

Patented Medicine Prices Review Board

2019–20

Departmental Plan

The Honourable Ginette Petitpas Taylor
Minister of Health

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Chairperson's message

I am pleased to present the 2019-20 Departmental Plan for the Patented Medicine Prices Review Board (PMPRB).

The PMPRB is an independent quasi-judicial body established by Parliament in 1987 under the *Patent Act* (Act). The PMPRB protects and informs Canadians by ensuring that the prices of patented medicines sold in Canada are not excessive and by reporting on pharmaceutical trends.

In 2019-20, the PMPRB will focus on completing the process for modernizing its regulatory framework first articulated in its 2015-18 Strategic Plan, by consulting on and finalizing new pricing Guidelines. Updated Guidelines are necessary in order to operationalize Health Canada's proposed amendments to the *Patented Medicines Regulations* (Regulations), which were pre-published in the Part I of the Canada Gazette in December 2017, and to formalize the PMPRB's long awaited move to a more risk-based approach to regulating the prices of patented medicines.

In 2018-19, the PMPRB pursued a two-track consultation process which involved striking a steering committee composed of key stakeholdersⁱ to provide high level feedback on a proposed new Guidelines framework and a working group of expertsⁱⁱ to help sort through some of the technical issues associated with operationalizing the more obscure elements of Health Canada's proposed regulatory amendments. Originally planned to conclude in the fall of 2018, in anticipation of the Minister's stated intention of having new regulations in place by January 2019, this work will continue into 2019 and end in a report which will be considered by the PMPRB's Board prior to the release of draft new Guidelines for broader public consultation later in the year.

In order to hit the ground running once regulatory modernization is completed, the PMPRB will continue implementation of its plan for using the additional funding allotted to it in Budget 2017. This includes the hiring of new staff as well as expanding our office space and converting it to Workplace 2.0 Fit-up Standards.

As we await next steps on the Regulations, we will continue to advance our thinking on the Guidelines through open and honest dialogue with all of our stakeholders and build up our capacity to deliver on the Minister's mandate letter commitment of improving the access to and affordability of prescription medicines for all Canadians.

Dr. Mitchell Levine

Plans at a glance and operating context

Priority 1 – Framework Modernization

- Finalize report from Steering Committee on Modernization of Price Review Process Guidelines (Steering Committee) and consult on draft new Guidelines once Health Canada’s proposed amendments to the Regulations are published in Part II of the Canada Gazette.

This priority is intended to address the Minister of Health’s mandate letter commitment of improving access to necessary prescription medicines by making them more affordable for Canadian consumers.

Priority 2 – Capacity Development

- Allocate additional funding from Budget 2017 to expand and convert office space to Workplace 2.0 Fit Up standards and hire new staff with the knowledge and skills needed to administer the new regulatory framework.

This priority is intended to provide the PMPRB with the capacity to apply the new excessive pricing factors in Health Canada’s proposed regulatory amendments to Category 1 medicines and manage the increase in Board hearings that is expected to result from their application.

Priority 3 – Employee Engagement

- Employee preparedness and buy-in is key to ensuring a successful transition to the PMPRB’s new regulatory framework. In addition to attracting and retaining new employees with the requisite skill sets, the PMPRB must inform and engage existing employees in the process of converting to a new approach to price regulation and provide them with the necessary training, tools and support to succeed in doing so.

This priority is intended to foster a capable, confident and high-performing workforce that embraces new ways of working. Engaged and motivated employees are also critical to the success of the PMPRB’s next round of strategic planning as it turns its attention to priorities for 2019-2022.

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

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

Core Responsibilities

Name of Core Responsibility - Regulate Patented Medicine Prices

Description

The Patented Medicine Prices Review Board (PMPRB) regulates the prices of patented medicines by setting non-excessive price ceilings and taking enforcement action before the Board in the event of non-compliance.

