

Patented Medicine Prices Review Board

2016–17

Report on Plans and Priorities

The Honourable Jane Philpott
Minister of Health

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Chairperson’s Message

I am pleased to present the 2016–17 Report on Plans and Priorities for the Patented Medicine Prices Review Board (PMPRB).

The PMPRB is an independent, quasi-judicial administrative agency with a mandate to protect consumers from excessively priced patented medicines and to report to Canadians on price trends of all medicines, and on patentees’ research and development (R&D) investments.

The PMPRB was conceived in 1987 through amendments to the *Patent Act* as part of a major overhaul of Canada’s drug patent regime which sought to balance potentially competing policy objectives. On the one hand, the government strengthened patent protection for drugs in an effort to encourage more pharmaceutical R&D investment in Canada. On the other hand, it sought to mitigate the financial impact of that change on Canadians by creating the PMPRB, a consumer protection agency with a mandate to ensure patented drug prices in Canada are not “excessive”.

As a member of the Health Portfolio, the PMPRB plays an important role in the broader objective of improving the health of Canadians through a responsible, accessible and sustainable health system.

All Canadians who pay for a patented prescription drug potentially stand to benefit from the PMPRB’s price ceilings. The PMPRB’s analytical and reporting work benefits the provinces and territories in their continuing efforts to implement pricing policies for generic drugs and negotiate lower prices for brand-name medicines. Through the National Prescription Drug Utilization Information System (NPDUIS) initiative, the PMPRB also provides objective and timely information on a variety of topics of interest to payers, policy makers and other pharmaceutical stakeholders, including generic drug use and cost, pipeline drugs and cost drivers in public and private plans.

Canada, like many countries, is facing escalating health care costs, as payers everywhere are struggling to reconcile finite drug budgets with patient access to promising new health technologies. While other developed countries have adopted targeted price reforms at a national level and have introduced measures to address affordability issues, maximize value for money, and keep pace with a rapidly evolving pharmaceutical market in recent years, the PMPRB’s legal framework¹ has remained largely unchanged since inception.

Having recently celebrated its 25th anniversary, the PMPRB finds itself at an important crossroads in its history. If the PMPRB is to remain a relevant and effective player in a sustainable pharmaceutical system when Canadian patented drug prices are outpacing those in

the PMPRB⁷ⁱⁱ (with the exception of the US) and other European countries, R&D is at a record low and payers are struggling to cope with an influx of high cost drugs, it must adopt a more consumer-centric approach to how it carries out its regulatory and reporting functions.ⁱⁱⁱ

To that end, in the coming year, the PMPRB will consult with stakeholders on whether and to what extent changes to its consumer protection powers are warranted to ensure that Canadian patented drug costs remain affordable. The PMPRB will also intensify its partnership with public payers to assist them in their negotiations and expand the topics it reports on to better serve private payers and consumers.

The PMPRB's recently released [Strategic Plan – 2015–2018](#)^{iv} plots a course toward reform that will enable it to deliver on the government's original policy objectives having regard to the realities of the modern day pharmaceutical market.

Mary Catherine Lindberg

Section I: Organizational Expenditure Overview

Organizational Profile

Appropriate Minister: The Honourable Jane Philpott

Institutional Head: Mary Catherine Lindberg, Chairperson

Ministerial Portfolio: Health

Enabling Instrument(s): *Patent Act*^v and *Patented Medicines Regulations*^{vi}

Year of Incorporation / Commencement: 1987

Other: The Minister of Health is responsible for the pharmaceutical provisions of the *Patent Act* (Act) set out in sections 79 to 103. Although the Patented Medicine Prices Review Board (PMPRB) is part of the Health Portfolio, because of its quasi-judicial responsibilities the PMPRB carries out its mandate at arm's length from the Minister. It also operates independently of Health Canada, which approves drugs for safety, efficacy and quality; other Health Portfolio members, such as the Public Health Agency of Canada, the Canadian Institutes of Health Research and the Canadian Food Inspection Agency; and federal, provincial and territorial (F/P/T) public drug plans, which approve the listing of drugs for their respective formularies for reimbursement purposes; and the Common Drug Review, administered by the Canadian Agency for Drugs and Technologies in Health (CADTH), which recommends drugs that should qualify for reimbursement purposes by participating public drug plans.

Organizational Context

Raison d’être

The PMPRB is an independent, quasi-judicial body created by Parliament in 1987. Its mandate is twofold:

- 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 research and development (R&D) spending by pharmaceutical patentees.

In carrying out its mandate, the PMPRB ensures that Canadians are protected from excessive prices for patented medicines sold in Canada and that stakeholders are informed on pharmaceutical trends.

Responsibilities

The PMPRB was created as a result of amendments to the *Patent Act* (Act) in 1987 (Bill C-22), and its remedial powers were modified by further amendments in 1993 (Bill C-91). Both sets of amendments were intended to balance the stronger patent protection for pharmaceuticals, which was intended to encourage the R&D efforts of pharmaceutical patentees, with the need to protect consumers from possible excessive patented drug prices.

