Patented Medicine Prices Review Board

2010-2011

Report on Plans and Priorities

The Honourable Leona Aglukkaq
Minister of Health

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Chairperson's Message

I am pleased to present the 2010-2011 Report on Plans and Priorities for the Patented Medicine Prices Review Board (PMPRB).

The PMPRB is an independent, quasi-judicial body established by Parliament in 1987 under the *Patent Act*. Its mandate is two-fold: Regulatory — to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive; and Reporting — to report on pharmaceutical trends of all medicines and on R&D spending by pharmaceutical patentees.

The PMPRB plays an important role in the broader objective of improving the health of Canadians by protecting consumers and the health care system from excessive patented drug prices.

After extensive consultation with key stakeholders, as required by the *Patent Act*, new Excessive Price Guidelines (Guidelines) were released on June 9, 2009, for implementation on January 1, 2010. Monitoring and evaluation of the application and impact of the changes will be a key focus in 2010-2011 and beyond.

In recent years, the PMPRB has experienced a significant increase in the number of hearings to determine if the price of a patented drug product is excessive. While some hearings were completed in 2009-2010, a number are still ongoing, and new hearings remain a possibility.

The PMPRB will continue to enhance educational outreach to patentees and other stakeholders while it implements the revised Guidelines. It will initiate the establishment of processes to streamline price reviews and investigations. The Board will also review its rules governing the hearing process with a view to completing hearings in a more timely and efficient manner.

The PMPRB reports annually to Parliament, through the Minister of Health, on its activities, on pharmaceutical trends relating to all patented drug products, and on the R&D spending by pharmaceutical patentees. The PMPRB will continue to work in collaboration with the Canadian Institute for Health Information (CIHI) and participating federal/provincial/territorial drug plans to produce analyses and reports under the National Prescription Drug Utilization Information System (NPDUIS). Through critical analyses of price, utilization and cost trends, the PMPRB provides Canada's health system with comprehensive, timely and accurate information on prescription drug trends and cost drivers.

The PMPRB remains committed to predictability, fairness and transparency in the fulfilment of its regulatory and reporting responsibilities, to ongoing engagement of its key stakeholders, and to continual monitoring of developments within the larger pharmaceutical environment.

Brien G. Benoit, MD
Chairperson

Section I — Board Overview

Raison d'être 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* (Act) in 1987 (Bill C-22). The Act was further amended in 1993 (Bill C-91). The revisions were intended to balance the extension of patent protection with the need to protect consumers from possible excessive patented drug prices.

The PMPRB has a dual role:

Regulatory — To ensure that prices charged by patentees for patented medicines sold in Canada are not excessive.

Reporting — To report on pharmaceutical trends of all medicines, and on R&D spending by pharmaceutical patentees.

Regulatory Role

The PMPRB is responsible for regulating the factory-gate prices that patentees charge for prescription and non-prescription patented drug products sold in Canada to wholesalers, hospitals, pharmacies or others, for human and veterinary use, to ensure that they are not excessive. The PMPRB regulates the price of each patented drug product (each strength of an individual, final dosage form of a drug). This is normally the level at which Health Canada assigns a Drug Identification Number (DIN) as part of the Notice of Compliance process. However, the Board's mandate also includes drug products available under the Special Access Programme; drug products available through a Clinical Trial Application; and Investigational New Drug Products.

The Federal Court of Appeal articulated the legal requirement as to when a patent will "pertain" to the medicine. In this regard, the Court established the "merest slender thread" requirement, which is wide in scope. The Board's jurisdiction is not limited to drug products for which the patent is on the active ingredient. Rather, the Board's jurisdiction also covers drug products for which the patents relate, but are not limited, to the processes of manufacture, the delivery system, dosage form, indication/use, and/or any formulation. Patented drug products are not limited to brand name drug products. A number of generic companies fall under the Board's jurisdiction by virtue of being licensees (i.e. authorized to sell the same drug product as the brand company is selling) or due to their own patents (e.g. related to processes of manufacture).

The PMPRB has no authority to regulate the prices of non-patented drug products and does not have jurisdiction over prices subsequently charged by wholesalers or retailers or over pharmacists' professional fees. In addition, matters such as whether drugs are

reimbursed by public drug plans, distribution channels and prescribing are outside the purview of the PMPRB.

