Patented Medicine Prices Review Board

2017–18

Departmental Plan

The Honourable Jane Philpott
Minister of Health

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Vice-Chairperson's message

As Vice-Chairperson and acting Chairperson, I am pleased to present the 2017-18 Departmental Plan for the Patented Medicine Prices Review Board (PMPRB).

Our 2017–18 Departmental Plan provides parliamentarians and Canadians with information on what we do and the results we are trying to achieve during the upcoming year. To improve reporting to Canadians, we are introducing a new, simplified report to replace the Report on Plans and Priorities.

The title of the report has been changed to reflect its purpose: to communicate our annual performance goals and the financial and human resources forecast to deliver those results. The report has also been restructured to tell a clearer, more straightforward and balanced story of the actual results we are trying to achieve, while continuing to provide transparency on how tax payers' dollars will be spent. We describe our programs and services for Canadians, our priorities for 2017–18, and how our work will fulfill our departmental mandate commitments and the government's priorities.

In 2017-18, the PMPRB's foremost priority is to support the Minister of Health in her continuing efforts to improve patient access to necessary prescription medications by reducing their costs and making them more affordable for Canadians. The PMPRB will do this by modernizing its regulatory framework to ensure it remains relevant and effective in protecting consumers from excessive prices in a dynamic and evolving pharmaceutical market. In 2016-17, the PMPRB received a record number of submissions from stakeholders and interested members of the public on its discussion paper on guideline reform. In 2017-18, the PMPRB will work collaboratively with officials at Health Canada to develop a policy response to these submissions and continue to consult with stakeholders with a view to bringing a new regulatory framework into effect by 2018-19. In terms of its reporting program, the PMPRB will continue to explore new pharmaceutical topics and trends upon which to report in order to better serve the information needs of our stakeholders and to support federal, provincial and territorial efforts to manage pharmaceutical expenditures in a sustainable manner.

Dr. Mitchell Levine
Vice-Chairperson

Plans at a glance

Priority 1 – Consumer-focused regulation and reporting

The PMPRB's regulatory mandate is to ensure that the prices of patented medicines sold in Canada are not excessive. By focusing its enforcement resources on cases that have potential precedential value and where payers lack countervailing power, the PMPRB will make the most of its consumer protection powers under the current regulatory framework. The PMPRB's reporting mandate is to provide stakeholders with information on pharmaceutical trends. By providing more targeted and timely market intelligence to payers, the PMPRB will empower them to better manage their pharmaceutical budgets.

Priority 2 – Framework modernization

As a first step towards modernizing its legal framework, last year the PMPRB began public consultations on guidelines reform. In 2017-18, the PMPRB will work with officials at Health Canada to develop a response to the feedback received from stakeholders and continue to consult on regulatory reform with a view to bringing a modern and streamlined regulatory regime into effect in 2018-19.

Priority 3 – Strategic partnerships and public awareness

In order to succeed in its efforts to streamline and modernize its regulatory framework, the PMPRB must build support for its mandate and foster greater awareness of its role within the Canadian pharmaceutical system. It will do this by building strategic partnerships with public and private payers and domestic and international pharmaceutical regulatory agencies and through more proactive communication of its work with the public.

The PMPRB will support the Minister of Health in her continuing efforts to advance her key mandate priorities to improve patient access to necessary prescription medications, by reducing their costs and making them more affordable for Canadians.

For more information on the PMPRB's plans, priorities and planned results, see the "Planned results" section of this report.

Raison d’être, mandate and role: who we are and what we do

Raison d’être

The Patented Medicine Prices Review Board (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.

Mandate and role

The PMPRB was created as a result of amendments to the *Patent Act* (Act) in 1987 (Bill C-22), and its remedial powers were supplemented by further amendments in 1993 (Bill C-91). These amendments were part of policy reforms intended to balance the PMPRB’s consumer protection mandate with patent protection measures intended to encourage the R&D efforts of pharmaceutical patentees.

The PMPRB has a dual mandate:

Regulatory

The PMPRB is responsible for ensuring the factory-gate 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, are not excessive. The PMPRB regulates the price of each patented medicine to which Health Canada has assigned a Drug Identification Number (DIN) as part of its price review process. The PMPRB’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 PMPRB on a complaints basis.