The PMPRB has a dual mandate:

Patented Medicine Prices Regulation

The PMPRB regulates “factory-gate” ceiling prices that patentees charge for prescription and non-prescription patented medicines sold in Canada to wholesalers, hospitals, pharmacies or others, for human and veterinary use, to ensure they are not excessive. The Board’s mandate also includes medicines that are available under the Special Access Programme; through a Clinical Trial Application; and Investigational New Drug Products. Over-the-counter (OTC) patented medicines and patented medicines for veterinary use are regulated by the Board on a complaints basis.

If Staff determines that the price of a patented medicine appears to be excessive the patentee may agree to a Voluntary Compliance Undertaking (VCU) to resolve the matter. If a consensual resolution of the issue cannot be reached with the patentee, the Chairperson may hold a hearing on the matter if she is of the view that it is in the public interest.

The PMPRB's adjudicative functions are carried out by the Board Members. At a hearing, a panel composed of Board members act as a neutral arbiter between Board Staff and the patentee. The Chairperson decides the composition of members on a panel. Provincial and Territorial Ministers of Health have a statutory right to appear before the panel as parties, and other interested parties or groups may seek leave to participate as interveners.

In the event that a panel finds that the price of a patented medicine is in fact excessive, it can order a reduction of the price to a non-excessive level. It can also order a patentee to make a monetary payment to the Government of Canada in the amount of the excess revenues earned and, in cases where the panel determines there has been a policy of excessive pricing, it can double the amount of the monetary payment.

Pharmaceutical Trends Reporting

The PMPRB reports annually to Parliament through the Minister of Health on its price review activities, the prices of patented medicines and price trends of all prescription drugs, and on the R&D expenditures reported by pharmaceutical patentees. In addition, as a result of the establishment of the [National Prescription Drug Utilization Information System](#)^{vii} (NPDUIS) by F/P/T Ministers of Health in September 2001, the PMPRB conducts critical analysis of price, utilization, and cost trends for patented and non-patented prescription drugs so that key participants in Canada's health care system have more comprehensive, accurate information on how all prescription drugs are being used and on the sources of cost pressures. This function is aimed at providing F/P/T governments and other interested stakeholders with a centralized credible source of information on pharmaceutical trends.

Strategic Outcome and Program Alignment Architecture

1. Strategic Outcome: Canadians are protected from excessive prices for patented medicines sold in Canada and stakeholders are informed on pharmaceutical trends.

1.1 Program: Patented Medicine Prices Regulation Program

1.2 Program: Pharmaceutical Trends Program

Internal Services

Organizational Priorities

Priority: Consumer-focused regulation and reporting

Description

If the PMPRB is to remain true to its description as the “consumer protection pillar” of Bill C-22, at a time when Canadian patented drug prices are outpacing those in the PMPRB7 (with the exception of the US) and other European countries, and R&D investment is at a record low, it must adopt a more consumer-centric approach to how it carries out its regulatory and reporting functions.

*Priority Type*¹ – New

Key Supporting Initiatives

Planned Initiatives	Start Date	End Date	Link to Department's Program Alignment Architecture
On the regulatory side, the PMPRB will: <ul style="list-style-type: none"> focus its enforcement resources on cases that are most relevant to payers, and that will raise issues which could clarify certain aspects of the PMPRB's regulatory framework and make it a more effective consumer champion. 	Ongoing		The PMPRB has only one Strategic Outcome (SO) and all risks are linked to that SO. This priority is linked to Program 1.1.

1. Type is defined as follows: previously committed to—committed to in the first or second fiscal year prior to the subject year of the report; ongoing—committed to at least three fiscal years prior to the subject year of the report; and new—newly committed to in the reporting year of the Report on Plans and Priorities or the Departmental Performance Report.

Planned Initiatives	Start Date	End Date	Link to Department's Program Alignment Architecture
<ul style="list-style-type: none"> • examine options to bring more precision and policy coherence to its price ceiling setting process, with the objective of achieving affordable patented drug costs for Canadians. 	January 2016	March 2017	The PMPRB has only one SO and all risks are linked to that SO. This priority is linked to Program 1.1.
<p>On the reporting side, the PMPRB will:</p> <ul style="list-style-type: none"> • work with public and private payers to pursue opportunities for further collaboration, including putting systems in place which will facilitate and standardize the sharing of pricing, utilization and cost data so that insurers can make better informed and more timely reimbursement decisions. 	January 2016	March 2017	The PMPRB has only one SO and all risks are linked to that SO. This priority is linked to Program 1.2.

Priority: Framework modernization

Description

Recently, Canadian patented drug prices have been steadily rising relative to prices in the PMPRB7. Whereas in 2005 Canadian prices were third lowest of these seven countries, in 2013 they were third highest, nearly at par with Germany. Among the five lower priced countries of the PMPRB7 in 2013, prices in the UK, France and Italy were all 20% below Canadian prices. As prices in Canada rise, R&D is declining. Since 2003, Innovative Medicines Canada (formerly Canada's Research-Based Pharmaceutical Companies (Rx&D)) members have failed to meet their 10% commitment and the latest publicly reported ratio stands at a 5.4% of sales. This is the lowest recorded figure since 1988, when the PMPRB first began reporting on R&D. In contrast, the average R&D ratio of the PMPRB7 countries has held steady at above 20%. In light of this, the PMPRB will consult on whether and to what extent changes to its consumer protection powers are warranted if it is to ensure that patented drug costs are affordable for Canadians.

