacturers will continue to comply with the Guidelines. As part of its regulatory mandate, the PMPRB will continue to monitor prices to ensure this is the case. In addition, the PMPRB has published articles in its October

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4 To monitor the trends in manufacturers’ prices of patented drugs, the PMPRB maintains the PMPI. The PMPI measures average year-over-year changes in the transaction prices of patented drug products sold in Canada based on the price and sales information reported by patentees. For additional information on the PMPI see the 2002 Annual Report available on the website: www.pmprb-cepmb.gc.ca, under Publications.

5 For more information on the CPI Methodology, the Compendium of Guidelines, Policies and Procedures is available on our website www.pmprb-cepmb.gc.ca, under Legislation, Regulations and Guidelines.
2003 and January 2004 issues of the NEWSletter reminding patentees of the provisions of the Guidelines.6

**Cross-border drug sales**

In North America, increased awareness of the disparity of prices between the US and other countries, in particular Canada, has led to a growing business in cross-border sales of less expensive Canadian drugs to US consumers (usually via the internet). Canada’s proximity to the US and the similarity of its drug approval process to that of the US make it a convenient source for cross-border drug sales.

**Hoechst Marion Roussel/Nicoderm – Judicial review**

In September 1999 and September 2000, Hoechst Marion Roussel Canada Inc. (HMRC, now Aventis Pharma) filed applications in the Federal Court of Canada for judicial review of decisions of the Board affirming its jurisdiction to conduct a hearing into the price of the nicotine patch, Nicoderm. This matter was initiated when the Board issued a Notice of Hearing in April 1999 to determine if the price of Nicoderm is or had been excessive under section 83 of the *Patent Act*. On June 25, 2003, the Prothonotary of the Federal Court heard a motion for production of documents filed by HMRC seeking production of the Board Staff Report to the Chairperson. In a decision rendered November 14, 2003, the Prothonotary denied HMRC’s request. This decision was appealed to the Federal Court. On March 31, 2004, the Federal Court issued its decision denying HMRC’s request for production of the Board Staff Report.

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6 Copies of the NEWSletter are available on the website: [www.pmprb-cepmb.gc.ca](http://www.pmprb-cepmb.gc.ca), under Publications.
### Section IV

**Plans and Priorities by Strategic Outcomes**

<table>
<thead>
<tr>
<th>Strategic Outcomes</th>
<th>Priorities</th>
<th>Associated Resources (000’s)</th>
<th>Type of Priority</th>
</tr>
</thead>
</table>
| 1. To provide assurance that manufacturers’ prices for patented medicines are not excessive | - review 100% of the manufacturers’ prices of patented medicines sold in Canada  
- take enforcement measures (VCUs & Hearings) as required  
- to establish timelines and milestones in the price review process for new patented medicines | $ 5,351.0                    | - ongoing        |
| 2. To report on trends in manufacturers’ prices of all medicines in Canada       | - conduct analysis of trends in manufacturers’ prices of all medicines in Canada  
- conduct analysis of expenditure trends, price levels and cost drivers facing public drug benefit plans (NPDUIIS) | - ongoing                    | - ongoing        |
| 3. To report on the pharmaceutical research and development expenditures of patentees in Canada | - conduct analysis of R&D expenditures to sales revenues of patentees in Canada supplied by patentees | - ongoing                    | - ongoing        |
| 4. To continue to be a transparent, dynamic and accountable public agency recognized as adding value to pharmaceutical policy development in Canada | - implementation of the Board’s decisions on the recommendations of the Working Group on Price Review Issues  
- conduct an evaluation of the transparency initiative  
- continue implementation of the modern comptrollership initiative | - ongoing                    | - ongoing        |
Strategic Outcome #1 - To provide assurance that manufacturers’ prices for patented medicines are not excessive

Under the *Patented Medicines Regulations*, (Regulations), patentees are required to report information 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. 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;

- 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. These Guidelines form part of an education and communication program to inform patentees of compliance requirements and obligations.

The Guidelines are not a rigid set of decision-making rules and are not binding on the Board or on patentees. Rather, they are policies which have been approved by the Board and are used by Board Staff to review the prices being charged by patentees for their products. The Guidelines are based on the price determination factors in section 85 of the *Patent Act* and were developed in consultation with stakeholders including provincial and territorial ministers of health, consumer groups, health care associations and the pharmaceutical industry.

Under the 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 in determining 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 duties and powers to the PMPRB.

