Patented Medicine Prices Review Board

2018–19

Departmental Plan

The Honourable Ginette Petitpas Taylor
Minister of Health

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Chairperson's message

I am pleased to present the 2018-19 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 2018-19, the PMPRB's focus will be on completing the regulatory framework modernization process it embarked on in 2015 with the release of its 2015-18 Strategic Plan, by consulting on and finalizing new Guidelines. The changes to the Guideline are further to Health Canada's proposed amendments to the Patented Medicines Regulations ("Regulations") which were pre-published in the Part I of the Canada Gazette on December 2, 2017.

The Regulations are a key deliverable for the Minister of Health in her continuing efforts to improve patient access to necessary prescription medications including by making them more affordable and appropriately prescribed. In December 2017, the PMPRB published a Guidelines scoping paper[i] which provided an outline of how it envisages operationalizing the Regulations through new Guidelines. A first draft of the new Guidelines will be published in the spring of 2018 and public consultations will run through the summer and fall of 2018. The new regulatory framework is expected to be finalized by no later than January 1, 2019.

As it transitions toward a modern, risk-based approach to drug price regulation in 2018-19, the PMPRB will also begin the first phase of its plan for using the additional funding allotted to it in Budget 2017. This plan includes the hiring of substantial new staff, expanding and converting its office space, and transforming its IT infrastructure to enable a more flexible, mobile and dynamic working environment.

The PMPRB celebrated its 30th year of existence in December 2017. We can think of no better way to mark this important milestone in our history than by completing our ongoing transformation into a modern and effective regulator with the right tools to protect consumers in an era increasingly dominated by high cost drugs. We welcome the confidence the Minister of Health has placed in our organization as a delivery vehicle for her commitment to improve access to needed pharmaceuticals and look forward to working with our federal, provincial and territorial health partners as we leverage, complement and enhance our respective roles in ensuring a sustainable Canadian health system.

Dr. Mitchell Levine
Chairperson

Plans at a glance

Priority 1 – Framework Modernization

- Complete regulatory framework modernization by consulting on and finalizing new Guidelines which operationalize Health Canada's proposed amendments to the Patented Medicines Regulations.

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

NEW GUIDELINES

Publication of a first draft of the PMPRB's new Guidelines is planned for the spring of 2018.

Priority 2 – Consumer-focused Regulation

- Begin transition toward new, risk-based approach to price regulation through implementation of TB submission plan for year one allocation of Budget 2017 funding, including hiring new staff, expanding office space, commencing Workplace 2.0 retrofit and transforming IT infrastructure.

This priority is intended to provide the PMPRB with the capacity to apply the new factors set out in Health Canada's proposed amendments to focus on the high cost drugs that pose the greatest risk of excessive pricing.

Priority 3 – Strategic Partnerships and Public Awareness

- Continue building strategic partnerships and raising public awareness of PMPRB's consumer protection mandate by being more responsive to the specific information needs of public and private payers and the interests of a broader stakeholder audience (e.g., academia, patient groups, health care providers and civil society).

This priority will provide the PMPRB's broader stakeholder community with the information needed to make better, more informed choices with respect to pharmaceuticals.

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

Regulate patented medicine prices

Description

The 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 2018-19, working within the confines of its current regulatory framework, the PMPRB will conduct price reviews on new and existing patented drug products sold in Canada in an effort of achieving a targeted 50% of patented drug prices being below the median price of the PMPRB's comparator countries.[ii]

In 2018-19 the PMPRB is striving for a 95% rate of compliance with its current Guidelines. The Guidelines provide non-binding interpretive guidance and direction from the Board to patentees on how to comply with the Patent Act (the Act) and the Regulations. In 2018-19 the PMPRB will continue to target enforcement resources on cases that are most relevant to payers, and/or that raise regulatory issues which would benefit from judicial elucidation.

REGULATORY REFORM

The Government of Canada is focused on making prescription drugs more accessible and affordable, working with partner organizations and provinces and territories. The Minister of Health is currently consulting on proposed amendments to the Patented Medicines Regulations. The Patent Act and proposed amendments to the Regulations provide the PMPRB the legal authority to regulate the prices of patented medicines sold in Canada.

In December 2017, the PMPRB published a Guidelines scoping paper to provide stakeholders and interested members of the public with an outline of its preliminary thoughts on how it intends to operationalize, through non-binding Guidelines, the proposed amendments to the Regulations, which were pre-published in Part I of the Canada Gazette on December 2, 2017.

The PMPRB will publish a first draft of the new Guidelines in spring 2018 and hold public consultations through the summer and fall of 2018. The consultations are meant as a platform for

stakeholders and the public to engage in an open, frank and transparent exchange of views and ideas on how best to operationalize Health Canada's proposed amendments. The new Guidelines are expected to be finalized in December and come into force January 1, 2019 at the same time as the Regulations.