Priority Type – New

Key Supporting Initiatives

Planned Initiatives	Start Date	End Date	Link to Department's Program Alignment Architecture
The PMPRB will: <ul style="list-style-type: none"> consult with stakeholders on options to modernize and simplify its pricing guidelines. 	April 2016	March 2017	The PMPRB has only one SO and all risks are linked to that SO. This priority is linked to Program 1.1.
<ul style="list-style-type: none"> engage with and assist federal, provincial and territorial partners in any future discussions on broader regulatory and legislative reform, taking into account international best practices. 	Ongoing	n/a	The PMPRB has only one SO and all risks are linked to that SO. This priority is linked to Program 1.1.

Priority: Strategic partnerships and public awareness

Description

If the PMPRB is to succeed in its efforts to simplify and modernize its Guidelines and bring broader reform to federal regulation and legislation, it must engage with a heterogeneous network of pharmaceutical industry stakeholders, each with its own unique interest and perspective on these changes. To do so effectively, the PMPRB must enhance awareness of its consumer protection mandate and build on its reputation as an honest broker with stakeholders and the public at large.

Priority Type – New

Key Supporting Initiatives

Planned Initiatives	Start Date	End Date	Link to Department's Program Alignment Architecture
The PMPRB will focus on: <ul style="list-style-type: none"> intensifying its partnership with public payers to provide more timely and relevant market intelligence; 	April 2016		The PMPRB has only one SO and all risks are linked to that SO. This priority is linked to Program 1.2.

Planned Initiatives	Start Date	End Date	Link to Department's Program Alignment Architecture
<ul style="list-style-type: none"> expanding the topics it reports on to provide private payers and consumers with information to help them make better, more cost effective choices; 	Ongoing		The PMPRB has only one SO and all risks are linked to that SO. This priority is linked to Program 1.2.
<ul style="list-style-type: none"> working closely with international counterparts in sharing knowledge and best practices; and, 	Ongoing		The PMPRB has only one SO and all risks are linked to that SO. This priority is linked to Programs 1.1 and 1.2.
<ul style="list-style-type: none"> adopting a more proactive approach to communicating its regulatory and reporting achievements to stakeholders and the public. 	Ongoing		The PMPRB has only one SO and all risks are linked to that SO. This priority is linked to Program 1.2.

Priority: Employee Engagement

Description

The PMPRB's greatest asset is its people. To maintain standards of excellence and convince employees that the PMPRB is a desirable organization in which to build a career, it must attract, recruit, retain and rejuvenate a highly qualified, skilled, motivated and diverse workforce.

Priority Type – New

Key Supporting Initiatives

Planned Initiatives	Start Date	End Date	Link to Department's Program Alignment Architecture
<p>The PMPRB will:</p> <ul style="list-style-type: none"> continue to inform and engage employees in the strategic planning process as it unfolds and annual priorities are developed and refined; 	Ongoing		The PMPRB has only one SO and all risks are linked to that SO. This priority is linked to Programs 1.1 and 1.2.

Planned Initiatives	Start Date	End Date	Link to Department's Program Alignment Architecture
<ul style="list-style-type: none"> • provide employees clear direction on work objectives and expected behaviours in order to promote a culture of consistent high performance; 	Ongoing		
<ul style="list-style-type: none"> • implement a comprehensive internal communications strategy to enable more structured dialogue between branches, management and employees; 	Ongoing		The PMPRB has only one SO and all risks are linked to that SO. This priority is linked to Program 1.2.
<ul style="list-style-type: none"> • provide employees with a wider range of learning and developmental opportunities; and, 	Ongoing		
<ul style="list-style-type: none"> • hire new employees from both inside and outside the government with the experience and abilities to enable the PMPRB to deliver on its other organizational priorities. 	Ongoing		

For more information on organizational priorities, see the Minister of Health's mandate letter on the [Prime Minister of Canada's website](#).^{viii}