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7 For more information on the Excessive Price Guidelines see the website: [www.pmprb-cepmb.gc.ca](http://www.pmprb-cepmb.gc.ca) under Legislation, Regulations, Guidelines; *Compendium of Guidelines, Policies and Procedures*, Chapter 1
The results of the PMPRB’s price review activities are published in the Board’s Annual Report and the quarterly NEWSletter which are available on the website: www.pmprb-cepmb.gc.ca, under Publications.

The PMPRB continues to pursue its mandate as well as initiatives directed towards enhancing its price review process.

In the second report of the Working Group on Price Review Issues dealing with the PMPRB’s price review process for new patented medicines, the Working Group recommended that the PMPRB establish milestones and timelines for the price reviews of new patented drugs.\(^8\) The Board agreed with the Working Group and initiated the timelines project.

At the same time, Federal/Provincial/Territorial (F/P/T) governments have been developing the Common Drug Review (CDR). The CDR was announced by Ministers of Health in September 2001, and involves participating federal, provincial and territorial drug plans. The CDR is designed to ensure a consistent and rigorous approach to the review of drugs for purposes of decisions on coverage under public drug plans across Canada by replacing multiple review and recommendation processes with one common approach.

In addition, the federal government’s Speech from the Throne in September 2002 made a commitment to “speed up the regulatory process for drug approvals to ensure that Canadians have faster access to the safe drugs they need, creating a better climate for research in pharmaceuticals” under the Government of Canada’s Smart Regulation Strategy. Subsequently, the 2003 First Ministers’ Accord on Health Care Renewal committed federal, provincial and territorial governments to further collaboration to promote optimal drug use, best practices in drug prescription and to better manage the costs of all drugs, including generic drugs, to ensure that drugs are safe, effective and accessible in a timely and cost-effective manner.

In response to these commitments, Health Canada has developed a Therapeutics Access Strategy (TAS) to improve regulatory performance, enhance post-market surveillance and improve access to appropriate and cost-effective drug therapies for Canadians.

As a result of these government initiatives, the PMPRB has modified its timelines project to include examining ways to strengthen its price review process to keep pace with other improvements in the Canadian pharmaceuticals regulatory system. Through investments under the TAS, the PMPRB will build the necessary capacity to keep pace with improvements in Health Canada’s marketing approval and bring the timelines for price review more in line with the

\(^8\) All of the Working Group’s reports are available on our website under Working Group on Price Review Issues; Reports.
Common Drug Review (CDR) for FPT formulary listing. The investments will also be used to enhance the information that the PMPRB uses in its price review and public reporting.

To meet the its objectives in the TAS, the PMPRB will redesign its price review processes to build the necessary immediate and ongoing capacity to strengthen its price review processes and enhance the information the PMPRB uses in its price review and includes in its public reports. As a first step, the PMPRB will accelerate the implementation of its timelines project. Starting in 2003-04 and continuing into 2004-05 the PMPRB will complete work on: mapping of the current price review process; conducting a time analysis of the process; identifying improvements to the current process; and developing, documenting, consulting on and publishing standards and/or guidelines for the price review process.

**Strategic Outcome #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 sales of 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](http://www.pmprb-cepmb.gc.ca) under Publications.

Furthermore, the Act authorizes the Minister of Health to require the Board to conduct inquiries into matters as determined by the Minister. Pursuant to the Minister’s authority under s. 90 of the *Patent Act*, the Minister of Health has directed and funded the PMPRB to inquire into trends in pharmaceutical prices, expenditures and cost drivers, and such other analytical studies, under the National Prescription Drug Utilization Information System (NPDUIS).

The PMPRB continues to work collaboratively with the Canadian Institute for Health Information (CIHI) to develop and to maintain the NPDUIS, each organization taking the lead in areas in which that organization has the expertise/experience:

- CIHI is the custodian of the NPDUIS, responsible for developing and maintaining standards, collecting, scrubbing and processing data, producing standardized reports (including web-based outputs), completing ad hoc requests for information, and conducting analytical studies.

- The PMPRB is responsible for conducting analytical studies.
• In some cases, both organizations will collaborate in the development of reports and analytical studies.

The PMPRB and CIHI are currently negotiating a Memorandum of Understanding (MOU) to define their working relationship under the NPDUIS. Among other things, the MOU provides for an Operations Committee to coordinate activities and minimize duplication of effort as well as a mechanism for resolving disputes should they arise. An F/P/T Steering Committee provides strategic direction and advice to the NPDUIS.

In addition, Health Canada has asked the PMPRB and CIHI to begin work on the possible expansion of the NPDUIS to include the private drug plan data and to develop approaches for linkages to other health databases.

