# **Patented Medicine Prices Review Board**

2006-2007

**Report on Plans and Priorities** 

The Honourable Tony Clement Minister of Health and the Minister for the Federal Economic Development Initiative for Northern Ontario

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# **SECTION I – OVERVIEW**

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## Chairperson's Message

I am pleased to present the 2006-2007 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: the regulatory mandate to ensure that the prices of patented drugs sold in Canada are not excessive and a reporting mandate to contribute to informed policymaking by governments through reports on pharmaceutical prices and trends, utilization, and research and development.

Pharmaceutical policy has been the subject of considerable debate in Canada over the years. The main constant in this debate has been the issue of how best to bring Canada's intellectual property regime in line with new international agreements, while providing access to affordable medications for all Canadians. In more recent years, rising pharmaceutical expenditures have taken centre stage with public programs and consumers. The Canadian Institute for Health Information (CIHI) reported that drugs represented over 16% of total health care spending in 2004, surpassing physician spending as the second highest category of health care spending after hospitals.

Public drug programs have introduced new measures to contain costs and promote appropriate prescribing and utilization practices as federal, provincial and territorial (F/P/T) Ministers of Health continue to explore new approaches to collaboration.

The PMPRB is part of that process. The PMPRB is the federal expert body on questions related to drug prices. It is responsible for analysis 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 more comprehensive and accurate information on how prescription drugs are being used and on cost drivers.

Building further on F/P/T collaboration, First Ministers signed a *10-Year Plan to Strengthen Health Care* in 2004. Part of this agreement included the development and implementation of a National Pharmaceuticals Strategy. Recently, Health Ministers reiterated their commitment to better align their regulatory and reimbursement regimes to ensure the best possible outcomes for Canadians. Among other initiatives announced at their annual meeting in October 2005, the Ministers agreed that the PMPRB should be given responsibility to monitor and report on non-patented prescription drug prices. Beginning in the spring of 2006, the PMPRB will publish quarterly reports on a number of key areas: Canadian sales and price trends; generic to brand name price comparisons; and cost of therapy and utilization patterns, to name a few.

Important advances in health care policy are being made to respond to the changing needs of Canadians. By raising issues and encouraging open debate, the PMPRB can contribute to better decision-making, and ultimately to healthy Canadians with access to quality health care, including non-excessive prices for pharmaceuticals.

Brien G. Benoit Chairperson

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# **Management Representation Statement**

I submit for tabling in Parliament, the 2006-2007 Report on Plans and Priorities (RPP) for the Patented Medicine Prices Review Board.

This document has been prepared based on the reporting principles contained in the *Guide for the Preparation of Part III of the 2006-2007 Estimates: Reports on Plans and Priorities and Departmental Performance Reports*:

- It adheres to the specific reporting requirements outlined in the TBS guidance;
- It is based on the department's approved Program Activity Architecture structure as reflected in its Management, Resource and Results Structure (MRRS);
- It presents consistent, comprehensive, balanced and accurate information;

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- It provides a basis of accountability for the results achieved with the resources and authorities entrusted to it; and
- It reports finances based on approved planned spending numbers from the Treasury Board Secretariat in the RPP.

Name: Brien G. Benoit Title: Chairperson

# **Summary Information**

#### **Reason for Existence** – The PMPRB has a dual role:

Regulatory – To protect consumers and contribute to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive;

Reporting – To contribute to informed decisions and policy making by reporting on pharmaceutical trends and on the R&D spending by pharmaceutical patentees.

#### **Financial Resources (\$ thousands)**

1					
2006-2007	2007-2008	<b>2008-2009</b> <sup>1</sup>			
\$6,512.0	\$6,480.0	\$4,948.0			

#### **Human Resources**

2006-2007	2007-2008	2008-2009
48.0	$47.0^{2}$	39.0 <sup>1</sup>

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The reduction in the estimated planned spending and FTEs for 2008-2009 is due to the expiration of the Memorandum of Understanding between the PMPRB and Health Canada to fund the PMPRB's work under the NPDUIS and a reduction in funding the PMPRB received to enhance its price review process through Health Canada's Therapeutic Access Strategy. It is expected that new funding arrangements will have been negotiated prior to the expiration of the current MOU.