Risk Analysis

Key Risks

Risk	Risk Response Strategy	Link to Program Alignment Architecture
As the provinces and territories move to formalize the pCPA ^{ix} and achieve even greater price reductions from pharmaceutical manufacturers, there is a risk that the price ceilings set by the PMPRB will become less relevant to public payers.	<ul style="list-style-type: none"> • The PMPRB will intensify its partnership with public payers by providing timely and relevant market intelligence to inform and empower their negotiations with manufacturers. • The PMPRB will conduct targeted regulatory interventions that focus on cases that matter most to payers, such as high cost niche drugs where countervailing power is lacking. 	The PMPRB has only one SO and all risks are linked to that SO.
There is a risk that continued efforts by pharmaceutical pricing and reimbursement authorities in the EU to lower prices will soon result in Canada having the second highest patented drug prices, below only the US, of the PMPRB's seven comparator countries, and/or prices that are higher than the international median.	<ul style="list-style-type: none"> • The PMPRB will consult on whether and to what extent changes to its consumer protection powers are needed to ensure that patented drug costs remain affordable for Canadians. • The PMPRB will strengthen ties with pricing and reimbursement authorities in other countries to share market intelligence and stay abreast of the latest developments on cost containment. • The PMPRB will also examine options to bring more precision and policy coherence to its price ceiling setting process, with the objective of achieving affordable patented drug costs for Canadians. 	The PMPRB has only one SO and all risks are linked to that SO.
Implementation of pending multilateral trade agreements may prompt debate as to whether the current balance in pharmaceuticals between intellectual property rights and consumer protection is working as originally intended.	<ul style="list-style-type: none"> • The PMPRB will consult on whether and to what extent changes to its consumer protection powers are needed to ensure that patented drug costs remain affordable for Canadians. 	The PMPRB has only one SO and all risks are linked to that SO.
There are multiple outstanding court cases at various levels that challenge the PMPRB's jurisdiction and/or the constitutionality of its enabling provisions. There is a risk that these cases may circumscribe the PMPRB's jurisdiction and make it less able to carry out its consumer protection mandate.	<ul style="list-style-type: none"> • The PMPRB is working closely with the Attorney General in defending these cases so as to mitigate any risk that its consumer protection powers will be curtailed as a result of an adverse court decision. 	The PMPRB has only one SO and all risks are linked to that SO.

Risk	Risk Response Strategy	Link to Program Alignment Architecture
Given the highly specialized nature of its consumer protection mandate, the PMPRB may not be able to attract and retain the subject matter experts it needs to fulfil its mandate.	<ul style="list-style-type: none"> • The PMPRB has made employee engagement one of its four strategic priorities and is in the process of hiring new staff with the skill sets to advance its priorities. • The PMPRB will continue to create a culture that values employees and recognizes and rewards their contribution in a variety of ways. 	The PMPRB has only one SO and all risks are linked to that SO.

The PMPRB was described as the “consumer protection pillar” of its originating legislation, Bill C-22. That description has been endorsed on multiple occasions by the courts, including by the Supreme Court of Canada in 2011. The originally stated purpose of the PMPRB was to ensure that patentees did not abuse their newly strengthened patent rights by charging consumers excessive prices during the statutory monopoly period. Bill C-22 was very contentious at the time, and the credibility and effectiveness of the PMPRB as a regulator was seen as key to ensuring the long-term viability of the policy compromise embodied within it.

The coupling of high Canadian patented drug prices and record low investment in R&D has many questioning the effectiveness of the PMPRB in meeting the government’s original policy objectives. This viewpoint was echoed most recently by the Advisory Panel on Healthcare Innovation in its July 17, 2015 report, *“Unleashing Innovation: Excellent Healthcare for Canada”* when it concluded that the PMPRB needs to be “strengthened” to better “protect consumers from high patented drug prices.” Similarly, the Liberal Government’s electoral platform included a commitment to “consult with industry and review the rules used by the Patented Medicine Prices Review Board to ensure value for the money governments and individual Canadians spend on brand name drugs.”

Despite periodic adjustment, the PMPRB’s current legal framework remains grounded in an understanding of the Canadian and global pharmaceutical sector circa 1987. The PMPRB’s recently released 2015-2018 Strategic Plan plots a course toward reform that will enable it to deliver on the government’s original policy objectives having regard to the realities of the modern day pharmaceutical market. The foregoing priorities and initiatives are all drawn from the Strategic Plan – 2015-2018, which is available on the PMPRB’s website at: <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1197>.

Planned Expenditures

Budgetary Financial Resources (dollars)

2016–17 Main Estimates	2016–17 Planned Spending	2017–18 Planned Spending	2018–19 Planned Spending
10,965,108	10,965,108	10,965,108	10,965,108

Human Resources (Full-Time Equivalents [FTEs])

2016–17	2017–18	2018–19
71	71	71

Budgetary Planning Summary for Strategic Outcome(s) and Program(s) (dollars)

Strategic Outcome, Programs and Internal Services	2013–14 Expenditures	2014–15 Expenditures	2015–16 Forecast Spending	2016–17 Main Estimates	2016–17 Planned Spending	2017–18 Planned Spending	2018–19 Planned Spending
Strategic Outcome: 1. Canadians are protected from excessive prices for patented medicines sold in Canada and stakeholders are informed on pharmaceutical trends.							
Patented Medicine prices Regulation Program	*6,395,602	3,543,891	5,153,100	6,646,758	**6,646,758	6,646,758	6,646,758
Pharmaceutical Trends Program	1,146,790	1,301,871	1,749,520	1,704,508	1,704,508	1,704,508	1,704,508
Subtotal	7,542,392	4,845,762	6,902,620	8,351,266	8,351,266	8,351,266	8,351,266
Internal Services Subtotal	2,998,175	3,084,518	2,536,900	2,613,842	2,613,842	2,613,842	2,613,842
Total	10,540,567	7,930,280	9,439,520	10,965,108	10,965,108	10,965,108	10,965,108

* Expenditures for 2013–14 were significantly higher than expenditures in 2014–15. This variance is due in large part to a Federal Court decision that quashed a Board Order and directed the PMPRB return to the patentee the sum of \$2,801,275 paid to the Board as a payment of excess revenues earned, plus appropriate interest and costs.