If passed in their current form, the proposed amendments would allow the PMPRB to move to a risk-based framework that scrutinizes drugs with the greatest potential for excessive pricing and takes into account both their value to, and financial impact on, consumers and payers in the health system when setting ceiling prices. This would constitute a paradigm shift in how the PMPRB regulates patented drug prices but would not depart from or expand on its original mandate.

In terms of its reporting mandate, the PMPRB will continue building strategic partnerships and raising awareness of its activities by being more 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 pan Canadian Pharmaceutical Alliance (pCPA) drug price negotiations and continue providing analytical support for F/P/T dialogue on exploring the need for a national formulary.

In keeping with the Government of Canada's renewed commitment to Gender-based Analysis Plus (GBA+)[iii] 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 important factors in the accessibility, affordability and appropriate use of prescription drugs and medical devices. Differences in sex and gender+ roles, income and utilization of health care services can affect access to drugs and health insurance, prescribing patterns and drug use and may have important repercussions for health and well-being.[iv]

The PMPRB applies a uniform approach in its price reviews which could lead to unequal impacts as it does not account for the diversity of user groups or their economic situation. However, lower drug 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 high cost drugs which will be the focus of the PMPRB's new risk-based regulatory framework often treat rare diseases that are more prevalent in certain minority ethnic groups that share the same relevant genotype.

Planned results

Departmental Results	Departmental Result Indicators	Target	Date to achieve target	2014–15 Actual results	2015–16 Actual results	2016–17 Actual results
Affordable patented drug prices	% of patented drug prices in Canada below the median price of the PMPRB's comparator countries	50%[a]	March 31, 2019	n/a[b]	n/a	58%[c]
	% of patented drug prices in Canada are within the thresholds set out in the PMPRB's Excessive Price Guidelines	95%	March 31, 2019	95.3%	93%	92.3

[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 drug prices being below the median price was established. Analysis in the PMPRB's 2015 Annual Report indicated that the percentage of patented drugs 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.

[b] This performance indicator was introduced in 2016-17 so comparative actual results for periods prior to 2016-17 are not available.

[c] The 58% of patented drug prices in Canada reported as being below the median international price includes a significant number of patented drugs being sold in fewer than five countries and therefore are not being compared to the actual median international price. Of the 1425 drugs sold in Canada in 2016, only 847 were sold in five or more countries. Of this 847, only 384 patented drugs (45%) had a Canadian price below the median price. This is a significant difference from the reported 58%.

In 2018-19, the PMPRB will work to correct this indicator to make it a more meaningful reflection of how Canadian prices compare to those in other countries.

Through further analysis of the first indicator above, the PMPRB has become aware of some deficiencies with respect to the calculation of the actual results for 2016-17. The indicator does not differentiate between an interim median international price and the actual median international price which as stated in the PMPRB's Compendium of Policies, Guidelines and Procedures is calculated at the end of three years of sales or when the same patented drug product is sold in at least five countries, whichever occurs first. [v]

Budgetary financial resources (dollars)

2018–19 Main Estimates	2018–19 Planned spending	2019–20 Planned spending	2020–21 Planned spending
11,227,006	11,227,006	13,445,565	14,644,227

Human resources (full-time equivalents)

2018–19 Planned full-time equivalents	2019–20 Planned full-time equivalents	2020–21 Planned full-time equivalents
51.0	60.5	61.5

Financial, human resources and performance information for the PMPRB's Program Inventory is available in the GC InfoBase.[vi]

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 (IT); Real Property Services; Materiel Services; and Acquisition Services.

Budgetary financial resources (dollars)

2018–19 Main Estimates	2018–19 Planned spending	2019–20 Planned spending	2020–21 Planned spending
3,644,866	3,644,866	3,271,769	3,050,283

Human resources (full-time equivalents)

2018–19 Planned full-time equivalents	2019–20 Planned full-time equivalents	2020–21 Planned full-time equivalents
21.0	21.5	21.5

Planning highlights

The PMPRB is in a period of significant transition not only in how it regulates prices but internally as well. Over the next year, the PMPRB will seek to mitigate any potential negative impact of these changes on its employees through clear and consistent communication and