The reduction in the number of FTEs for 2007-2008 is due to a reduction in funding provided through a Memorandum of Understanding between the PMPRB and Health Canada for the PMPRB to monitor and report on prices of non-patented prescription drugs.

**Departmental Priorities** 

Departmental I	Hornes				
			Planned S <sub>1</sub>	<b>pending</b> (\$ tl	nousands)
			2006-2007	2007-2008	2008-2009
Strategic Outco	me:				
Prices charged b	y manufactu	rers of patented medicines so	ld in Canada aı	e not excessi	ve.
	Type				
Priority #1 Compliance and enforcement	Ongoing	Activity: Review prices for new and existing patented medicines sold in Canada and update Board Guidelines as needed Expected results: All manufacturers' prices for new and existing patented medicines sold in Canada are reviewed in a timely manner and in accordance with the PMPRB's Excessive Price Guidelines.	3,107.0	3,112.2	3,229.2
Priority #2 Report on pharmaceutical trends	Ongoing	Activity: Identify and provide more informative information on key pharmaceutical issues of interest to Canadian consumers and other stakeholders.  Expected results: Canadian consumers and other stakeholders have complete and accurate information on trends in manufacturers' prices of patented medicines sold in Canada and on patentees' research-and-development expenditures.	1,455.0	1,457.8	1,158.8

			Planned Spending (\$ thousands)		
			2006-2007	2007-2008	2008-2009
Priority #2 Report on pharmaceutical trends (cont'd)	Ongoing	Activity: Provide critical analyses of price, utilization and cost trends for prescription drugs sold in Canada.  Expected results: F/P/T drug plans and Canada's health system will have more accurate information on how prescription drugs are being used and on sources of cost indices through critical analyses of price utilization and cost trends.	1,350.0	1,350.0	-
		Activity: Monitor and report on non-patented prescription drug prices in Canada.  Expected results: F/P/T Governments and other stakeholders will have critical analyses and comprehensive information on non-patented prescription drugs.	600.0	560.0	560.0

## **Departmental Plans and Priorities**

## **Priority #1** Compliance and enforcement

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 the 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.

The PMPRB is responsible for regulating the prices that patentees charge, the "factory-gate" price, for prescription and non-prescription patented drugs sold in Canada to wholesalers, hospitals, pharmacies, or others for human and veterinary use, to ensure that they are not excessive.

Board Staff reviews the prices of patented medicines sold in Canada to ensure that they are within the Board's Excessive Price Guidelines (Guidelines).<sup>3</sup> When it finds that the price of a patented drug product appears to exceed the Guidelines, and the circumstances meet the criteria for commencing an investigation, Board Staff will conduct an investigation to determine the facts.<sup>4</sup> An investigation could result in:

- its closure where it is concluded that the price was within the Guidelines;
- a Voluntary Compliance Undertaking (VCU) by the manufacturer to reduce the price and take other measures to comply with the Guidelines; or
- a public hearing by the Board to determine if the price is excessive and to make a remedial order.

Over the past decade, Canada has experienced considerable stability in the pricing of medicines in Canada. In 2004 the PMPRB received information that indicated that the situation may be changing. In response to this information, the PMPRB launched a discussion paper, in March 2005, soliciting stakeholder input on the issue of price increases for existing patented drugs. The discussion paper explored the evolution of the Guideline for price increases of patented medicines, historical price trends and observations that suggested a possible change in patented medicine price stability in Canada.

The PMPRB received 19 submissions in response to its Discussion Paper. Stakeholders raised a number of complex issues related to how drugs are categorized for price review purposes,

Procedures which is available on the PMPRB website: <a href="www.pmprb-cepmb.gc.ca">www.pmprb-cepmb.gc.ca</a>, under Legislation, Regulations and Guidelines.