** Planned spending in 2016-17 and future years is based on the assumption that the PMPRB will spend the full \$2.47 million held in the SPA reserved for conducting public hearings. This is done because these expenditures are dependent on the number of hearings, and the length and complexity of the hearings held, which are difficult to predict.

Alignment of Spending With the Whole-of-Government Framework

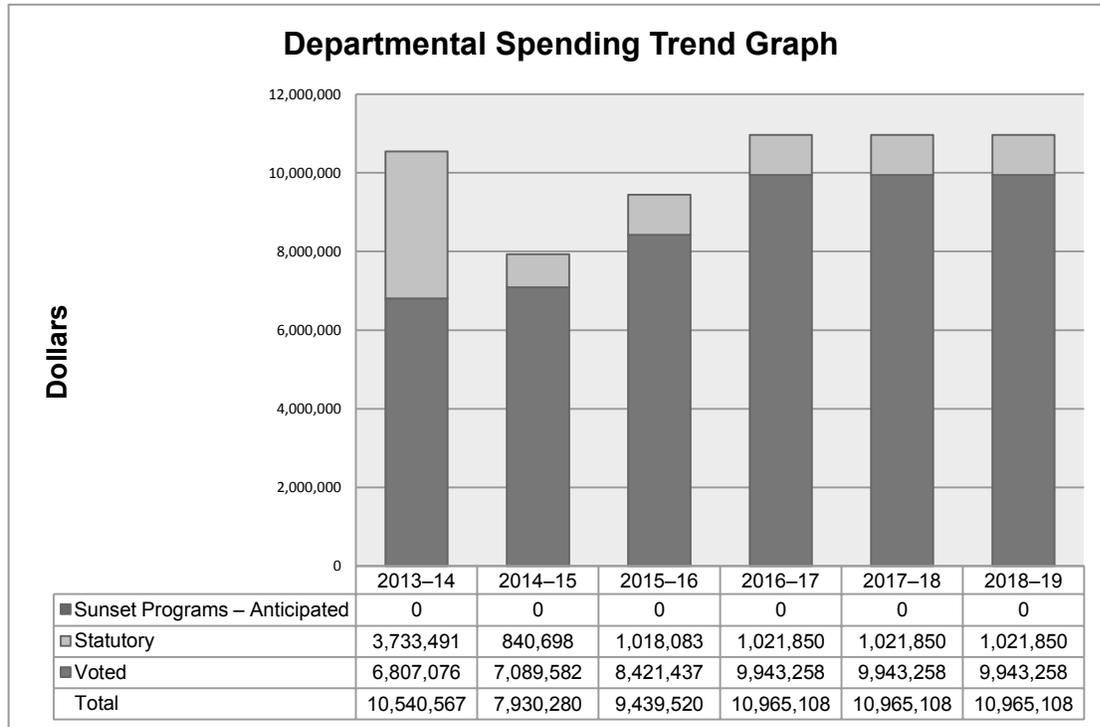
Alignment of 2016–17 Planned Spending With the **Whole-of-Government Framework**^x (dollars)

Strategic Outcome	Program	Spending Area	Government of Canada Outcome	2016–17 Planned Spending
Canadians are protected from excessive prices for patented medicines sold in Canada and stakeholders are informed on pharmaceutical trends.	Patented Medicine Prices Regulation Program	Social affairs	Healthy Canadians	6,646,758
	Pharmaceutical Trends Program	Social affairs	Healthy Canadians	1,704,508

Total Spending by Spending Area (dollars)

Spending Area	Total Planned Spending
Economic affairs	
Social affairs	8,351,266
International affairs	
Government affairs	

Departmental Spending Trend



The variance between Statutory Expenditures for 2013–14 and 2014–15 is largely due to additional funding received through an adjustment warrant to cover the amount ordered by the Federal Court to refund to a patentee. The Federal Court quashed a Board Order and directed in its judgement that a payment of excess revenues in the sum of \$2,801,285 be returned by the PMPRB to the patentee with appropriate interest and specified costs.

The 2015–16 Main Estimates amount includes funding for a Special Purpose Allotment (SPA) in the amount of \$2,470,000. The SPA is for conducting Public Hearings and can only be used to cover costs such as external legal counsel, expert witnesses, etc. Any unspent SPA funds are returned to the Consolidated Revenue Fund (CRF).

Due to challenges related to forecasting the number and complexity of hearings, for purposes of forecasting Planned Spending for 2016–17 and future years it is assumed that the entire SPA funding will be spent.

Estimates by Vote

For information on the PMPRB's organizational appropriations, consult the [2016–17 Main Estimates](#).^{xi}

Section II: Analysis of Programs by Strategic Outcome

Strategic Outcome:

Canadians are protected from excessive prices for patented medicines sold in Canada and stakeholders are informed on pharmaceutical trends.