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 (NPDUIS)[i] by federal/provincial/territorial (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 to provide Canada's health system with 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 pharmaceutical trends. Increasingly, as part of its reporting function, the PMPRB works closely with provincial and territorial (P/T) governments through NPDUIS, and directly with lead jurisdictions through the Council of the Federation, to provide relevant pricing and market analyses aimed at reducing the prices of prescription drugs purchased by public payers in Canada.

For more general information about the department, see the "Supplementary information" section of this report. For more information on the department's organizational mandate letter commitments, see the Minister's mandate letter on the Prime Minister of Canada's website.[ii]

Operating context: conditions affecting our work

The PMPRB operates in a complex environment, marked by intersecting and sometimes conflicting political, economic, social, legal, commercial and technological issues and interests.

By its nature, the pharmaceutical industry is one of the most heavily regulated in the world. Canada is no exception, as pharmaceutical regulation is a shared jurisdictional responsibility. At the federal level, Health Canada reviews new drugs for safety, efficacy and quality and the PMPRB sets their ceiling price for as long as they are patented. The Canadian Agency for Drugs and Technologies (CADTH), an independent, not-for-profit agency funded by Federal, Provincial and Territorial Ministers (F/P/T) governments, conducts economic evaluations of new drugs and makes reimbursement recommendations to participating public payers. At the provincial and territorial level, health ministries and drug plan managers decide which drugs to reimburse for their beneficiary populations and negotiate prices directly with pharmaceutical manufacturers. Outside of government, private health insurers manage employer-sponsored drug plans and also negotiate prices directly with manufacturers. The rules governing whether and to what extent private insurers are bound by reimbursement decisions by public drug plans, or benefit from their price negotiations, vary by province.

Canadian patented drug prices have been steadily rising relative to prices in the seven countries to which Canada compares itself under its regulations (France, Germany, Italy, Sweden, Switzerland, the UK and the US – the "PMPRB7") and are now third highest, behind only Germany and the US. Since 2000, Canada's growth in patented drug expenditures as a share of GDP has increased by 184%, outpacing all the PMPRB7 countries over that period. Outside of the PMPRB7, prices in Australia, Austria, Spain, Finland, the Netherlands and New Zealand are between 14% and 34% lower than Canadian prices. Looking beyond just patented drugs to all prescription drugs, Canada spends more *per capita* and as a percentage of GDP than most other countries.

As prices in Canada rise, R&D investment is declining. Since 2003, Innovative Medicines Canada (IMC) members have failed to meet their 10% commitment and the current ratio stands at 4.9% of sales. This is the second lowest recorded ratio since 1988 (the lowest occurring in 2014 at 4.8%), 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%.

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 1987 policy objectives. This viewpoint was echoed recently by the Advisory Panel on Healthcare Innovation in its July 17, 2015 report *Unleashing Innovation: Excellent Healthcare for Canada*, which concluded that the PMPRB needs to be "strengthened" to better "protect consumers from high

patented drug prices.” These same concerns are what prompted the PMPRB to undertake a year-long strategic planning process, the results of which seek to reaffirm the organization as an effective check on the patent rights of pharmaceutical manufacturers and a valued source of market intelligence for policy makers and payers. The former of these two objectives will require adjustments to the PMPRB’s regulatory framework. These adjustments are consonant with and complementary to the ongoing efforts of F/P/T Ministers of Health to “reduce pharmaceutical prices” while “enhancing the affordability, accessibility and appropriate use of prescription drugs.”

Key risks: things that could affect our ability to achieve our plans and results

Key risks

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 industry R&D investment in Canada. On the other, 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".

At the time of the PMPRB's creation, little was known about the relationship between price, intellectual property (IP) protection and R&D investment. Efforts by public and private payers to control prescription drug costs were in their relative infancy, including the concept of "international reference pricing" (i.e. benchmarking prices in one country to prices in other countries). Industry R&D efforts were focused on bringing medicines to market which treated the most common diseases and conditions, such as high cholesterol, high blood pressure and depression, and which were generally priced within reach of consumers and payers. Official "list" prices for medicines approximated the true price paid in the market and did not vary significantly between different types of payers (e.g. public vs. private). Finally, the government believed pharmaceutical companies would generally seek to avoid abusing their newly strengthened patent rights out of consideration for the political capital that had been spent securing passage of the underlying legislation.