Under the Act, patentees are required to inform the PMPRB of their intention to sell a new patented drug product. Upon the sale of such a patented drug product, as per the Patented Medicines Regulations, patentees are required to file price and sales information for the first day's sales and, thereafter, twice a year for six month periods (January to June and July to December) for each strength of each dosage form of each patented drug product sold in Canada for price review/regulation purposes, for the duration of the patent(s).

Although patentees are not required to obtain the PMPRB's approval of the price of a patented drug product before it is sold, they are required to comply with the Act to ensure that prices of patented drug products sold in Canada are not excessive. If a patented drug product is sold before the patent issues, the PMPRB will review the price of the product as of date of first sale, as long as this is after the date on which the patent application was laid open for public inspection.

In the event that the Board finds, after a public hearing, that a price is or was excessive in any market, it may order the patentee to reduce the price and take measures to offset any excess revenues it may have received.

Reporting Role

The PMPRB reports annually to Parliament, through the Minister of Health, on its activities, on pharmaceutical trends relating to all patented drug products, and on the R&D spending by pharmaceutical patentees. In addition to these reporting responsibilities, under section 90 of the Act the Minister of Health has the authority to direct the PMPRB to inquire into any matter. Under this provision, the Minister has directed the Board to undertake two initiatives: the National Prescription Drug Utilization Information System (NPDUIS), and monitoring and reporting on Non-Patented Prescription Drug Prices (NPPDP).

National Prescription Drug Utilization Information System (NPDUIS)

Since 2001, pursuant to an agreement by federal, provincial and territorial Ministers of Health, the PMPRB has been conducting research under the NPDUIS. The purpose of the NPDUIS is to provide critical analyses of price, utilization and cost trends so that Canada´s health system has more comprehensive and accurate information on how prescription drugs are being used and on sources of cost drivers.

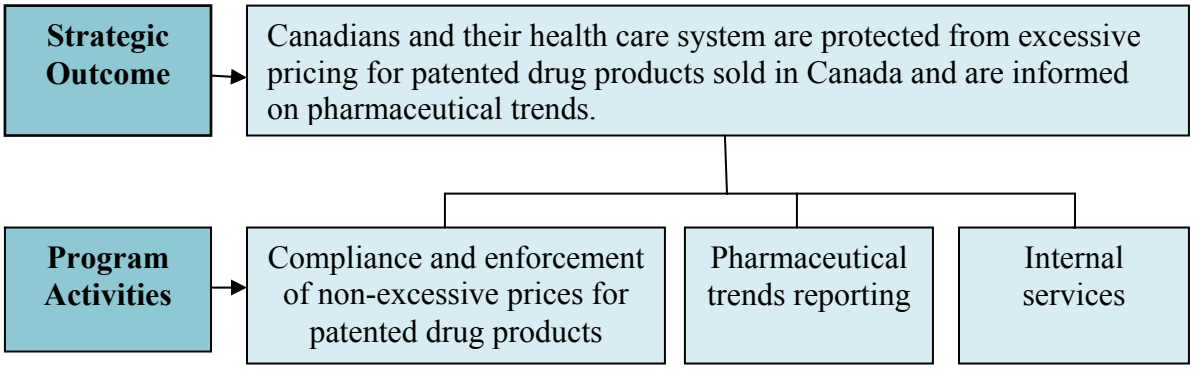
Non-Patented Prescription Drug Prices (NPPDP)

In 2005, the Minister of Health, on behalf of federal, provincial and territorial Ministers of Health, directed the PMPRB to monitor and report on non-patented prescription drug prices. This function is aimed at providing a centralized credible source of information on

non-patented prescription drug prices. Since April 2008, NPPDP studies are conducted under the umbrella of the NPDUIS.