Program 1.1: Patented Medicine Prices Regulation Program

Description

The PMPRB is an independent quasi-judicial body that is responsible for ensuring that the prices that patentees charge for patented medicines sold in Canada are not excessive based on the price review factors in the Act. To make this determination the Board must consider each of the following factors: prices at which the medicine and other medicines in the same therapeutic class have been sold in Canada and in the seven comparator countries listed in the *Patented Medicines Regulations* (Regulations); changes in the Consumer Price Index (CPI); and in accordance with the Act, such other factors as may be specified in any regulations made for the purposes of the price review.^{xiii} Under the Act, and as per the Regulations, patentees are required to file price and sales information for each patented medicine sold in Canada, for the duration of the patent(s). Board Staff reviews the introductory and ongoing information filed by patentees, for all patented medicines sold in Canada. When it finds that the price of a patented medicine appears to be excessive, Board Staff will conduct an investigation into the price. An investigation could result in: its closure, where it is concluded that the price was non-excessive; a Voluntary Compliance Undertaking (VCU) by the patentee to reduce the price and offset excess revenues obtained as a result of excessive prices through a payment and/or a price reduction of another patented drug product; or a public hearing to determine if the price is excessive, including any remedial order determined by the Board. In the event that the Board Hearing Panel finds, after a public hearing, that a price is or was excessive, it may order the patentee to reduce the price and take measures to offset any excess revenues. This program, by reviewing the prices charged by patentees for patented medicines sold in Canada, protects Canadians and the health care system from excessive prices.

Budgetary Financial Resources (dollars)

2016–17 Main Estimates	2016–17 Planned Spending	2017–18 Planned Spending	2018–19 Planned Spending
6,646,758	6,646,758	6,646,758	6,646,758

Human Resources (Full-Time Equivalents [FTEs])

2016–17	2017–18	2018–19
40	40	40

Performance Measurement

Expected Results	Performance Indicators	Targets	Date to Be Achieved
Patentees comply with the <i>Patent Act</i> , the Regulations, and the Excessive Price Guidelines (Guidelines)	Percentage of patented medicines that are priced, as a result of voluntary compliance, within the Guidelines or at a price which does not trigger the investigation criteria	95%	March 31 of each year
	Percentage of compliance with Board Orders related to price and/or jurisdiction and with Voluntary Compliance Undertakings (VCUs)	100%	March 31 of each year
Canadian prices for patented medicines are on average in line with prices in the seven comparator countries listed in the Regulations	Canadian prices for patented medicines are below the median of international prices	50%	March 31 of each year

Planning Highlights

The PMPRB will focus its enforcement resources on cases that are most relevant to payers, and that will raise issues which could clarify certain aspects of the PMPRB's regulatory framework and make it a more effective consumer champion. The PMPRB will also consult on whether and to what extent changes to consumer protection powers are warranted to ensure Canadian patented drug costs remain affordable.

Program 1.2: Pharmaceutical Trends Program

Description

The PMPRB reports annually to Parliament through the Minister of Health on its price review activities, the prices of patented medicines and price trends for all drugs, and R&D expenditures as reported by pharmaceutical patentees. In supporting this requirement, the pharmaceutical trends program provides complete and accurate information on trends in manufacturers' prices of patented medicines sold in Canada and on patentees' research-and-development expenditures to interested stakeholders including: industry (i.e., brand-name, biotech, generic); F/P/T governments; consumer and patient advocacy groups; third party payers; and others. This information also provides assurance to Canadians that the prices of patented medicines are not excessive. In addition, as a result of the establishment of the NPDUIS by F/P/T Ministers of Health the Federal Minister of Health requested that the PMPRB conduct analysis of price, utilization and cost trends for patented and non-patented prescription drugs so that Canada's health system has more comprehensive, accurate information on how all prescription drugs are being used and on the sources of cost increases. This function is aimed at providing F/P/T governments and other interested stakeholders with a centralized credible source of information on all prescription drug prices.

Budgetary Financial Resources (dollars)

2016–17 Main Estimates	2016–17 Planned Spending	2017–18 Planned Spending	2018–19 Planned Spending
1,704,508	1,704,508	1,704,508	1,704,508

Human Resources (Full-Time Equivalents [FTEs])

2016–17	2017–18	2018–19
12	12	12

Performance Measurement

Expected Results	Performance Indicators	Targets	Date to Be Achieved
Information on pharmaceutical trends and cost drivers is available to stakeholders	Number of new reports/studies posted on the PMPRB website	12 reports/studies	March 31 of each year
	Number of presentations made by the PMPRB to an external audience	10 information sessions	March 31 of each year

Planning Highlights

The PMPRB will adopt a more proactive approach to communicating its regulatory and reporting achievements to the public and will build on its reputation as an honest broker in identifying, analyzing and reporting on pharmaceutical issues. This includes intensifying its partnership with public payers to better anticipate their market intelligence requirements and specific information needed in the context of pCPA negotiations, and expanding the scope of pharmaceutical topics on which it reports to provide private payers and consumers with information to help them make better, more cost effective choices. The PMPRB will also strengthen ties with pricing and reimbursement authorities in other countries in order to share market intelligence and stay abreast of the latest developments in this area. As in past years, the PMPRB will publish its NPDUIS Research Agenda which reflects the priorities identified by the NPDUIS Advisory Committee and lists the reports anticipated for completion and publication each year.

Internal Services

Description

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. Internal services include only those activities and resources that apply across an organization, and not those provided to a specific program. The groups of activities 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; and Acquisition Services.