Planning highlights

In December 2017, Health Canada pre-published proposed amendments to the *Patented Medicines Regulations* (Regulations) in Part I of the Canada Gazette. If passed, the amendments would give effect to the government's commitment to improve the affordability of prescription medicines by making the following three changes to the way in which the PMPRB sets ceiling prices for patented medicines:

1. Having the PMPRB compare Canadian list prices to list prices in countries with lower pharmaceutical prices (i.e, removing Switzerland and the US from the group and adding countries with prices closer to the OECD [Organisation for Economic Cooperation and Development] median)
2. Introducing factors beyond just domestic and international list prices that the PMPRB can consider in determining whether the Canadian price of a patented medicine is excessive (i.e, pharmacoeconomics, market size and GDP [Gross domestic product])
3. Providing the PMPRB with information it needs to calculate the true price pharmaceutical companies are charging public and private payers (i.e., net of confidential rebates)

The manner in which the changes would have this effect are complex but can be summarized in relatively simple terms. Changing the group of comparator countries would result in lower ceilings for list prices in Canada, which are currently third highest in the OECD countries. Allowing the PMPRB to consider pharmacoeconomics, market size and GDP addresses the two types of high priced medicines that are threatening sustainable spending on pharmaceuticals in Canada: 1) medicines for rare diseases that cost disproportionately more than other medicines that provide the same or greater health benefit (i.e. medicines that are not “cost effective”) and; 2) medicines for more common diseases that are cost effective but unaffordable because of the

large number of patients that need them. Finally, providing the PMPRB with information about what companies are truly charging for their medicines would enable it to set confidential ceiling prices (based on the new factors) that are meaningful and protect both public and private payers.

\$198 MILLION IN EXCESS REVENUES HAVE BEEN RECOVERED

by the PMPRB through Voluntary Compliance
Undertakings and Board Orders since 1993.

The PMPRB's Guidelines provide patentees with guidance on how to comply with the price review factors in the Act and the Regulations and avoid coming under investigation for excessive pricing. Normally, a regulator will issue guidance on how it intends to operationalize government-sponsored changes to its regulations after they have been approved by Treasury Board in final form. However, an exception was made with respect to potential changes to the PMPRB's Guidelines in an effort to respond to concerns from pharmaceutical industry stakeholders and others that the proposed Regulations did not provide enough information to properly evaluate their impact on drug prices and availability. Accordingly, in 2018-19, the PMPRB pursued a two-track consultation process, which involved striking a steering committee composed of key stakeholders to provide high level feedback on a proposed new Guidelines framework and a working group of experts to help sort through some of the technical issues associated with operationalizing the proposed new factors.

As the original January 2019 implementation date has passed, the PMPRB will continue with this consultation process and work towards publishing a draft set of new Guidelines for broader consultation once Health Canada's Regulations have been finalized. The PMPRB will also continue implementing its plan for allocating additional funding from Budget 2017 to expand and convert office space to Workplace 2.0 Fit Up standards and hire new staff with the knowledge and skills needed to administer the new regulatory framework.

Until the new framework is passed, the PMPRB will continue to administer its regulatory mandate under existing Regulations and Guidelines to achieve the best possible results for Canadians. It will conduct price reviews on new and existing patented medicines sold in Canada in an effort to achieve a targeted 50% of patented medicine prices being below the median price of the PMPRB's comparator countriesⁱⁱⁱ.

The PMPRB is again striving for a 95% rate of compliance with its Guidelines in 2019-20 and will continue to focus its enforcement resources on cases that are most relevant to payers, and/or that raise regulatory issues which would benefit from judicial clarification. In recent years, the PMPRB's regulatory efforts have fallen slightly below its 95% target. In 2015-16 the compliance rate was 93%; in 2016-17 it was 92.3%; and, in 2017-18 it was 91.0%. In each of these years, a number of patented medicines were still under review at the end of the fiscal year, which

lowered the compliance percentage. In some cases, compliance with the Guidelines is achieved through a Voluntary Compliance Agreement^{iv}.

In terms of its reporting mandate, the PMPRB will continue building strategic partnerships and raising awareness of its activities by being responsive to the specific information needs of payers and the interests of a broader stakeholder audience. More specifically, the PMPRB will provide information as needed to support the pan Canadian Pharmaceutical Alliance (pCPA) drug price negotiations and continue providing analytical support for federal, provincial and territorial (F/P/T) dialogue on pharmacare and the case for a national formulary.