Strategic Outcome and Program Activity Architecture

The PMPRB has one Strategic Outcome (SO) and three program activities (PAs) — representing its regulatory and reporting roles — which are illustrated in the following chart:



Planning Summary

Financial Resources ($ thousands)

2010-2011	2011-2012	2012-2013
$12,181.6	$11,816.2	$11,816.2

Human Resources (FTE)

2010-2011	2011-2012	2012-2013
76[1]	76	76

Planning Summary Table ($ thousands)

Strategic Outcome: Canadians and their health care system are protected from excessive pricing for patented drug products sold in Canada and are informed on pharmaceutical trends.					
Performance Indicator Canada's prices on average are in line with the seven comparator countries listed in the Regulations.		**Target** Canada's prices on average are at or below the median of international prices.			
Program Activity[2]	**Forecast Spending 2009-2010**	**Planned Spending**			**Alignment to Government of Canada Outcomes**
		2010-2011	**2011-2012**	**2012-2013**	
PA 1: Compliance and enforcement of non-excessive prices for patented drug products	$5,572.7	$7,648.8	$7,654.3	$7,654.3	Healthy Canadians
PA 2: Pharmaceutical trends reporting	$992.5	$1,624.8	$1,626.6	$1,626.6	Healthy Canadians
PA 3: Internal services	$3,333.6	$2,908.0	$2,535.3	$2,535.3	
Total Planned Spending	$9,898.8	$12,181.6	$11,816.2	$11,816.2	

[1] In addition, under the *Patent Act*, there are five Governor-in-Council appointees who serve on a part-time basis.
[2] For program activity descriptions/summaries, please see Section II.

Contribution of Priorities to Strategic Outcome

Operational Priorities

Operational Priority		
Implement and monitor the revised Excessive Price Guidelines (Guidelines), policies and procedures.	Type: New	Links[3] to Program Activity 1

Why is this a priority?

The PMPRB is responsible for ensuring that the prices that patentees charge, the "factory-gate" price, for patented drug products sold in Canada for human and veterinary use, are not excessive. The PMPRB relies on voluntary compliance whenever possible since it is less time consuming and less costly to all parties than hearings. Voluntary compliance by patentees is facilitated by published Guidelines on excessive prices, which are intended to assist patentees in setting prices that are not excessive by providing transparent and predictable information on how the price review will be carried out. The Guidelines are published in the PMPRB's *Compendium of Policies, Guidelines and Procedures* (Compendium) and are available on the Web site http://www.pmprb-cepmb.gc.ca, under Legislation, Regulations, and Guidelines. In order to ensure the Guidelines remain appropriate and effective in the modern pharmaceutical environment and that they also uphold the principles of fairness, transparency, openness and predictability, the Board initiated a process in 2005 to review its Guidelines, including consulting with key stakeholders as required by the Act. Revised Guidelines were released in June 2009 for implementation starting January 1, 2010.

It is essential to monitor and evaluate the application and impact of changes to the Guidelines to ensure anticipated intents are being achieved.

Plans for meeting the priority

- Implement the revised Guidelines.
- Continue proactive education to patentees and other stakeholders, including holding outreach sessions and exploring new communications opportunities and technologies.
- Monitor and evaluate the application and impact of changes to the Guidelines.

[3] The PMPRB has only one Strategic Outcome (SO), and all priorities are linked to that SO. Links to Program Activity (PA) are indicated in this column, for each operational and management priority.

Operational Priority		
Redevelop the Compliance Database.	Type: Previously committed to	Links to Program Activities 1 and 3

Why is this a priority?

The database housing price and sales information filed by patentees is a key tool for the conduct of regulatory activities. The twenty-year-old database requires redevelopment to:

- support price review and the new Guidelines;
- make more efficient and effective use of more recent information technology;
- ensure compliance with Government of Canada policies, guidelines and standards with respect to Common Look & Feel 2 (CLF2), official languages and security;
- achieve more cost-effective maintenance; and
- support future interoperability and information exchange and enhance data integrity.

Plans for meeting the priority

- Complete the work required to prepare for the implementation of the new Guidelines.
- Determine the requirements to satisfy longer-term business needs.
- Develop the project plan, architecture, cost estimates, prototype, communications and training plans, and data conversion plan.
- Develop the database and perform data conversion.
- Test the functionality of the new system.
- Implement the new database.

Operational Priority		
Ensure hearing processes are transparent and more efficient.	Type: Previously committed to	Links to Program Activity 1

Why is this a priority?