A summary of the Excessive Price Guidelines is available in Section II page 16 of this Report. Additional information on the Guidelines can be found in Chapter 1 of the *Compendium of Guidelines, Policies and* 

<sup>&</sup>lt;sup>4</sup> Additional information on the criteria for commencing an investigation can be found in Schedule 5 of the *Compendium of Guidelines, Policies and Procedures* which is available on the PMPRB website: <a href="https://www.pmprb-cepmb.gc.ca">www.pmprb-cepmb.gc.ca</a>, under Legislation, Regulations and Guidelines.

introductory price tests and variations in prices, possibly leading to some excessive pricing, at the level of specific classes of customers and/or in specific provinces/territories.

Categorization of new medicines: Stakeholders are questioning/challenging the relevance of the drug categories used for price review purposes. The pharmaceutical industry, in particular, is critical of the current categorization of new patented drugs on the grounds that it does not recognize incremental innovation.

Industry stakeholders point to patient compliance and quality of life as indications of moderate improvement. They argue that category 3 does not sufficiently distinguish these important innovations in drug delivery i.e., doesn't separate "moderate" from "little or no" improvement.

*Introductory Price Tests:* Provincial/territorial governments, policy experts and other stakeholders claim that introductory prices for patented medicines are a major cost-driver affecting public and private drug plans and consumers.

Under the current Guidelines, a Category 2 drug product is a breakthrough or provides a substantial improvement over existing treatment. According to the Guidelines, the introductory price of a Category 2 new drug product cannot exceed the median of the international prices charged for the same drug in the comparator countries listed in the *Patented Medicines Regulations*, 1994 (Regulations) France, Germany, Italy, Sweden, Switzerland, the U.K. and the U.S.. A Category 3 is new drug product that provides moderate, little or no therapeutic advantage over comparable medicines. The price of a Category 3 drug cannot exceed the prices of all of the comparable drug products based on a Therapeutic Class Comparison (TCC) Test.

Recent analysis conducted by the Board Staff showed that, for 25% of Category 3 new drugs whose prices were not considered excessive by virtue of a TCC test had prices that exceeded the median of the international prices in the 7 comparator countries. This means that some manufacturers of category 3 drugs achieved a Canadian price premium over the price that would have been allowed had their drug been categorized as a Category 2 "breakthrough". Such a result indicates a systemic problem and gives credence to stakeholder views that the PMPRB's introductory price tests are a cost-driver.

**Price Determination Factors:** Some stakeholders recommended, for price review purposes, a more thorough use of all the existing factors outlined in the *Patent Act* (e.g., including cost of making and manufacturing a drug). Others advocated the review of price increases based on new factors, such as research-and-development expenditures or promotional spending of patentees.

*Price Increases:* The Board's Guidelines provide that price increases for existing patented medicines are limited to changes in the Consumer Price Index (CPI); and the price of a patented drug in Canada may not, at any time, exceed the highest price for the same drug in the foreign countries listed in the Regulations. The Board has determined that its Guidelines remain appropriate in this regard. However, this is a matter that may be challenged in anticipated hearings.

*Price variations across markets:* Currently, the prices of individual patented drug products are reviewed in relation to an average transaction price (ATP) for Canada. The ATP is an average of the prices charged to individual customer classes (wholesalers, hospitals, pharmacists and others)

in each of the 13 provinces and territories, weighted by the volume of sales. Findings of preliminary research conducted by the PMPRB suggest that the prices of some drug products do vary significantly across jurisdictions and customer classes. The implication of this is that certain customers and provinces may be paying excessive prices while lower prices are offered to others for the same drug product.

The *Patent Act* states that the PMPRB's mandate is to determine whether a patentee "is selling or has sold the medicine in any market in Canada at a price that, in the Board's opinion, is excessive."

As a result of the findings of the various analyses conducted by the Board Staff and stakeholders comments, the Board believes it is important, for the fundamental credibility of its regulatory program, to engage in a major review of its Guidelines.

The PMPRB has begun significant analytical work and will undertake further consultations with stakeholders to identify and consider possible options for changes to the current Guidelines. This will also include a legal assessment of the need for commensurate changes to the *Patented Medicines Regulations*, 1994 and possibly the *Patent Act*. Next steps will be determined upon completion of this work. The work began in 2006-2007 and will continue into 2007-2008.