In contrast, today, the empirical evidence does not support the idea that price and IP are particularly effective policy levers for attracting pharmaceutical R&D. Other factors, such as head office location, clinical trials infrastructure and scientific clusters, appear to be much more influential determinants of where pharmaceutical investment takes place in a global economy. Confidential discounts off the list price have become the industry standard, frustrating efforts to contain pharmaceutical spending based on international public list prices, and enabling companies to discriminate between different payers based on perceptions of the other side's negotiating power and ability to pay. In Canada, this is resulting in a growing price gap between public payers, who are able to negotiate collectively through the pan-Canadian Pharmaceutical Alliance (pCPA), private payers, who may lack the flexibility to do so under competition laws, and cash customers, who have no ability to negotiate. In terms of industry focus, the era of mass-marketed, so-called "blockbuster" medicines has evolved towards one where the most profitable return on investment is made from very high-cost specialty medicines. These "nichebusters", as the most successful are often called, target less common, untreated, and severe illnesses and

conditions, but at a price even the best-funded payers struggle to afford. Finally, the position of today's Canadian pharmaceutical industry is that any obligations arising from reforms brought in the late 1980s and early 1990s must account for the passage of time and the fact that many of those changes have since become entrenched as minimal norms and standards under bilateral and multilateral trade agreements (e.g. NAFTA and WTO-TRIPs).

The present-day reality is that the only meaningful constraints on what pharmaceutical companies can charge for their products is what the market will bear or regulators can effectively impose. In circumstances where a company holds a monopoly over the only treatment option for a particular disease or condition, payers sometimes have no choice but to pay the asking price, no matter how exorbitant. While the system may be able to absorb one, two, or even dozens of extremely high-priced new medicines, it is at risk of collapsing under the burden of hundreds, no matter how therapeutically beneficial or conventionally "cost-effective" they may be. Growing concern over sustainability has led other countries with public health care systems to introduce measures to address affordability issues, maximize value for money and keep pace with a rapidly evolving pharmaceutical market.

Risks	Risk response strategy	Link to the department's Programs	Link to mandate letter commitments or to government-wide and departmental priorities
International reform of pricing and reimbursement regimes - Failure to keep pace with cost containment reforms by international pharmaceutical pricing and reimbursement authorities runs the risk that the price gap between Canada and the majority of OECD member countries will widen further such that Canadians may pay even higher prices relative to other industrialized countries.	The PMPRB will: - work with Health Canada officials to develop a policy response to feedback from stakeholders and the public on reforms to its regulatory framework, and - explore opportunities to further strengthen ties with international pricing and reimbursement authorities to share market intelligence and stay abreast of best practices.	Patented Medicine Prices Regulation Program Pharmaceutical Trends Program	Making prescription drugs more affordable

Risks	Risk response strategy	Link to the department's Programs	Link to mandate letter commitments or to government-wide and departmental priorities
Confidential product listing agreements (PLAs) and the pCPA - As a result of confidential PLAs and the increased F/P/T membership in pCPA, public payers have even more negotiating power relative to private insurers, who do not negotiate collectively. This may result in a widening price gap between public and private payers, the true extent of which cannot be calculated.	The PMPRB will: - work with Health Canada officials to develop a policy response to feedback from stakeholders and the public on reforms to its regulatory framework, - continue to focus enforcement resources on cases that are most important to both public and private payers, and - work to formalize its expanded reporting function in the context of supporting pCPA negotiations.	Patented Medicine Prices Regulation Program Pharmaceutical Trends Program	Making prescription drugs more affordable
Capacity to conduct hearings - The Board's capacity to conduct hearings is a function of how many members are on it; there are three Board vacancies to fill in 2017-18. Failure to fill these vacancies in a timely fashion could result in delay in the conduct of excessive price hearings, with the result that Canadians may end up paying excessive prices longer than would otherwise be the case.	The PMPRB will support Health Canada and the Privy Council Office (PCO) in their efforts to ensure that the vacancies are filled as soon as possible so that the full complement of five Board Members is available to conduct hearings.	Patented Medicine Prices Regulation Program	Making prescription drugs more affordable

Risks	Risk response strategy	Link to the department's Programs	Link to mandate letter commitments or to government-wide and departmental priorities
Managing legal challenges - The PMPRB will continue to face court cases at various levels that challenge its 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.	The PMPRB works 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.	Patented Medicine Prices Regulation Program	Making prescription drugs more affordable

Planned results: what we want to achieve this year and beyond

Programs

Program title – 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.[iii] 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.