Hearings have increased significantly in number and complexity in recent years. The ability to hold public hearings when needed is a core component of the Board's mandate and authority. As a quasi-judicial body, the PMPRB must give patentees a fair and timely hearing, as needed.

Plans for meeting the priority

- Review the Board's rules governing its hearing process aimed at processing matters before the Board in a more timely and efficient manner.

- Pre-consult with stakeholders.
- Formalize via publication in the *Canada Gazette*.

Operational Priority		
Enhance the profile and uptake of the research and analysis conducted by the PMPRB.	Type: New	Links to Program Activity 2

Why is this a priority?

Board members and senior management require high quality research and analysis on which to base policy decisions.

The PMPRB also needs to ensure that research and analysis conducted through the NPDUIS initiative continue to address the needs and priorities of participating federal, provincial and territorial public drug plans.

Other external audiences and stakeholders may also benefit from a greater awareness of the PMPRB's research and analysis related to pharmaceutical trends.

Plans for meeting the priority

- Continue to carry out economic analysis and produce reports necessary to support Board and senior management decision-making.
- Continue to engage participating federal, provincial and territorial public drug plans, through the NPDUIS Steering Committee, in terms of research and analytical priorities.
- Develop a communications strategy for enhancing the profile and uptake of research and analysis conducted through the NPDUIS initiative.

Management Priorities

Management Priority		
Strengthen internal capacity of Board Staff and the Board by staffing vacant positions.	Type: New	Links to Program Activities 1, 2 and 3

Why is this a priority?

Reference level adjustments have been made to address workload impacts arising from changes to the Guidelines, emerging scientific and price review issues and an increasing volume of regulatory filings, price reviews, investigations and hearings. The PMPRB shares with other small organizations the difficulty in attracting and retaining highly specialized subject matter experts. The organization made significant progress in staffing new positions in 2009-2010, but significant work remains.

In addition, the PMPRB will experience some turn-over at the senior management level as the Executive Director is expected to retire, and the terms of two Governor-in-Council (GIC) appointees will expire.

Plans for meeting the priority

- Ensure that human resource planning and business planning remain in alignment through regular reviews of resourcing plans.
- Build capacity in the human resources area by staffing a new PE position, to ensure operational staffing activities are equipped to support evolving organizational needs.
- Staff vacant positions throughout the Board, including the Executive Director position.
- Engage senior government officials and ministerial staff in the appointment process for GICs.

Management Priority		
Develop and implement IM plans and policies that will enhance capabilities to meet operational and reporting needs for information.	Type: New	Links to Program Activities 1 and 3

Why is this a priority?

The effective management of information is critical to the PMPRB's performance, from a regulatory perspective with respect to compliance and enforcement, and with respect to the public interest. A growing PMPRB organization, the number of hearings and increased performance management reporting requirements have changed the PMPRB's information management needs.

Plans for meeting the priority

- Develop a plan for implementing new information management strategies.
- Increase information management capacity.

Management Priority		
Prepare for evaluation of Compliance and Enforcement Program in 2011-2012.	Type: New	Links to Program Activity 3

Why is this a priority?

- In conjunction with the provision of increased resources in 2008-2009 and ongoing, the Board committed to an evaluation in 2011-12 to assess the extent to which the requested increase in resources have helped the PMPRB achieve its objectives.

- An Evaluation Framework was developed in 2009-2010 and provides a structure for future evaluation activities that will assess performance against desired outcomes of the Compliance and Enforcement Program.
- It is essential that the PMPRB implement data collection strategies to support the evaluation in 2011-2012.

Plans for meeting the priority

- Methodologies and data sources will be finalized.
- Sectors of the organization will be tasked with the collection of data specific to the performance indicators.

Risk Analysis

In recent years we have witnessed important economic, social, demographic and technological changes which have impacted Canadian health care and the pharmaceutical environment.

The PMPRB's capacity to carry out its statutory regulatory mandate is focused on its ability to conduct timely price reviews, investigations and, when needed, hearings. From its creation until 2005, the PMPRB had been largely able to carry out its mandate with limited recourse to public hearings due, at least in part, to the success of the Board's Excessive Price Guidelines (Guidelines) and its Voluntary Compliance Policy.