#### **Priority #2 – Report on pharmaceutical trends**

The PMPRB reports annually to Parliament through the Minister of Health. The PMPRB's Annual Report, which covers the calendar year, includes a review of its major activities, analyses of prices of patented medicines and of the price trends of all drugs, and reports on the R&D expenditures as reported by patent-holding drug manufacturers. The PMPRB also reports through its quarterly NEWSletter and various studies.

In addition, pursuant to an agreement by the Federal/Provincial/Territorial (F/P/T) Ministers of Health and at the request of the federal Minister of Health, the PMPRB conducts research under the National Prescription Drug Utilization Information System (NPDUIS). The purpose of 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 increases.

In the summer of 2005, the PMPRB conducted a NPDUIS Stakeholders Needs Assessment by surveying members of the NPDUIS Steering Committee (comprised of representatives of F/P/T drug plans, except Quebec). The purpose of the needs assessment was to determine what information is required to make informed decisions about strategic pharmaceutical management issues. As a result of the needs assessment, the following projects have been identified as priorities for 2006-2007:

- An annual report on trends and cost-drivers;
- Development of national guidelines for budget impact analysis; and
- Monitoring and reporting on the new drug pipeline.

As part of the September 2004 "10-year Plan to Strengthen Health Care", First Ministers committed to develop and implement a National Pharmaceuticals Strategy (NPS). Further, they directed Health Ministers to establish a Ministerial Task Force to develop and implement the NPS and report on progress by June 30, 2006.

The overall objective of the NPS is to ensure more timely, equitable, uniform and affordable access to drugs for all Canadians and to improve the management of drug costs and drug plans for all jurisdictions, including the federal government.

Recognizing the complexity and the magnitude of the Strategy, F/P/T officials identified five priority focus areas: catastrophic drug coverage; expensive drugs for rare diseases; common national formulary; real world drug safety and effectiveness; and, pricing and purchasing.

Multiple source (generic) drugs are ordinarily introduced at a lower price than the reference brand-name drugs. While multiple source drugs are generally less expensive than their brand-name equivalents, a number of studies have demonstrated that prices of the top-selling non-patented drugs in Canada – both multiple and single source – may be higher in Canada than in other countries.

Recent research results highlighted the need for more ongoing information on the prices of non-patented drugs. Regular reporting of prices and price trends could enable public drug plans to negotiate better prices for non-patented drugs and achieve international price parity, thus contributing to the sustainability of the public drug plans and the Canadian health care system.

In October 2005, the Federal Minister of Health on behalf of himself and his P/T colleagues directed the PMPRB to monitor and report on the prices of non-patented prescription drugs in Canada. On July 4, 2006, the PMPRB released the first of a series of quarterly reports on prices and trends for non-patented prescription drugs – Non-Patented Prescription Drug Prices: *Canadian and Foreign Price Trends*.

# SECTION II – ANALYSIS OF PROGRAM ACTIVITIES BY STRATEGIC OUTCOME

### **Analysis by Program Activity**

The PMPRB has one program, the Patented Medicine Prices Review. Its objective is to protect consumer interests and to contribute to Canadian health care by ensuring that the prices charged by manufacturers of patented medicines are not excessive and by reporting on trends in pharmaceutical prices and R&D.

#### **Strategic Outcome:**

Prices charged by manufacturers for patented medicines sold in Canada are not excessive.

#### **Program Activity Name:**

Patented Medicine Prices Review

#### **Financial Resources (\$ thousands):**

2006-2007	2007-2008	2008-2009 <sup>5</sup>
\$6,512.0	\$6,480.0	\$4,948.0

#### **Human Resources:**

200	06-2007	2007-2008	2008-2009
	48.0	$47.0^{6}$	39.0

The PMPRB is responsible for regulating the prices that patentees charge, the "factory-gate" price, for prescription and non-prescription patented drugs sold in Canada to wholesalers, hospitals, pharmacies, and others for human and veterinary use, to ensure that they are not excessive.<sup>7</sup>

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.