Planning highlights

In spite of the fact that approximately 95% of patented drugs reported to the PMPRB are priced within the guidelines, or at a price that does not trigger the investigation criteria, Canadian prices have been steadily rising relative to the PMPRB7 and over 50% of Canadian patented drugs are now priced above the PMPRB7 median. The PMPRB is currently consulting with stakeholders and the public on changes to its guidelines which would enable it to reverse these trends.

Framework Modernization

In 2016-17, the PMPRB received a record number of submissions from stakeholders and interested members of the public on its discussion paper on guideline reform. In 2017-18, the PMPRB will work collaboratively with officials at Health Canada to develop a policy response to these submissions and continue to consult with stakeholders with a view to bringing a new regulatory framework into effect by 2018-19.

Consumer-focused regulation and reporting

Although changes to the PMPRB's regulatory framework are under consideration, it will seek to make the most of its consumer protection powers under the existing regime by focusing its enforcement resources on cases that have potential precedential value and where payers lack countervailing power. In addition, as always, the PMPRB will encourage voluntary compliance with its guidelines by providing information sessions on their application and conducting price reviews of new and existing patented drug prices in accordance with established service standards.

Strategic Partnerships and Public Awareness

In order to succeed in its efforts to streamline and modernize its regulatory framework, the PMPRB must build support for its mandate and foster greater awareness of its role within the Canadian pharmaceutical system. It will do this by building strategic partnerships with public and private payers and domestic and international pharmaceutical regulatory agencies and through more proactive communication of its work with the public.

Planned results

Expected results	Performance indicators	Target	Date to achieve target	2013–14 Actual results	2014–15 Actual results	2015–16 Actual results
Patentees comply with the *Patent Act*, the Regulations, and the Excessive Price Guidelines (Guidelines)	Percentage of patented medicines that are priced within the Guidelines, or at a price which does not trigger the investigation criteria, as a result of voluntary compliance	95%[iv]	March 31 of each year	94.0%	95.3%	93%

Expected results	Performance indicators	Target	Date to achieve target	2013–14 Actual results	2014–15 Actual results	2015–16 Actual results
Patentees comply with the *Patent Act*, the Regulations, and the Excessive Price Guidelines (Guidelines)	Percentage of compliance with Board Orders related to price and/or jurisdiction and with Voluntary Compliance Undertakings (VCUs)	100%	March 31 of each year	100%	100%	100%
	Canadian prices for patented medicines are below the median of international prices[v]	50%	March 31 of each year	n/a	n/a	n/a

Budgetary financial resources (dollars)

2017–18 Main Estimates	2017–18 Planned spending	2018–19 Planned spending	2019–20 Planned spending
6,706,989	6,706,989	6,706,989	6,706,989

Human resources (full-time equivalents)

2017–18 Planned full-time equivalents	2018–19 Planned full-time equivalents	2019–20 Planned full-time equivalents
33	33	33

Program title – 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.

Planning highlights

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 honest broker reputation with stakeholders and the public at large.

Framework Modernization
Not applicable.

Consumer-focused regulation and reporting
In carrying out its reporting function, the PMPRB will pursue opportunities for further collaboration with public and private payers, 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 timelier decisions for the benefit of patients. 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. Finally, the PMPRB will continue to enhance and expand the scope of pharmaceutical topics on which it reports and promote its reporting function in order to educate and inform its stakeholders on key pharmaceutical issues.

Strategic Partnerships and Public Awareness

The PMPRB will continue to develop formal and informal analytical reports that are aligned to the needs of consumers and other interested stakeholders. In particular, the PMPRB will continue to support F/P/T efforts to sustainable pharmaceutical spending by providing timely, accurate information related to pricing initiatives, including generics and brand-name drug products.