In keeping with the Government of Canada's renewed commitment to Gender-based Analysis Plus (GBA+)^v in the development of policies, programs and legislation, the PMPRB recognizes that sex and gender differences, race, ethnicity, age and mental or physical disability are factors to consider in the accessibility, affordability and appropriate use of prescription medicines and medical devices. Differences in sex and gender+ roles, income and utilization of health care services can affect access to medicines and health insurance, prescribing patterns and medicine use and may have important repercussions for health and well-being^{vi}.

The PMPRB's price review process does not take explicit account of the diversity of user groups or their economic situation. However, lower medicine prices, and associated savings for all payers, will benefit all, both sex and gender+ populations directly through lower out of pocket costs and indirectly through health system reinvestments and improved access to better care. In addition, the very high-cost medicines, which will be the focus of the PMPRB's new risk-based regulatory framework, often treat rare diseases that can impact certain minority ethnic groups disproportionately.

Planned results

Departmental Results	Departmental Result Indicators	Target	Date to achieve target	2015–16 Actual results	2016–17 Actual results	2017–18 Actual results
Affordable patented medicine prices	% of patented medicine prices in Canada are below the median of the PMPRB's comparator countries	50% ^(a)	March 31, 2020	n/a ^(b)	58.0% ^(c)	56.4% ^(c)
	% of patented medicine prices in Canada within the thresholds set out in the Guidelines	95% ^(d)	March 31, 2020	93.0%	92.3% ^(e)	91.0% ^(f)
<p>^(a) Operating under the premise that the PMPRB would continue to conduct its price reviews without significant changes in its regulatory framework a target of 50% of patented medicine prices being below the median price was established. Analysis in the PMPRB's 2015 Annual Report indicated that the percentage of patented medicines priced below the median price of the PMPRB's comparator countries was 51.8%, a decline from the previous two years. Based on these factors, it was determined that 50% would be a reasonable target.</p> <p>^(b) This performance indicator was introduced in 2016-17 so comparative actual results for periods prior to 2016-17 are not available.</p> <p>^(c) For purpose of this performance indicator, the median international price is the median of prices observed among the PMPRB7. The US exercises a significant influence over the average ratio of median international prices relative to Canadian prices because often the US is the only country for which an ex-factory price for a patented medicine sold in Canada is available. When Canadian prices are compared to OECD countries, the percentage below the median international price was 48.2% in 2017 and 51.5% in 2016.</p> <p>^(d) This percentage, based on the number of price reviews completed at March 31 of the fiscal year referred to, is calculated as follows:</p> <ul style="list-style-type: none"> 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 medicines for which the price review was completed at March 31 of the fiscal year. <p>^(e) As of March 31, 2018, 25 patented medicines were still under review, 122 were under investigation and one was the subject of a hearing.</p> <p>^(f) As of March 31, 2017, the compliance status of 39 patented generic medicines had not been reported. For this reason, the denominator used to calculate the percentage of compliance was reduced by this amount in the calculation of the compliance rate for 2016-17.</p>						

Budgetary financial resources (dollars)

2019–20 Main Estimates	2019–20 Planned spending	2020–21 Planned spending	2021–22 Planned spending
13,370,895	13,370,895	14,564,842	15,555,172

Human resources (full-time equivalents)

2019–20 Planned full-time equivalents	2020–21 Planned full-time equivalents	2021–22 Planned full-time equivalents
62	63	63

Financial, human resources and performance information for the PMPRB's Program Inventory is available in the [GC InfoBase](#).^{vii}

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 services that support Program delivery in the organization, regardless of the Internal Services delivery model in a department. These services are:

- Management and Oversight Services
- Communications Services
- Legal Services
- Human Resources Management Services
- Financial Management Services
- Information Management Services
- Information Technology Services
- Real Property Management Services
- Materiel Management Services
- Acquisition Management Services

Budgetary financial resources (dollars)

2019–20 Main Estimates	2019–20 Planned spending	2020–21 Planned spending	2021–22 Planned spending
3,241,616	3,241,616	3,016,713	3,022,125

Human resources (full-time equivalents)

2019–20 Planned full-time equivalents	2020–21 Planned full-time equivalents	2021–22 Planned full-time equivalents
20	20	20

Planning highlights

In 2019-20, the PMPRB will continue hiring new staff with the knowledge and skills needed to operationalize the envisaged new regulatory framework. However, given the uncertainty around the timing of new Regulations, some staffing actions may take place later than originally anticipated. In either event, there is a risk that the PMPRB will not be able to attract highly qualified individuals in certain specified fields. This is because of the competing demand for their skills from industry, academia and other government regulators. The PMPRB will take full advantage of the flexibilities in the Public Service Commission's New Direction on Staffing to customize its staffing processes so that it can identify and hire individuals in both the public and private sector with the needed education, background and experience.