In 2005-2006, the PMPRB identified a risk under its regulatory mandate stemming largely from an unprecedented number of investigations and anticipated hearings into excessive drug prices. This, coupled with renewed stakeholder attention to drug prices and concerns about high introductory drug prices and other issues, prompted the Board to initiate a comprehensive process to review its Guidelines, including consulting with key stakeholders as required by the *Patent Act* (Act).

This review was aimed at ensuring the effectiveness, fairness, transparency and predictability of the price review process. The consultations, along with the input of five working groups, were aimed at determining whether, where and how the Guidelines should be updated to be more appropriate and relevant in today's modern pharmaceutical environment. The Board released its new Excessive Price Guidelines on June 9, 2009, with an implementation date of January 1, 2010.

The PMPRB may experience some challenges related to operationalization of the revised Guidelines. The increased complexity of scientific reviews (due to additional therapeutic improvement factors) and price reviews (including new reviews at the level of sub-markets and a new CPI "Delinking" methodology when price increases are due to changes in benefits for customers) will add to workload demands. The revised Guidelines may lead to more investigations and hearings as patentees adjust to the revised

Guidelines, although in the long run it is expected that the new Guidelines will enhance voluntary compliance. In addition, workload pressures will likely continue, for at least the short term, with respect to more complex hearings. These areas will need to be closely monitored and assessed with adjustments in capacity and process, and potentially even the Guidelines, undertaken as needed.

Resource requirements have been identified to monitor and evaluate the impact of the revised Guidelines and to analyze and provide advice on emerging scientific and price review issues. Board Staff will undertake these activities while managing the increasing volume of regulatory filings, carrying out price reviews and investigations within reasonable timelines, and participating in hearings in a reasonably expeditious manner. Staff will also be required to participate in a major information technology renewal project. Provisions were made in the 2009-2010 adjustment to the PMPRB's Annual Reference Level Update (ARLU); however, significant attention will need to be paid to the allocation of these resources, especially given the difficulty in projecting actual workload impacts arising from changes to the Guidelines.

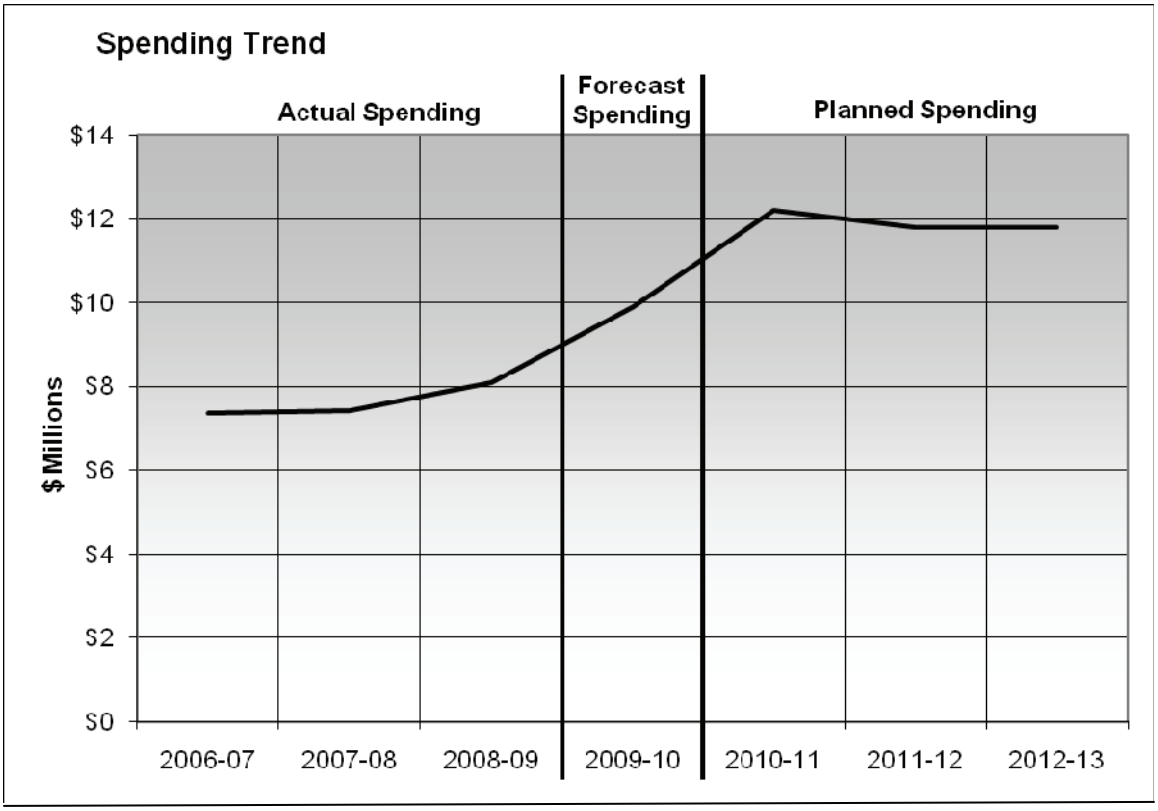
The PMPRB shares with other small organizations the difficulty in attracting and retaining highly specialized subject matter experts and the length of time required to engage new staff. The organization made significant progress in staffing new positions in 2009-2010, but significant work remains. Training must also be provided to address skill and knowledge gaps.