The PMPRB will also continue to strengthen and expand ties with pricing and reimbursement authorities in other countries in order to share market intelligence and stay abreast of the latest developments in cost containment internationally through such activities as its membership in the Pharmaceutical Pricing and Reimbursement Information (PPRI) and its collaborative work with the World Health Organization on the fair pricing of pharmaceuticals.

Planned results

Expected results	Performance indicators	Target	Date to achieve target	2013–14 Actual results	2014–15 Actual results	2015–16 Actual results
Information on pharmaceutical trends and cost drivers is available to stakeholders	Number of new reports/studies posted on the PMPRB website[vi]	12 reports/ studies	March 31 of each year	n/a	15 new reports/ studies	15 new reports/ studies
	Number of presentations made by the PMPRB to an external audience	10 information sessions	March 31 of each year	8 information sessions[vii]	25 information sessions	13 information session

Budgetary financial resources (dollars)

2017–18 Main Estimates	2017–18 Planned spending	2018–19 Planned spending	2019–20 Planned spending
1,575,179	1,575,179	1,575,179	1,575,179

Human resources (full-time equivalents)

2017–18 Planned full-time equivalents	2018–19 Planned full-time equivalents	2019–20 Planned full-time equivalents
13	13	13

Internal Services

Description

Internal Services are those groups of related activities and resources that the federal government considers to be services in support of programs and/or required to meet corporate obligations of an organization. Internal Services refers to the activities and resources of the 10 distinct service categories that support Program delivery in the organization, regardless of the Internal Services delivery model in a department. The 10 service categories 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.

Planning highlights

The PMPRB will continue implementing Information Management digitization practices, including digitizing all information currently on hand. This is expected to be completed in fiscal year 2018-2019. The PMPRB will continue to enhance its electronic document management system, RIMS. The PMPRB will continue to strengthen its business processes in order to increase their value to the organization and reduce administrative burden, where possible.

Budgetary financial resources (dollars)

2017–18 Main Estimates	2017–18 Planned spending	2018–19 Planned spending	2019–20 Planned spending
2,584,153	2,584,153	2,584,153	2,584,153

Human resources (full-time equivalents)

2017–18 Planned full-time equivalents	2018–19 Planned full-time equivalents	2019–20 Planned full-time equivalents
20	20	20

Spending and human resources

Planned spending

Budgetary planning summary for Programs and Internal Services (dollars)

Programs and Internal Services	2014–15 Expenditures	2015–16 Expenditures	2016–17 Forecast spending	2017–18 Main Estimates	2017–18 Planned spending	2018–19 Planned spending	2019–20 Planned spending
Patented Medicine Prices Regulation Program	3,543,891	5,399,127	6,057,857	6,706,989	6,706,989	6,706,989	6,706,989
Pharmaceutical Trends Program	1,301,871	1,688,584	1,719,073	1,575,179	1,575,179	1,575,179	1,575,179
Subtotal	**4,845,762**	**7,087,711**	**7,776,930**	**8,282,168**	**8,282,168**	**8,282,168**	**8,282,168**
Internal Services	3,084,518	2,410,650	2,580,715	2,584,153	2,584,153	2,584,153	2,584,153
Total	**7,930,280**	**9,498,361**	**10,357,645**	**10,866,321**	**10,866,321**	**10,866,321**	**10,866,321**

The PMPRB's funding includes a Special Purpose Allotment (SPA) to conduct Public Hearings, of $2,438,000. The SPA can only be used to cover the costs of public hearings, such as external legal counsel and expert witnesses, etc. Any unspent amount is returned to the Consolidated Revenue Fund (CRF).

In 2015-16 actual spending was significantly higher than actual spending in 2014-15. This variance is due in large part to expenditures from the SPA of $1,213,627 most of which related to costs associated with the Soliris Hearing. Costs related to this hearing were also incurred in 2016-17.

Planned spending for 2017-18 and beyond is based on the assumptions that the PMPRB will spend the full $2.44 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.