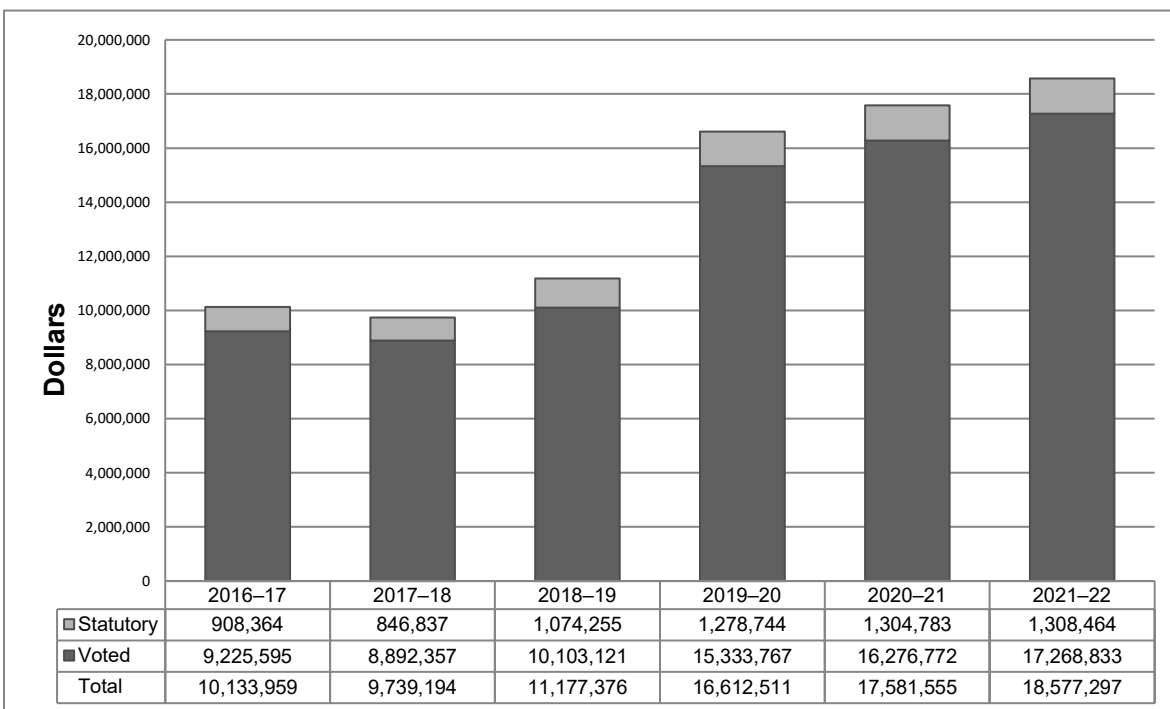
The PMPRB will also continue work on refitting its existing space to Workplace 2.0 Fit-up Standards to accommodate the additional Full Time Equivalents (FTEs) it is hiring in anticipation of framework modernization. The PMPRB is working in collaboration with Public Services and Procurement Canada on this initiative, which it expects to complete by the end of 2019-20. The PMPRB has a detailed plan for addressing its accommodations needs and transformation, which includes contingency plans for acquiring space, should the need arise. The plan also includes a monitoring process to ensure changes and/or delays are identified early so that appropriate corrective actions can be taken.

2019-20 will also see the implementation of an information management software, via the Automatic Classification and Metadata Enhancements (ACME) Project, which will reduce the manual information end-users are required to input by automating processes such as: classification; metadata generation and tagging; and, information governance. It will also improve the user experience by having a more user-friendly interface and increased e-discovery and searchability.