In addition, the PMPRB will experience some turn-over at the senior management level due to retirement, and will welcome new Board members as their terms expire.

The opportunity, and the challenge, over the planning period will be to ensure that human resource planning and business planning remain in alignment, and that operational staffing activities and other support services are equipped to support the evolving organizational needs and directions. The PMPRB's integrated business and human resources planning framework ensures the identification, review and documentation of human resources requirements on a quarterly basis, and frequent review of the status of staffing activities. Increased capacity in Human Resources will enhance support to program areas.

For the most part, matters before the Board have focused on the scientific and price issues related to brand name patented drug products. Some more recent cases have also centred on the Board's jurisdiction, for example, with regard to drugs sold from outside the country through Health Canada's Special Access Programme, and to patented generic drug products. While proceedings before the Board are time sensitive, resource intensive, and require dedication and thoughtful deliberation, they also provide patentees with an opportunity to be heard by the Board on issues vital to their operations. Board proceedings have, in some cases, resulted in judicial review applications before the Federal Court and the Federal Court of Appeal, which ultimately provide both the Board and patentees with clarification on key legal issues but may give rise to changes in the scope and conduct of the Board's regulatory mandate.

Expenditure Profile



In recognition of increasing workload pressures, the PMPRB was provided program integrity funding in the amounts of $4.9 million for 2006-2007 (in Supplementary Estimates A) and $5.0 million for 2007-2008 from the Treasury Board Risk Management Reserve to augment its $5 million A-base budget.

Those amounts included $4.4 million and $3.2 million respectively for hearings in 2006-2007 and 2007-2008, which were placed in an existing Special Purpose Allotment (SPA) in the amount of $300 thousand. The ability to hold public hearings when needed is a core component of the Board's mandate and authority. Due to the difficulty in forecasting the number and complexity of hearings in any given year, the amounts related to external hearing costs (legal counsel, expert witnesses, etc.) are placed in the SPA so that they are reserved strictly for that purpose. Any unspent amount lapses at year end.

In anticipation of the sunsetting of the temporary program integrity funding in 2008-2009, the PMPRB was granted permanent funding in the amount of $4.7 million, in addition to the core A-base of $5.8 million, to enable the PMPRB to meet its workload pressures and continue ongoing initiatives related to the delivery of its mandate.

Treasury Board approved authority to increase reference levels in Vote 35 (Program expenditures) by $5.6 million for 2009-2010, $6.2 million for 2010-2011, and $5.8

million for 2011-2012 and future years (including EBP and excluding Public Works and Government Services Canada accommodation charges).

As part of these increased resources, authority was given to increase the Special Purpose Allotment of $300 thousand to conduct Public Hearings in Vote 35 (Program Expenditures) by $1.9 million in 2008-2009, $2.2 million in 2009-2010, $2.8 million in 2010-2011, and $2.8 million in 2011-2012 and future years. This was intended to provide assurance that the PMPRB would have the necessary resources to hold hearings even in the most exceptional years.