Planned human resources

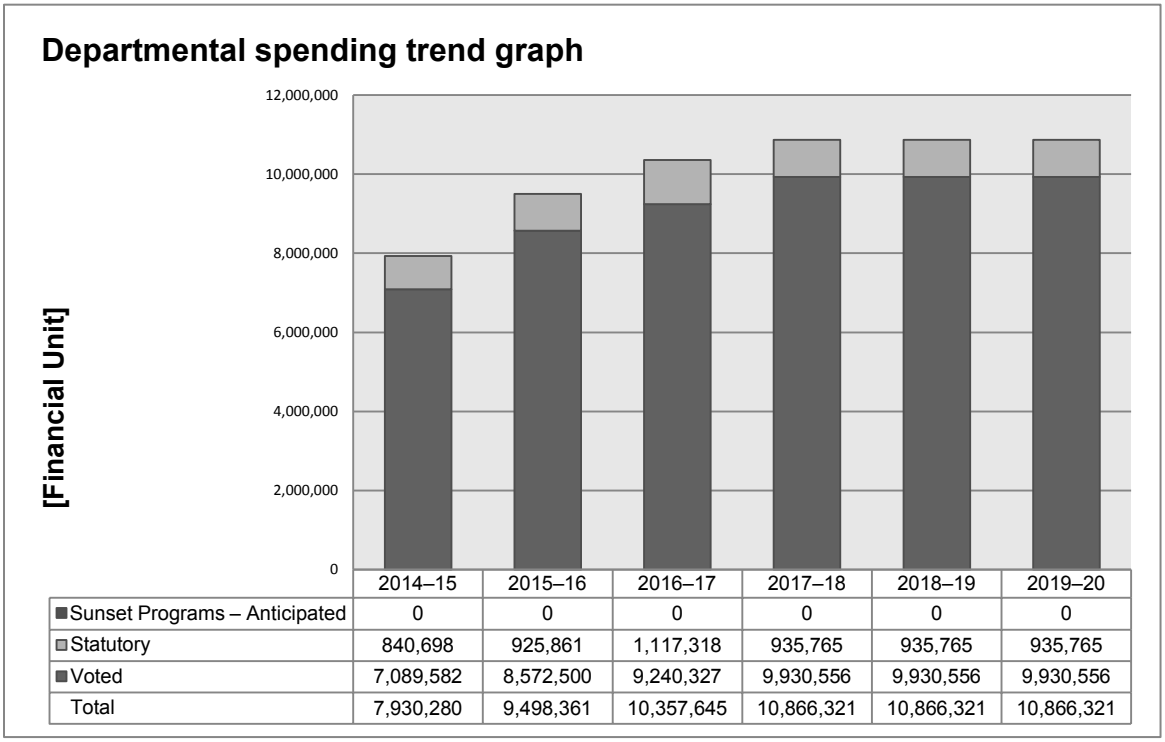
Human resources planning summary for Programs and Internal Services (full-time equivalents)

Programs and Internal Services	2014–15 Full-time equivalents	2015–16 Full-time equivalents	2016–17 Forecast full-time equivalents	2017–18 Planned full-time equivalents	2018–19 Planned full-time equivalents	2019–20 Planned full-time equivalents
Patented Medicine Prices Regulation Program	24.7	31.1	32.6	33.0	33.0	33.0
Pharmaceutical Trends Program	9.2	12.8	12.7	13.0	13.0	13.0
Subtotal	**33.9**	**43.9**	**45.3**	**46.0**	**46.0**	**46.0**
Internal Services	22.3	18.6	19.8	20.0	20.0	20.0
Total	**56.2**	**62.5**	**65.1**	**66.0**	**66.0**	**66.0**

In 2015-16 the PMPRB conducted an internal realignment moving FTEs from internal services to the trends program to better reflect the activities being performed by staff. In addition, staff in the regulatory program was increased to address workload changes.

Staffing for the regulatory program and internal services was completed in 2016-17. The PMPRB is now at its full complement of FTEs.

The fluctuation between forecast FTEs in 2016-17 and planned FTEs in 2017-18 is mainly due to management’s efforts to stabilize and control future salary requirements and realignment of resources in order to meet program needs.