Spending and human resources

Planned spending

Departmental spending trend graph



NOTE: The graph above shows the PMPRB's planned and actual statutory and voted spending trend over time. The bars for 2016-17 and 2017-18 show actual spending; the bar for 2018-19 shows forecasted spending to the end of that fiscal year; and, the bars for 2019-20 and beyond show planned spending.

The PMPRB's funding for 2019-20 includes a Special Purpose Allotment (SPA) to conduct Public Hearings, in Vote 1 (Program expenditures) of \$4,276,566. 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.

Forecasted spending for 2018-19 is significantly higher than actual spending in 2017-18 because of increased funding and hiring of new staff to prepare for implementation of the new Guidelines. Forecasted spending for 2019-20 and beyond increases significantly from 2018-19 due to continued funding increases related to hiring of new staff and the enforcement of the new regulatory framework.

For purposes of forecasting Planned Spending for 2019-20 and future years, it is assumed that the entire SPA funding for hearings will be spent. This is because these expenditures are dependent on the number of hearings, and the length and complexity of the hearings held, which

are difficult to predict. The amount of the SPA for 2019-20 is \$4,276,566; 2020-21 is \$5,257,786; 2021-22 is \$6,206,486; and, for 2022-23 and beyond the amount of the SPA is \$4,463,361. Because of the implementation of the new Guidelines in 2020, it is anticipated that by 2022-23, Board Staff and patentees will have a better understanding of the working of the new Guidelines and there will be fewer pricing issues.

Budgetary planning summary for Core Responsibilities and Internal Services (dollars)

Core Responsibilities and Internal Services	2016–17 Expenditures	2017–18 Expenditures	2018–19 Forecast spending	2019–20 Main Estimates	2019–20 Planned spending	2020–21 Planned spending	2021–22 Planned spending
Regulate Patented Medicine Prices	7,714,937	7,109,924	8,060,229	13,370,895	13,370,895	14,564,842	15,555,172
Subtotal	7,714,937	7,109,924	8,060,229	13,370,895	13,370,895	14,564,842	15,555,172
Internal Services	2,419,022	2,629,270	3,117,147	3,241,616	3,241,616	3,016,713	3,022,125
Total	10,133,959	9,739,194	11,177,376	16,612,511	16,612,511	17,581,555	18,577,297

2019–20 Budgetary planned gross spending summary (dollars)

Core Responsibilities and Internal Services	2019–20 Planned gross spending	2019–20 Planned gross spending for specified purpose accounts	2019–20 Planned revenues netted against expenditures	2019–20 Planned net spending
Regulate Patented Medicine Prices	13,370,895	0	0	13,370,895
Subtotal	13,370,895	0	0	13,370,895
Internal Services	3,241,616	0	0	3,241,616
Total	16,612,511	0	0	16,612,511

Planned human resources

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

Core Responsibilities and Internal Services	2016–17 Actual full-time equivalents	2017–18 Actual full-time equivalents	2018–19 Forecast full-time equivalents	2019–20 Planned full-time equivalents	2020–21 Planned full-time equivalents	2021–22 Planned full-time equivalents
Regulate Patented Medicine Prices	44.4	42.3	48.0	62.0	63.0	63.0
Subtotal	44.4	42.3	48.0	62.0	63.0	63.0
Internal Services	19.3	18.0	20.0	20.0	20.0	20.0
Total	63.7	60.3	68.0	82.0	83.0	83.0

Estimates by vote

Information on the PMPRB's organizational appropriations is available in the [2019–20 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. The forecast and planned spending amounts presented in other sections of the Departmental Plan are prepared on an expenditure basis; as a result, 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](#).

Future-Oriented Condensed Statement of Operations
for the year ending March 31, 2020 (dollars)

Financial information	2018–19 Forecast results	2019–20 Planned results	Difference (2019–20 Planned results minus 2018–19 Forecast results)
Total expenses	12,025,415	18,187,140	6,161,725
Total revenues	1,172	-	(1,172)
Net cost of operations before government funding and transfers	12,024,243	18,187,140	6,162,897

The PMPRB is projecting \$18.2M in expenses based on 2019-20 Main Estimates and accrued information. This amount does not include future supplementary estimates. It represents an increase of \$6.2M from 2018-19 projections.