**Strategic Outcome #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 expenditures made by patentees 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](http://www.pmprb-cepmb.gc.ca) under Publications.

**Strategic Outcome #4-**  To continue to be a transparent, dynamic and accountable public agency recognized as adding value to pharmaceutical policy development in Canada

Transparency continues to be an important objective of the PMPRB. The PMPRB believes that increased transparency and openness in the price review process can contribute to an environment that facilitates evidence-based decision-making for stakeholders, researchers and policy-makers. In its Research Agenda, the Board has committed to conducting an evaluation of the transparency initiative in 2004-05.

In its review of the Guidelines for category 3 new drugs, the Working Group on Price Review Issues (Working Group) recommended that it is appropriate for the
Board to consider the “value” of new drugs in the price review process to a greater extent than is currently done by the Guidelines (i.e., to better reflect the incremental value of new drugs). However, the Working Group did not define what is meant by the “value” of new drugs and how “value” could be measured or linked to price review. The Working Group did not suggest that the Board’s Guidelines are inappropriate given its mandate, nor did it state that other countries are addressing this issue more effectively.

In the Board’s review of the Working Group’s recommendation, it identified the need for further research on this subject. Board Staff is currently conducting an international review of practices in assessing the relative value of new drugs.

In its Research Agenda, published in the January 2004 issue of the NEWSletter, the PMPRB committed to an evaluation of the complaints-driven approach to regulating the prices of veterinary drugs. The evaluation was completed and a report of the findings was presented to the Board at its September meeting. The Board approved the recommendation to adopt a full complaints-driven approach and directed Board Staff to begin work on seeking a regulatory change to formalize the approved approach. It was noted that in adopting this approach the Board in no way abdicates its jurisdiction over patented veterinary drug products.

As a result of the federal government’s Modern Comptrollership initiative and in light of the new Values and Ethics Code for the Public Service, the PMPRB reviewed its Statement of Values and with minor changes found it to be valid and relevant for the organization. In 2004-05 the PMPRB will continue its implementation of the new Values and Ethics Code.

In addition, under the Modern Comptrollership initiative, the PMPRB has a responsibility to actively monitor the soundness of its management and control frameworks. In this regard, the PMPRB incorporated a risk assessment process into its strategic planning process. This activity is intended to ensure that management is aware of significant issues of risk or other problems in a timely manner, and that appropriate remedial action plans are developed and successfully implemented.
**Section V**

**Organization**

### 5.1 Strategic Outcomes and Business line

<table>
<thead>
<tr>
<th>Business Line</th>
<th>Strategic Outcomes</th>
<th>Total (000’s)</th>
</tr>
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<tbody>
<tr>
<td>PMPRB</td>
<td>assurance that manufacturers’ prices for patented medicines are not excessive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>report on trends in manufacturers’ prices of all medicines in Canada</td>
<td></td>
</tr>
<tr>
<td></td>
<td>report on the pharmaceutical research and development expenditures of patentees in Canada</td>
<td></td>
</tr>
<tr>
<td></td>
<td>continue to be a transparent, dynamic and accountable public agency recognized as adding value to pharmaceutical policy development in Canada</td>
<td>$5,351.0</td>
</tr>
</tbody>
</table>

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

### 5.2 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.

The Compliance and Enforcement Branch is largely responsible for the review of prices for patented medicines and the Compliance and Enforcement Policy. The Policy and Economic Analysis Branch is largely responsible for conducting analyses and preparing reports on price trends and other economic studies. The Secretariat, Corporate Services Branch and Senior Counsel provide regulatory, reporting and administrative support.
5.3 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 5.1
Patented Medicine Prices Review Board – Planned Spending