Although expenditures (i.e. actual) rose each year from 2006-2007 to 2008-2009, there were fewer hearings than anticipated. Some were settled through the submission of Voluntary Compliance Undertakings (VCUs). In addition, the staffing of some positions has presented a challenge. The PMPRB expects to report expenditures of $9.6 million from an expected final reference level of $11.8 million in 2009-2010.

Voted and Statutory Items ($ thousands)

Vote Number or Statutory Item (s)	Truncated Vote or Statutory Wording	2009-2010 Main Estimates	2010-2011 Main Estimates
35	Program expenditures	$10,369.0	$11,163.3
(S)	Contributions to employee benefit plans	$989.0	$1,018.3
	Total PMPRB	$11,358.0	$12,181.6

Section II — Analysis of Program Activities by Strategic Outcome

Strategic Outcome

The Patented Medicine Prices Review Board (PMPRB) has one strategic outcome: Canadians and their health care system are protected from excessive prices for patented drug products sold in Canada and are informed on pharmaceutical trends.

The performance indicator for the strategic outcome is: Canada's prices on average are in line with the seven comparator countries listed in the Regulations.

The target for the strategic outcome is: Canada's prices on average are at or below the median of international prices.

The strategic outcome is supported by three Program Activities.

Program Activities

Program Activity 1: Compliance and enforcement of non-excessive prices for patented drug products					
Human Resources (FTEs) and Planned Spending ($ thousands)					
2010-2011		**2011-2012**		**2012-2013**	
FTEs	**Planned Spending**	**FTEs**	**Planned Spending**	**FTEs**	**Planned Spending**
44	$7,648.8	44	$7,654.3	44	$7,654.3

Expected Results	Performance Indicators	Targets
Prices charged by patentees for patented drug products in Canada are not excessive according to the factors of the *Patent Act*.	Percentage of patented drug products that are within the Guidelines	95% of patented drug products are within Guidelines.

Summary of Program Activity

The PMPRB is responsible for regulating the prices that patentees charge for patented drug products sold in Canada for human and veterinary use. Through this program activity, the PMPRB reviews the prices that patentees charge for patented drug products, based on the price review factors in the *Patent Act*, to ensure that these prices are not excessive. In the event that the Board finds, following a public hearing, that a price is excessive in any market, it may order the patentee to reduce the price and take measures to offset any excess revenues it may have received as a result of excessive prices.

Planning Highlights

The PMPRB is responsible for ensuring that the prices that patentees charge, the "factory-gate" price, for patented drug products sold in Canada for human or veterinary use, are not excessive. The PMPRB relies on voluntary compliance whenever possible since it is less time consuming and less costly to all parties. Voluntary compliance by patentees is facilitated by published Excessive Price Guidelines (Guidelines), which are intended to assist patentees in setting prices that are not excessive by providing transparent and predictable information on how the price review will be carried out.

In order to ensure the Guidelines remain appropriate and effective in the modern pharmaceutical environment and that they also uphold the principles of fairness, transparency, openness and predictability, the Board initiated a process in 2005 to review its Guidelines, including consulting with key stakeholders as required by the *Patent Act* (Act). Revised Guidelines were released in June 2009 for implementation starting January 1, 2010.

The key priorities for the Compliance and Enforcement program over the planning period are:

- Implement and monitor the revised Excessive Price Guidelines (Guidelines), policies and procedures.
- Redevelop the Compliance Database.
- Ensure hearing processes are transparent and more efficient.
- Develop and implement IM plans and policies that will enhance capabilities to meet operational and reporting needs for information.

Benefits for Canadians

This program activity contributes to the Government of Canada outcome of Healthy Canadians by ensuring that prices of patented drug products are not excessive. Price reviews, investigations and, when necessary, hearings must be conducted in a transparent, effective and timely fashion so as to protect the interests of consumers and the Canadian health care system.

Policy and economic analysis ensures that the PMPRB's regulatory activities remain relevant, appropriate and effective in the context of the evolving pharmaceutical environment.