This increase is primarily attributable to:

- \$1.8M in additional funding in 2019-20 to reform Canada's patented medicine price regulation framework;
- A \$2.9M lapse in the SPA reserved for public hearings in 2018-19, due to a low number of hearings. 2019-20 planned results are based on the assumption that the PMPRB will spend the full \$4.3M funding available in the SPA. This assumption has been made because these expenditures are dependent on the number of hearings, and the length and complexity of the hearings held, which are difficult to predict;
- A \$0.5M salary lapse in 2018-19 due to delays in planned staffing, primarily as a result of delayed reforms to the PMPRB's price regulation framework; and
- A \$1M lapse in 2018-19, mostly because of unforeseen delays in the Workplace 2.0 refit and associated expenditures.

Additional information

Corporate information

Organizational profile

Appropriate minister: The Honourable Ginette Petitpas Taylor

Institutional head: Dr. Mitchell Levine, Chairperson

Ministerial portfolio: Health

Enabling instrument[s]: *Patent Act*^{ix} and *Patented Medicines Regulations*^x

Year of incorporation / commencement: 1987

Other:

The Minister of Health is responsible for the pharmaceutical provisions of the *Patent Act* set out in sections 79 to 103. Although the 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.

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

“Raison d'être, mandate and role: who we are and what we do” is available on the [PMPRB's website](#)^{xi}.

Reporting framework

Shown below, the PMPRB's Departmental Results Framework and Program Inventory of record for 2019–20.

Departmental Results Framework	Core Responsibility: Regulate Patented Medicine Prices		Internal Services
	Departmental Result: Affordable patented medicine prices	Indicator 1: % of patented medicine prices in Canada are below the median price of the PMPRB comparator countries	
		Indicator 2: % of patented medicine prices in Canada within the thresholds set out in the Guidelines	
Program Inventory	Patented Medicine Price Regulation Program		
	Pharmaceutical Trends Program		

Supporting information on the Program Inventory

Supporting information on planned expenditures, human resources, and results related to the PMPRB's Program Inventory is available in the [GC InfoBase](#).^{xii}

Supplementary information tables

The following supplementary information tables are available on the [PMPRB's website](#):

- ▶ [Departmental Sustainable Development Strategy](#)
- ▶ [Gender-based analysis plus](#)

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, as well as evaluations, research papers and gender-based analysis. The tax measures presented in this report are the responsibility of the Minister of Finance.

Organizational contact information

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Website: www.pmprb-cepmb.gc.ca

Appendix: 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)

A report on the plans and expected performance of an appropriated department over a three-year period. Departmental Plans are tabled in Parliament each spring.

Departmental Result (résultat ministériel)

Any change 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 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 Framework (cadre ministériel des résultats)

The department's Core Responsibilities, Departmental Results and Departmental Result Indicators.

Departmental Results Report (rapport sur les résultats ministériels)

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

evaluation (évaluation)

In the Government of Canada, the systematic and neutral collection and analysis of evidence to judge merit, worth or value. Evaluation informs decision-making, improvements, innovation and accountability. Evaluations typically focus on programs, policies and priorities and examine questions related to relevance, effectiveness and efficiency. Depending on user needs, however, evaluations can also examine other units, themes and issues, including alternatives to existing

interventions. Evaluations generally employ social science research methods.

experimentation (expérimentation)

Activities that seek to explore, test and compare the effects and impacts of policies, interventions and approaches, to inform evidence-based decision-making, by learning what works and what does not.

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.

gender-based analysis plus (GBA+) (analyse comparative entre les sexes plus [ACS+])

An analytical process used to help identify the potential impacts of policies, Programs and services on diverse groups of women, men and gender-diverse people. The “plus” acknowledges that GBA goes beyond sex and gender differences. We all have multiple identity factors that intersect to make us who we are; GBA+ considers many other identity factors, such as race, ethnicity, religion, age, and mental or physical disability.

government-wide priorities (priorités pangouvernementales)

For the purpose of the 2019–20 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 initiative (initiative horizontale)

An initiative where two or more departments are given funding to pursue a shared outcome, often linked to a government priority.