	2014–15	2015–16	2016–17	2017–18	2018–19	2019–20
Sunset Programs – Anticipated	0	0	0	0	0	0
Statutory	840,698	925,861	1,117,318	935,765	935,765	935,765
Voted	7,089,582	8,572,500	9,240,327	9,930,556	9,930,556	9,930,556
Total	7,930,280	9,498,361	10,357,645	10,866,321	10,866,321	10,866,321

The PMPRB's funding includes a Special Purpose Allotment (SPA) to conduct Public Hearings, in Vote 1 (Program expenditures) of $2,438,000. The SPA can only be used to cover the costs of public hearings, such as external legal counsel and expert witnesses, etc. Any unspent amount is returned to the Consolidated Revenue Fund (CRF).

PMPRB spending in 2015-16 is significantly higher than spending in 2014-15 largely due to more spending on hearings. In 2015-16 the PMPRB spent $1.2 million as compared to $154,000 in 2014-15.

Due to challenges related to forecasting the number and complexity of hearings, for purposes of forecasting Planned Spending for 2017-18 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 2017–18 Main Estimates.[viii]

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 Departmental Plan are prepared on an expenditure basis, amounts may differ.

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

Future-Oriented Condensed Statement of Operations for the year ended March 31, 2018 (dollars)

Financial information	2016–17 Forecast results	2017–18 Planned results	Difference (2017–18 Planned results minus 2016–17 Forecast results)
Total expenses	11,591,051	11,991,436	400,385
Total revenues	448	-	(448)
Net cost of operations before government funding and transfers	11,590,603	11,991,436	400,833

PMPRB is projecting $12.0M in expenses based on 2017-18 Main Estimates and accrued information. This amount does not include future supplementary estimates. It represents an increase of $0.4M from 2016-17 projections.

This increase is primarily attributable to:

- Planned spending in 2017–18 is based on the assumption that the PMPRB will spend the full $2.44 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

Corporate information

Organizational profile

Appropriate minister(s): The Honourable Jane Philpott

Institutional head: Mitch Levine, Vice Chairperson[x]

Ministerial portfolio: Health

Enabling instrument(s): *Patent Act*[xi] and *Patented Medicines Regulations*[xii]

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.

Reporting framework

The Patented Medicine Prices Review Board's Strategic Outcome and Program Alignment Architecture (PAA) of record for 2017–18 are shown below:

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

Supporting information on lower-level programs

The PMPRB does not have any lower-level programs. The PMPRB only has one strategic outcome, two supporting programs and internal services.

Federal tax expenditures

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 Report on Federal Tax Expenditures.[xiii] This report also provides detailed background information on tax expenditures, including descriptions, objectives, historical information and references to related federal spending programs. The tax measures presented in this report are the responsibility of the Minister of Finance.

Organizational contact information

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Appendix A: definitions

appropriation (crédit)

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

budgetary expenditures (dépenses budgétaires)

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

Core Responsibility (responsabilité essentielle)

An enduring function or role performed by a department. The intentions of the department with respect to a Core Responsibility are reflected in one or more related Departmental Results that the department seeks to contribute to or influence.

Departmental Plan (Plan ministériel)

Provides information on the plans and expected performance of appropriated departments over a three-year period. Departmental Plans are tabled in Parliament each spring.

Departmental Result (résultat ministériel)

A Departmental Result represents the change or changes that the department seeks to influence. A Departmental Result is often outside departments' immediate control, but it should be influenced by program-level outcomes.

Departmental Results Framework (cadre ministériel des résultats)

Consists of the department's Core Responsibilities, Departmental Results and Departmental Result Indicators.

Departmental Result Indicator (indicateur de résultat ministériel)

A factor or variable that provides a valid and reliable means to measure or describe progress on a Departmental Result.

Departmental Results Report (Rapport sur les résultats ministériels)

Provides information on the actual accomplishments against the plans, priorities and expected results set out in the corresponding Departmental Plan.

drug product (produit médicamenteux)

A particular presentation of a medicine characterized by it pharmaceutical dosage form and the strength of the active ingredient(s).

full-time equivalent (équivalent temps plein)

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-wide priorities (priorités pangouvernementales)

For the purpose of the 2017–18 Departmental Plan, government-wide priorities refers to those high-level themes outlining the government's agenda in the 2015 Speech from the Throne, namely: Growth for the Middle Class; Open and Transparent Government; A Clean Environment and a Strong Economy; Diversity is Canada's Strength; and Security and Opportunity.

horizontal initiatives (initiative horizontale)

A horizontal initiative is one in which two or more federal organizations, through an approved funding agreement, work toward achieving clearly defined shared outcomes, and which has been designated (e.g. by Cabinet, a central agency, etc.) as a horizontal initiative for managing and reporting purposes.