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The reduction in the estimated planned spending and FTEs for 2008-2009 is due to the expiration of the Memorandum of Understanding between the PMPRB and Health Canada to fund the PMPRB's work under the NPDUIS and a reduction in funding the PMPRB received to enhance its price review process through Health Canada's Therapeutic Access Strategy. It is expected that new funding arrangements will have been negotiated prior to the expiration of the current MOU.

The reduction in the number of FTEs for 2007-2008 is due to a reduction in funding provided through a memorandum of understanding between the PMPRB and Health Canada for the PMPRB to monitor and report on prices of non-patented prescription drugs.

The PMPRB has no authority over the prices of non-patented drugs, including generic drugs sold under compulsory licenses, and does not have jurisdiction over prices charged by wholesalers or retailers or over pharmacists' professional fees. Also, matters such as distribution and prescribing are outside the purview of the PMPRB.

The PMPRB reviews the pricing information for all patented medicines sold in Canada on an ongoing basis to ensure that the prices charged by patentees comply with the Excessive Price Guidelines established by the Board. The Guidelines are published in the PMPRB's *Compendium of Guidelines, Policies and Procedures* (Compendium) and are available on the website: <a href="www.pmprb-cepmb.gc.ca">www.pmprb-cepmb.gc.ca</a>, under Legislation, Regulations and Guidelines.

The Guidelines are based on the price determination factors in section 85 of the *Patent Act* and have been developed and modified in consultation with stakeholders, including the provincial and territorial Ministers of Health, consumer groups and the pharmaceutical industry. The Guidelines reflect the expected results for the program activity. In summary, the Guidelines provide that:

- prices for most new patented drugs are limited such that the cost of therapy for the new drug
  does not exceed the highest cost of therapy for existing drugs used to treat the same disease
  in Canada;
- prices of breakthrough patented drugs and those which bring a substantial improvement are generally limited to the median of the prices charged for the same drug in other industrialized countries listed in the Regulations (France, Germany, Italy, Sweden, Switzerland, U.K. and U.S.);
- price increases for existing patented medicines are limited to changes in the Consumer Price Index (CPI); and
- the price of a patented drug in Canada may not, at anytime, exceed the highest price for the same drug in the foreign countries listed in the Regulations.

The expect result of the price review program activity is that all manufacturers' prices for new and existing patented medicines sold in Canada are reviewed in a timely manner and are in accordance with the Board's Excessive Price Guidelines; and that information on pharmaceutical prices and trends is reported to Canadians.

The program activity supports the Government's priority of healthy Canadians with access to quality health care by ensuring that Canadians have access to patented pharmaceutical products at prices that are not excessive.

The indicators that show the PMPRB is achieving its expected results and thus its strategic outcome are:

- prices of patented medicines sold in Canada are within the Guidelines;
- enforcement measures are used to correct prices that exceed the Guidelines;
- trends show that price increases for existing patented medicines are not higher than changes in the CPI; and
- trends show that Canadian prices of patented drugs are, on average, below the median international prices of the foreign countries in the Regulations.

The PMPRB reports annually to Parliament on its major activities, analyses of prices of patented medicines and of price trends for all drugs, and R&D expenditures as reported by patent-holding drug manufacturers.

Patentees are required, under the Regulations, to report their total sales of drugs in Canada, both patented and non-patented, to the PMPRB. Patentees are also required to submit detailed information, by product and class of purchaser, on their sales of currently patented drugs. This information allows the PMPRB to directly calculate sales of patented drugs for each patentee, and to infer the amount of each patentee's total drug sales attributed to non-patented drugs. To complete the calculations, the PMPRB obtains estimates of generic sales by members of the Canadian Generic Pharmaceutical Association (CGPA) from IMS Health.<sup>8</sup>

The PMPRB maintains the Patented Medicine Price Index (PMPI) to monitor trends in prices of patented drug products sold in Canada. It is updated annually using price and sales information reported by patentees.<sup>9</sup>

In accordance with the *Patent Act*, and the Regulations, patentees must also report all publicly available ex-factory prices of patented drugs in seven foreign countries: France, Germany, Italy, Sweden, Switzerland, the U.K. and the U.S.