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.

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 Information Profile (profil de l'information sur le rendement)

The document that identifies the performance information for each Program from the Program Inventory.

performance reporting (production de rapports sur le rendement)

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

plan (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.

planned spending (dépenses prévues)

For Departmental Plans and Departmental Results Reports, planned spending refers to those amounts 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.

priority (priorité)

A plan or project 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 Departmental Results.

Program (programme)

Individual or groups of services, activities or combinations thereof that are managed together within the department and focus on a specific set of outputs, outcomes or service levels.

Program Inventory (répertoire des programmes)

Identifies all of the department's programs and describes how resources are organized to contribute to the department's Core Responsibilities and Results.

result (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.

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 The Terms of Reference for the Working Group to Inform the Patented Medicine Prices Review Board (PMPRB) Steering Committee on Modernization of Price Review Process Guidelines can be found on the PMPRB website: <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1377&lang=en>
- ii The Terms of Reference for the Steering Committee on Modernization of Price Review Process Guidelines can be found on the PMPRB website: <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1377&lang=en>
- iii The seven countries to which Canada compares its medicine prices under the Patented Medicines Regulations are France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States – also known as the “PMPRB7”.
- iv A Voluntary Compliance Undertakings (VCU) is a written undertaking by a patentee to adjust its price to conform to the Board’s Guidelines. Under the Guidelines, patentees are given an opportunity to submit a VCU when Board Staff concludes, following an investigation, that the price of a patented medicine sold in Canada appears to have exceeded the thresholds set out in the Guidelines. A VCU represents a compromise between the PMPRB and the patentee as a result of negotiations between the parties geared towards a satisfactory resolution of an investigation initiated by Board Staff as per the Guidelines. A VCU takes into account the specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value.

A list of signed VCU’s can be found on the PMPRB website: <http://www.pmprb-cepmb.gc.ca/en/vcus>
- v An analytical process used to help identify the potential impacts of policies, Programs and services on diverse groups of women, men and gender-diverse people. The “plus” acknowledges that GBA goes beyond sex and gender differences. We all have multiple identity factors that intersect to make us who we are; GBA+ considers many other identity factors, such as race, ethnicity, religion, age, and mental or physical disability.
- vi Under Canada’s mixed system of private and public drug coverage, where out of pocket spending on premiums, deductibles, co-pays and direct purchases is common, economic status is a key determinant of accessibility and affordability. While the wage gap has narrowed, and the incidence of low income has decreased over the last three decades, women’s incomes remain lower than men’s in all age groups and female-led lone parent families still have the lowest average income of all family types.

An estimated 20% of Canadians either are under-insured or have no effective access to prescription drug benefits, private or public, and women are less likely than men to have such access perhaps because they are more likely to be in part-time work for which benefits

are not offered (recognizing some individuals are covered through a family member's employer-sponsored plan).

Sex is a key consideration in the biochemical response to drugs, which is different for males and females, and needs to be considered with respect to drug safety, efficacy and effectiveness. For some drugs, a smaller dose for females is more beneficial than the full dose for males; this has potential to influence pricing. Females are under-represented in clinical trials resulting in insufficient evidence on risks, benefits and optimal use.

- vii GC InfoBase, <https://www.tbs-sct.gc.ca/ems-sgd/edb-bdd/index-eng.html#start>
- viii 2018–19 Main Estimates, <https://www.canada.ca/en/treasury-board-secretariat/services/planned-government-spending/government-expenditure-plan-main-estimates.html>
- ix *Patent Act*, <https://laws-lois.justice.gc.ca/eng/acts/P-4/page-1.html>
- x Patented Medicines Regulations, <https://laws-lois.justice.gc.ca/eng/regulations/SOR-94-688/page-1.html>
- xi The PMPRB website, <http://www.pmprb-cepmb.gc.ca/about-us/mandate-and-jurisdiction/>
- xii GC InfoBase, <https://www.tbs-sct.gc.ca/ems-sgd/edb-bdd/index-eng.html#start>
- xiii Report on Federal Tax Expenditures, <http://www.fin.gc.ca/purl/taxexp-eng.asp>