Management, Resources and Results Structure (Structure de la gestion, des ressources et des résultats)

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.

medicine (médicament)

Any substance or mixture of substances made by any means, whether produced biologically, chemically, or otherwise, that is applied or administered in vivo in humans or animals to aid in the diagnosis, treatment, mitigation or prevention of disease, symptoms, disorders, abnormal physical states, or modifying organic functions in humans or animals, however administered. For greater certainty, this definition includes vaccines, topical preparations, anaesthetics and diagnostic products used in vivo, regardless of delivery mechanism (e.g., transdermal, capsule form, injectable, inhaler, etc.). This definition excludes medical devices, in vivo diagnostic products and disinfectants that are not used in vivo.

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

patent (brevet)
An instrument issued by the Commissioner of Patents in the form of letters patent for an invention that provides its holder with a monopoly limited in time, for the claims made within the patent. A patent gives its holder and its legal representatives, the exclusive right of making, constructing and using the invention and selling it to others to be used.

patentee (breveté)
As defined by subsection 79(1) of the *Patent Act*, "the person for the time being entitled to the benefit of the patent for the invention and includes, where any other person is entitled to exercise any rights in relation to that patent other than under a license continued by subsection 11(1) of the *Patent Act Amendment Act, 1992*, that other person in respect of those rights."

performance (rendement)
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 (indicateur de rendement)
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 (production de rapports sur le rendement)
The process of communicating evidence-based performance information. Performance reporting supports decision making, accountability and transparency.

planned spending (dépenses prévues)
For Departmental Plans and Departmental Results Reports, 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 Departmental Plans and Departmental Results Reports.

plans (plan)

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.

PMPRB7 (CEPMB7)

The seven foreign comparator countries for which patentees must report publicly available prices of patented drug products for price review purposes: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States.

priorities (priorité)

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 (programme)

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 (architecture d'alignement des programmes)

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

results (résultat)

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 (dépenses législatives)

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 (résultat stratégique)

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

sunset program (programme temporisé)

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 (cible)

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 (dépenses votées)

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

Endnotes

i 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

ii The Minister's mandate letter, http://pm.gc.ca/eng/mandate-letters

iii 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.

iv This percentage, based on the number of price reviews completed at March 31of the fiscal year referred to, is calculated as follows: the sum of the number of price reviews found to be within the Guidelines, plus the number of price reviews which did not trigger an investigation, plus the number of Voluntary Compliance Undertakings; divided by the total number of patented drug products at March 31 of the fiscal year referred to, minus the number of drug products still under review

v This performance indicator was introduced in 2016-17 so comparative actual results for previous years are not available.

vi This performance indicator was introduced in 2014-15 so comparative actual results for fiscal year 2013-14 are not available.

vii In 2013-14, the PMPRB participated in 26 external events and made presentations at 8 of these events.

viii. 2017–18 Main Estimates, http://www.tbs-sct.gc.ca/hgw-cgf/finances/pgs-pdg/gepme-pdgbpd/index-eng.asp

ix Patented Medicine Prices Review Board: http://www.pmprb-cepmb.gc.ca/home

x In accordance with subsection 92(3) of the *Patent Act*, if the Chairperson is absent or incapacitated or if the office of the Chairperson is vacant, the Vice-Chairperson has all the powers and functions of the Chairperson during the absence, incapacity or vacancy.

xi *Patent Act:* http://laws-lois.justice.gc.ca/eng/acts/P-4/page-1.html

xii *Patented Medicines Regulations:* http://laws-lois.justice.gc.ca/eng/regulations/SOR-94-688/page-1.html

xiii Report on Federal Tax Expenditures, http://www.fin.gc.ca/purl/taxexp-eng.asp