Budgetary Financial Resources (dollars)

2016–17 Main Estimates	2016–17 Planned Spending	2017–18 Planned Spending	2018–19 Planned Spending
2,613,842	2,613,842	2,613,842	2,613,842

Human Resources (FTEs)

2016–17	2017–18	2018–19
19	19	19

Planning Highlights

As a micro agency, the PMPRB boasts a small but agile workforce with a diverse range of skill sets and professional backgrounds. To maintain standards of excellence and convince employees that the PMPRB is a desirable organization in which to build a career, the PMPRB will continue to inform and engage employees in the strategic planning process, and provide them clear direction on work objectives and expected behaviours in order to promote a culture of consistent high performance. It will implement a comprehensive internal communications strategy to enable more structured dialogue between branches, management and employees and it will put systems in place to enable employees to rate their managers on the degree to which they are meeting their engagement objectives. The PMPRB will also provide access to a wide range of learning and developmental opportunities, including, but not limited to, mentoring and developmental assignments.

Section III: Supplementary Information

Future-Oriented Condensed Statement of Operations

The Future-Oriented Condensed Statement of Operations provides a general overview of the PMPRB's operations. The forecast of financial information on expenses and revenues is prepared on an accrual accounting basis to strengthen accountability and to improve transparency and financial management.

Because the Future-Oriented Condensed Statement of Operations is prepared on an accrual accounting basis, and the forecast and planned spending amounts presented in other sections of the Report on Plans and Priorities are prepared on an expenditure basis, amounts may differ.

A more [detailed Future-Oriented Statement of Operations and associated notes^{xiii}](#), including a reconciliation of the net cost of operations to the requested authorities, are available on the PMPRB's website.

Future-Oriented Condensed Statement of Operations For the Year Ended March 31, 2016 (dollars)

Financial Information	2015–16 Forecast Results	2016–17 Planned Results	Difference (2016–17 Planned Results minus 2015–16 Forecast Results)
Total expenses	10,563,636	12,157,399	1,593,763
Total revenues ¹	48	-	(48)
Net cost of operations before government funding and transfers	10,563,588	12,157,399	1,593,811

¹ The PMPRB collects non-respendable revenue as a result of 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 or territory respecting the distribution to that province/territory of amounts received by the Receiver General, less any costs incurred in relation to the collection and distribution of those amounts. As at December 31, 2015, the PMPRB collected \$5,752,812.62 in non-respendable revenue for fiscal year 2015–16. Revenues that are non-respendable are not available to discharge the PMPRB's liabilities. While the Deputy Head is expected to maintain accounting control, she has no authority regarding the disposition of non-respendable revenues. As this revenue cannot be accessed by the PMPRB, it is reported as Revenue earned on behalf of the Government of Canada and a decrease to the gross departmental revenues.

PMPRB is projecting \$12.2M in expenses based on 2016-17 Main Estimates and accrued information. This amount does not include future supplementary estimates. It represents an increase of \$1.6 M from 2015-16 projections.

This increase is primarily attributable to:

- Planned spending in 2016–17 is based on the assumption that the PMPRB will spend the full \$2.47 million held in the SPA reserved for conducting public hearings. This is done because these expenditures are dependent on the number of hearings, and the length and complexity of the hearings held, which are difficult to predict.

Supplementary Information Tables

The supplementary information tables listed in the 2016–17 Report on Plans and Priorities are available on the PMPRB’s website.

- ▶ [Departmental Sustainable Development Strategy](#)^{xiv}
- ▶ [Upcoming Internal Audits and Evaluations Over the Next Three Fiscal Years](#)^{xv}

Tax Expenditures and Evaluations

The tax system can be used to achieve public policy objectives through the application of special measures such as low tax rates, exemptions, deductions, deferrals and credits. The Department of Finance Canada publishes cost estimates and projections for these measures each year in the [Tax Expenditures and Evaluations](#)^{xvi} publication. The tax measures presented in that publication are the responsibility of the Minister of Finance.

Section IV: Organizational Contact Information

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Appendix: Definitions

Appropriation: Any authority of Parliament to pay money out of the Consolidated Revenue Fund.

budgetary expenditures: Operating and capital expenditures; transfer payments to other levels of government, organizations or individuals; and payments to Crown corporations.

Departmental Performance Report: Reports on an appropriated organization's actual accomplishments against the plans, priorities and expected results set out in the corresponding Reports on Plans and Priorities. These reports are tabled in Parliament in the fall.

full-time equivalent: A measure of the extent to which an employee represents a full person-year charge against a departmental budget. Full-time equivalents are calculated as a ratio of assigned hours of work to scheduled hours of work. Scheduled hours of work are set out in collective agreements.

Government of Canada outcomes: A set of 16 high-level objectives defined for the government as a whole, grouped in four spending areas: economic affairs, social affairs, international affairs and government affairs.