<table>
<thead>
<tr>
<th></th>
<th>Forecast(1)</th>
<th>Planned Spending</th>
<th>Planned Spending</th>
<th>Planned Spending</th>
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<tbody>
<tr>
<td>Patented Medicine Prices Review Board</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Budgetary Main Estimates (gross)</td>
<td>4,738.0</td>
<td>5,351.0</td>
<td>4,402.0</td>
<td>4,402.0</td>
</tr>
<tr>
<td>Non- Budgetary Main Estimates (gross)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Less: Respendable revenue</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td><strong>Total Main Estimates</strong></td>
<td>4,738.0</td>
<td>5,351.0</td>
<td>4,402.0</td>
<td>4,402.0</td>
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<tr>
<td>Adjustments (Planned Spending not in Main Estimates)</td>
<td></td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Collective Agreement</td>
<td>50.0</td>
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<tr>
<td>Implementation of Health Canada’s Therapeutic Access Strategy</td>
<td>424.0</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td><strong>Total Adjustments</strong></td>
<td>474.0</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Net Planned Spending</strong></td>
<td>5,212.0</td>
<td>5,351.0</td>
<td>4,402.0</td>
<td>4,402.0</td>
</tr>
<tr>
<td>Less: Non-Respendable revenue</td>
<td>(7,834.8)(2)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Plus: Cost of services received without charge</td>
<td>703.9</td>
<td>825.5</td>
<td>788.9</td>
<td>767.5</td>
</tr>
<tr>
<td><strong>Net cost of Program</strong></td>
<td>(1,918.9)</td>
<td>6,176.5</td>
<td>5,190.9</td>
<td>5,169.5</td>
</tr>
<tr>
<td><strong>Full Time Equivalents</strong></td>
<td>44.0</td>
<td>44.0</td>
<td>37.0</td>
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</tbody>
</table>

(1) Reflects the best forecast of total planned spending to the end of the fiscal year including funding allocated for the NPDUIS and the TAS. (For more information on the NPDUIS see Strategic Outcome # 2 in this document. For more information on the TAS see Strategic Outcome #1 in this document.)

(2) The money reported as non-respendable revenue does not represent revenues generated by the PMPRB. This money is a result of payments made by patentees to the Government of Canada through Voluntary Compliance Undertakings (VCUs) or Board orders to offset excess revenues. In 2003-04, the Board accepted two VCUs. The first was submitted by Schering Canada Inc. with respect to the drug Remicade. The other was submitted by Pfizer Canada Inc. with respect to the drug Dostinex. The terms and conditions of the VCUs were agreed to between Board Staff and the patentees and included payments to the Government of Canada in the amount of $7.792 million and $0.042 million respectively, to offset excess revenues.

(3) The reduction in estimated total planned spending and full time equivalents for 2005-2006 and 2006-2007 is a result of the fact that funding arrangements for the NPDUIS have not yet been finalized beyond 2004-2005.
Table 6.1  
**Sources of Non-respendable Revenue***

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patented Medicine Prices Review Board</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sources of non-respendable revenue</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voluntary Compliance Undertakings</td>
<td>7,834.8</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total Non-Respondable Revenue</td>
<td>7,834.8</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

* 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 6.2  
**Net Cost of Program for the Estimates Year**

<table>
<thead>
<tr>
<th>(thousands of dollars)</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Planned Spending (Total Main Estimates plus Adjustments as per the Planned Spending table)</td>
<td>5,351.0</td>
</tr>
<tr>
<td>Plus: Services Received without Charge</td>
<td></td>
</tr>
<tr>
<td>Accommodation provided by the Public Works and Government Services Canada (PWGSC)</td>
<td>578.1</td>
</tr>
<tr>
<td>Contributions covering employers’ share of employees’ insurance premiums and expenditures paid by the TBS (excluding revolving funds)</td>
<td>247.4</td>
</tr>
<tr>
<td></td>
<td>825.5</td>
</tr>
<tr>
<td>Less: Non-respendable Revenue</td>
<td>-</td>
</tr>
<tr>
<td>2004-2005 Net cost of Program</td>
<td>6,176.5</td>
</tr>
</tbody>
</table>
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, 2004 the Board members were:

Chairperson:

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

Vice-Chairperson:

Réal Sureau, FCA

Members:

Thomas E. (Tim) Armstrong, Q.C., O. Ont.
Anthony Boardman, B.A., Ph.D.
Ingrid S. Sketris, BSc (Phm), Pharm.D., MPA (HSA)

Statutory Annual Reports and Other PMPRB Reports

Legislation Administered and Associated Regulations


- Patented Medicines Regulations, 1994 SOR/94 - 688, as amended by SOR/95 – 172; SOR/98 - 105
Guidelines

- Compendium of Guidelines, Policies and Procedures
- (Proposed) Rules of Practice and Procedure (June 2001)

ANNUAL REPORT Series (1989 to 2002)


Study Series

S-0215 Verification of Foreign Patented Drug Prices, January 2002
S-0216 Foreign Price Trends for Patented Medicines (2002), January 2003
S-0217 A Comparison of Pharmaceutical Research and Development Spending, January 2003

F/P/T Studies

Top Selling Non-Patented Single Source Drug Products; International Price Comparison, April 2003

A Study of the Prices of the Top Selling Multiple Source Medicines in Canada, June 2003