The expected result of this key service is that Canadian consumers and other stakeholders have complete and accurate information on trends in manufacturers' prices of patented medicines sold in Canada and on patentees' research-and-development expenditures. This information will provide assurance to Canadians that the prices of patented drug products are not excessive.

The National Prescription Drug Utilization Information System (NPDUIS) provides 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 increases. The Canadian Institute for Health Information (CIHI) and the PMPRB are partners in the NPDUIS. A steering committee, comprised of representatives of F/P/T public drug plans (excluding Quebec) and Health Canada, advises CIHI and the PMPRB on the development of NPDUIS and identifies priorities for analytical studies.

The expected result of this key service is that F/P/T drug plans and Canada's health system will have more accurate information on how prescription drugs are being used and on sources of cost indices through critical analyses of price utilization and cost trends. This information will contribute to informed decisions and policy making about affordable access to quality health care.

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<sup>8</sup> IMS Health, Canadian Health and Pharmacy Audit

See the PMPRB's A description of the Laspeyres Methodology used to construct the Patented Medicine Price Index (PMPI), March 1997, revised June 2000, for a detailed explanation of the PMPI. The PMPI measures the overall change in the prices of existing patented drug products, and is constructed by taking a sales-weighted average of rates of price change at the level of individual products. It is not designed to measure the effects of changes in the quantities of drugs consumed or substitution among drugs (for example, the use of newer drugs in place of older, and possibly less costly drugs) on sales. As of the 1999 Annual Report, the PMPI encompasses prices of patented drugs for human use only.

In the fall of 2005, F/P/T Health Ministers agreed that the PMPRB be asked to monitor and report on the prices of non-patented prescription medicines. In October 2005, the PMPRB entered into a Memorandum of Understanding with Health Canada to fund this work and in November, the Federal Minister of Health formally directed the PMPRB to undertake this work pursuant to section 90 of the *Patent Act*.

The PMRPB will produce four quarterly reports each year. These reports will cover a range of topics including a profile of the market for non-patented drugs in Canada, information on sales trends, Canadian price trends, notable price changes, new off-patent markets, generic versus brand comparisons, international price comparisons and market structure trends. The first quarterly report was released July 2006.

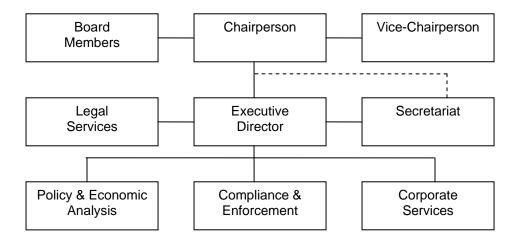
The expected result of this key service is that F/P/T Governments and other stakeholders will have critical analyses and comprehensive information on non-patented prescription drug prices.

The indicators that show the PMPRB is achieving its expected results in reporting pharmaceutical trends are:

- An annual report to Parliament on the PMPRB's major activities, analyses of prices of
  patented medicines and of the price trends of all drugs, and R&D expenditures as filed by
  patent-holding drug manufacturers;
- Studies completed under NPDUIS; and
- Reports on non-patented prescription drug prices.

# **SECTION III – SUPPLEMENTARY INFORMATION**

# **Organizational Information**



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. In June 2006, the Vice-Chairperson, Dr. Benoit, was appointed as Chairperson and Mary Catherine Lindberg was appointed Member and Vice-Chairperson for a 5 year term. At present one Board position remains vacant.

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 patented medicine prices 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 Board communications, administrative and legal support.