Program Activity 2: Pharmaceutical trends reporting					
Human Resources (FTEs) and Planned Spending ($ thousands)					
2010-2011		**2011-2012**		**2012-2013**	
FTEs	**Planned Spending**	**FTEs**	**Planned Spending**	**FTEs**	**Planned Spending**
13	$1,624.8	13	$1,626.6	13	$1,626.6

Expected Results	Performance Indicators	Targets
Stakeholders are more aware of pharmaceutical trends and cost drivers.	Number of requests for PMPRB publications	5% increase in requests over previous year
	Number of presentations by PMPRB at external meetings	10 events per year

Summary of Program Activity

Through this program activity, the PMPRB provides analysis of pharmaceutical price trends and research and development spending by pharmaceutical patentees. It also provides critical analyses of price, utilization and cost trends for prescription drugs, and information on non-patented prescription drug prices. The PMPRB reports on these analytical studies and its price review and enforcement activities as they relate to excessive pricing for patented drug products, annually to Parliament through the Minister of Health.

Planning Highlights

The key priority for the Pharmaceutical Trends Reporting program over the planning period is:

- Enhance the profile and uptake of the research and analysis conducted by the PMPRB.

Benefits for Canadians

This program activity contributes to the Government of Canada outcome of Healthy Canadians by:

- reporting on pharmaceutical trends and on R&D spending by patentees to inform drug policy decision-making; and
- providing critical analyses of price, utilization and cost trends so that Canada's health system has more comprehensive and accurate information on how prescription drugs are being used and on sources of cost pressures.

Program Activity 3: Internal services					
Human Resources (FTEs) and Planned Spending ($ thousands)					
2010-2011		**2011-2012**		**2012-2013**	
FTEs	**Planned Spending**	**FTEs**	**Planned Spending**	**FTEs**	**Planned Spending**
19	$2,908.0	19	$2,535.3	19	$2,535.3

Program Activity Summary

Internal Services are groups of related activities and resources that are administered to support the needs of programs and other corporate obligations of an organization. These groups are: Management and Oversight Services; Communications Services; Legal Services; Human Resources Management Services; Financial Management Services; Information Management Services; Information Technology Services; Real Property Services; Materiel Services; Acquisition Services; and Travel and Other Administrative Services. Internal Services include only those activities and resources that apply across an organization and not to those provided specifically to a program.

Planning Highlights

This program activity will continue to be devoted largely to ongoing activities designed to support program areas in the provision of their programs.

The key priorities for the Internal Services program over the planning period are:

- Redevelop the Compliance Database.
- Strengthen internal capacity of Board Staff and the Board by staffing vacant positions.
- Develop and implement IM plans and policies that will enhance capabilities to meet operational and reporting needs for information.
- Prepare for evaluation of Compliance and Enforcement Program in 2011-2012.

Section III — Supplementary Information

Supplementary Information Tables

All electronic supplementary information tables found in the 2010-2011 Report on Plans and Priorities can be found on the Treasury Board of Canada Secretariat's web site at *http://www.tbs-sct.gc.ca/rpp/2010-2011/index-eng.asp*

Sources of Non-Respendable Revenue

Green Procurement

Upcoming Evaluations Over the Next Three Fiscal Years

Other Items of Interest

PMPRB Annual Report 2008 (http://www.pmprb-cepmb.gc.ca/English/View.asp?x=91&mp=68)

Quarterly NEWSletter (http://www.pmprb-cepmb.gc.ca/english/View.asp?x=287&mp=68)

Patentee's Guide to Reporting (http://www.pmprb-cepmb.gc.ca/english/view.asp?x=146)

Compendium of Guidelines, Policies and Procedures (March 2008) (http://www.pmprb-cepmb.gc.ca/english/view.asp?x=1034)

Compendium of Policies, Guidelines and Procedures, June 2009 (implementation January 1, 2010) http://www.pmprb-cepmb.gc.ca/english/View.asp?x=1206&mp=808

Patent Act (*http://laws.justice.gc.ca/en/P-4/index.html*)

Patented Medicines Regulations (*http://laws.justice.gc.ca/en/P-4/SOR-94-688/index.html*)