Management, Resources and Results Structure: A comprehensive framework that consists of an organization's inventory of programs, resources, results, performance indicators and governance information. Programs and results are depicted in their hierarchical relationship to each other and to the Strategic Outcome(s) to which they contribute. The Management, Resources and Results Structure is developed from the Program Alignment Architecture.

non-budgetary expenditures: Net outlays and receipts related to loans, investments and advances, which change the composition of the financial assets of the Government of Canada.

performance: What an organization did with its resources to achieve its results, how well those results compare to what the organization intended to achieve, and how well lessons learned have been identified.

performance indicator: A qualitative or quantitative means of measuring an output or outcome, with the intention of gauging the performance of an organization, program, policy or initiative respecting expected results.

performance reporting: The process of communicating evidence-based performance information. Performance reporting supports decision making, accountability and transparency.

planned spending: For Reports on Plans and Priorities (RPPs) and Departmental Performance Reports (DPRs), planned spending refers to those amounts that receive Treasury Board approval by February 1. Therefore, planned spending may include amounts incremental to planned expenditures presented in the Main Estimates.

A department is expected to be aware of the authorities that it has sought and received. The determination of planned spending is a departmental responsibility, and departments must be able to defend the expenditure and accrual numbers presented in their RPPs and DPRs.

plans: The articulation of strategic choices, which provides information on how an organization intends to achieve its priorities and associated results. Generally a plan will explain the logic behind the strategies chosen and tend to focus on actions that lead up to the expected result.

priorities: Plans or projects that an organization has chosen to focus and report on during the planning period. Priorities represent the things that are most important or what must be done first to support the achievement of the desired Strategic Outcome(s).

program: A group of related resource inputs and activities that are managed to meet specific needs and to achieve intended results and that are treated as a budgetary unit.

Program Alignment Architecture: A structured inventory of an organization's programs depicting the hierarchical relationship between programs and the Strategic Outcome(s) to which they contribute.

Report on Plans and Priorities: Provides information on the plans and expected performance of appropriated organizations over a three-year period. These reports are tabled in Parliament each spring.

results: An external consequence attributed, in part, to an organization, policy, program or initiative. Results are not within the control of a single organization, policy, program or initiative; instead they are within the area of the organization's influence.

statutory expenditures: Expenditures that Parliament has approved through legislation other than appropriation acts. The legislation sets out the purpose of the expenditures and the terms and conditions under which they may be made.

Strategic Outcome: A long-term and enduring benefit to Canadians that is linked to the organization's mandate, vision and core functions.

sunset program: A time-limited program that does not have an ongoing funding and policy authority. When the program is set to expire, a decision must be made whether to continue the program. In the case of a renewal, the decision specifies the scope, funding level and duration.

target: A measurable performance or success level that an organization, program or initiative plans to achieve within a specified time period. Targets can be either quantitative or qualitative.

voted expenditures: Expenditures that Parliament approves annually through an Appropriation Act. The Vote wording becomes the governing conditions under which these expenditures may be made.

whole-of-government framework: Maps the financial contributions of federal organizations receiving appropriations by aligning their Programs to a set of 16 government-wide, high-level outcome areas, grouped under four spending areas.

Endnotes

- i The PMPRB's legal framework includes the *Patent Act*, the *Patented Medicines Regulations* and the Board's Excessive Price Guidelines.
- ii The PMPRB7 are the seven comparator countries listed in the *Patented Medicines Regulations* namely: France, Italy, Germany, Sweden, Switzerland, the United Kingdom and the United States.
- iii The Board scope of the PMPRB's consumer protection powers and the constitutionality of its price control scheme were reaffirmed most recently by the Federal Court of Appeal in November 2015.
- iv The PMPRB's Strategic Plan – 2015-2018 can be found on the PMPRB website: <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1197&lang=en>
- v *Patent Act*: <http://laws-lois.justice.gc.ca/eng/acts/P-4/page-1.html>
- vi *Patented Medicines Regulations*: <http://laws-lois.justice.gc.ca/eng/regulations/SOR-94-688/page-1.html>
- vii Additional information on the National Prescription Drug Utilization Information System can be found on the PMPRB website: <http://www.pmprb-cepmb.gc.ca/en/npduis/about-npduis>
- viii Prime Minister of Canada's website, <http://pm.gc.ca/eng/minister-health-mandate-letter>
- ix More information on the pan-Canadian Pharmaceutical Alliance can be found on the following website, <http://www.pmprovinceterritoires.ca/en/initiatives/358-pan-canadian-pharmaceutical-alliance>
- x Whole-of-government framework, <http://www.tbs-sct.gc.ca/ems-sgd/wgf-ipp-eng.asp>
- xi 2016–17 Main Estimates, <http://www.tbs-sct.gc.ca/hgw-cgf/finances/pgs-pdg/gepme-pdgbpd/index-eng.asp>
- xii When consideration of the foregoing factors does not enable the Board to make a determination as to whether the medicine is or has been sold at an excessive price, it may also consider the cost of making and marketing the medicine and such other factors it believes are relevant in the circumstances.
- xiii A more detailed Future-Oriented Statement of Operations and associated notes, including a reconciliation of the net cost of operations to the requested authorities, can be found on the PMPRB's website: <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1230&lang=en>
- xiv Departmental Sustainable Development Strategy: <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1228&lang=en>
- xv Upcoming Internal Audits and Evaluations Over the Next Three Fiscal Years: <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1229&lang=en>
- xvi Tax Expenditures and Evaluations publication, <http://www.fin.gc.ca/purl/taxexp-eng.asp>