**Table 1: Departmental Planned Spending and Full Time Equivalents** 

(\$ thousands)	Forecast Spending 2005-200	<b>Spending</b>	Planned Spending 2007-2008	Planned Spending 2008-2009
Patented Medicine Prices Review				
Budgetary Main Estimates (gross)	4,373.0	<b>6,512.0</b> 11	6,480.0 11	4,948.0 <sup>13</sup>
Less: Respendable revenue	-	-	-	-
Total Main Estimates	4,373.0	6,512.0	6,480.0	4,948.0
Adjustments:				
Second Governor General Special Warrants				
For work under the National Prescription Drug Utilization Information System and for the reporting of non-patented drug prices in Canada under the National Pharmaceuticals Strategy	370.0	-	-	-
Third Governor General Special Warrants				
For work under the National Prescription Drug Utilization Information System and for the reporting of non-patented drug prices in Canada under the National Pharmaceuticals Strategy	863.0	-	-	-
Other				
Employee Benefit Plan (EBP) Year-end adjustment	18.3			
Total Adjustments	1,251.3	-	-	-
<b>Total Planned Spending</b>	5,624.3	6,512.0	6,480.0	4,948.0
Total Planned Spending	5,624.3	6,512.0	6,480.0	4,948.0
Less: Non-Respendable revenue	(1,413.3)	10	-	-
Plus: Cost of services received without charge	779.6	871.2	877.4	832.9
Net cost of Program	4,990.6	7,383.2	7,357.4	5,780.9
Full Time Equivalents	45.0	<b>48.0</b> 12	47.0	39.0 <sup>13</sup>

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 2005-2006 the Board accepted 5 VCUs. Additional information on VCUs is available on the website: <a href="www.pmprb-cepmb.gc.ca">www.pmprb-cepmb.gc.ca</a>, under Publications, Voluntary Compliance Undertakings.

- The Treasury Board Ministers have approved supplementary funding of \$5.1 million for fiscal years 2006-2007 and 2007-2008 for the PMPRB to conduct public hearing and modernize the Excessive Price Guidelines. In 2007-2008 the PMPRB will seek approval to revise its permanent funding to reflect ongoing operational needs.
- The increase in the number of FTEs for 2006-2007 and 2007-2008 is a result of additional resources provided through a Memorandum of Understanding between the PMPRB and Health Canada for the PMPRB to monitor and report on prices of non-patented prescription drugs.
- The reduction in the estimated planned spending and FTEs for 2008-2009 is due to the expiration of the Memorandum of Understanding between the PMPRB and Health Canada to fund the PMPRB's work under the NPDUIS and a reduction in funding the PMPRB received to enhance its price review process through Health Canada's Therapeutic Access Strategy. It is expected that new funding arrangements will have been negotiated prior to the expiration of the current MOU.

**Table 2: Program Activities** 

2006-2007						
(\$ thousands)						
Program Activity	Operating	Gross	Respendable Revenue	Net	Total Main Estimates	Total Planned Spending
Patented Medicine Prices Review	6,512.0	6,512.0	-	6,512.0	6,512.0	6,512.0
Total	6,512.0	6,512.0	-	6,512.0	6,512.0	6,512.0

**Table 3: Voted and Statutory Items listed in Main Estimates** 

2006-2007									
(\$ thousands)									
Vote or Statutory Item	Truncated Vote or Statutory Wording	2006-2007 Main Estimates	2005-2006 Main Estimates <sup>14</sup>						
30	Program expenditures	5,800.0	3,848.0						
(S)	Contributions to employee benefit plans	712.0	525.0						
	<b>Total Agency</b>	6,512.0	4,373.0						

The reduction in estimated total planned spending and full-time equivalents for 2005-2006 is a result of the fact that funding arrangements for NPDUIS had not been finalized beyond 2004-2005. Continued funding for NPDUIS was approved in 2006-2007.

**Table 4: Services Received Without Charge** 

(\$ thousands)	2006-2007
Accommodation provided by Public Works and Government Services Canada (PWGSC)	590.0
Contributions covering employers' share of employees' insurance premiums and expenditures paid by Treasury Board of Canada Secretariat (excluding revolving funds) Employer's contribution to employees' insured benefits plans and expenditures paid by TBS	281.2
2006-2007 Services received without charge	871.2

# **Table 5: Sources of Non-Respendable Revenue**

Non-Respendable Revenue

(\$ thousands)	Forecast Revenue 2005-2006		Planned Revenue 2006-2007	Planned Revenue 2007-2008	Planned Revenue 2008-2009
Patented Medicine Prices Review					
Source of non-respendable revenue					
Voluntary Compliance Undertakings	1,413.3	15	-	-	-
Total Non-Respendable Revenue	1,413.3		-	_	-

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 or Board orders to offset excess revenues. The Minister of Health 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.