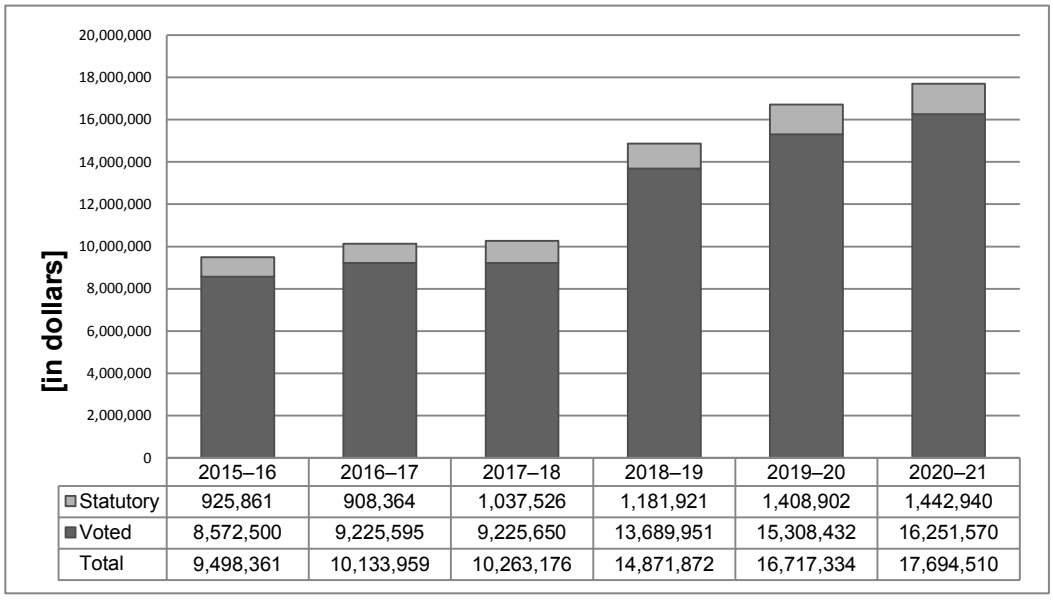
consultation with staff throughout the transition process. In 2018-19 the PMPRB will receive new funding to implement more relevant and effective tools to protect Canadians from excessive prices for patented drugs. This funding is necessary to hire additional staff, convert and expand office space and modernize IT infrastructure. More specifically, the PMPRB will be hiring new staff with the skill sets and expertise needed to fully operationalize the new regulatory framework. The PMPRB will also be refitting its existing space to accommodate the additional Full Time Equivalents (FTEs) following the Workplace 2.0 Fit-up Standards. Additionally, the PMPRB will be modernizing its IT in order to improve capacity and experiment with more flexible work arrangements. The PMPRB will also seek to acquire Special Purpose Space for dedicated hearing room facilities.

2018-19 will also mark the completion of the PMPRB's Information Management Digitization of Records project. This project was initiated to address a Library and Archives requirement that Information Resources of Enduring Value created after 2017 be stored in digital format. It is expected that digitization of corporate records will result in better quality control, file integrity, corporate memory retention and cost savings through reduced off-site storage.

Spending and human resources

Planned spending

Departmental spending trend graph



	2015–16	2016–17	2017–18	2018–19	2019–20	2020–21
Statutory	925,861	908,364	1,037,526	1,181,921	1,408,902	1,442,940
Voted	8,572,500	9,225,595	9,225,650	13,689,951	15,308,432	16,251,570
Total	9,498,361	10,133,959	10,263,176	14,871,872	16,717,334	17,694,510

The PMPRB's funding includes a Special Purpose Allotment (SPA) to conduct Public Hearings, in Vote 1 (Program expenditures) of $3,419,481. 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.

Actual spending in 2016-17 was significantly higher than actual spending in 2015-16 largely due to increased spending on hearings. In 2016-17 the PMPRB spent $1,883,121 from the SPA as compared to $1,213,627 in 2015-16, a difference of $669,494.

For purposes of forecasting Planned Spending for 2017-18 and future years it is assumed that the entire SPA funding for hearings will be spent. 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. Also, in 2017-18 there was a significant increase in forecasted statutory spending as a result of the signing of several collective agreements which resulted in increased employee benefit plan (EBP) costs.

As announced in the 2017 Budget, the PMPRB received additional funding for future years; $3,849,215 in 2018-19, $5, 694,677 in 2019-20, $6,671,853 in 2020-21, $7,668,725 in 2021-22 and $5,680,633 in 2022-23 and ongoing, including EBP and increased funding for the SPA.

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

Core Responsibilities and Internal Services	2015–16 Expenditures	2016–17 Expenditures	2017–18 Forecast spending	2018–19 Main Estimates	2018–19 Planned spending	2019–20 Planned spending	2020–21 Planned spending
Regulate patented medicine prices	7,087,711	7,714,937	7,561,962	11,227,006	11,227,006	13,445,565	14,644,227
Subtotal	**7,087,711**	**7,714,937**	**7,561,962**	**11,227,006**	**11,227,006**	**13,445,565**	**14,644,227**
Internal Services	2,410,650	2,419,022	2,701,214	3,644,866	3,644,866	3,271,769	3,050,283
Total	**9,498,361**	**10,133,959**	**10,263,176**	**14,871,872**	**14,871,872**	**16,717,334**	**17,694,510**

Planned human resources

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

Core Responsibilities and Internal Services	2015–16 Actual	2016–17 Actual	2017–18 Forecast	2018–19 Planned	2019–20 Planned	2020–21 Planned
Regulate patented medicine prices	43.9	44.4	42.5	51.0	60.5	61.5
Subtotal	**43.9**	**44.4**	**42.5**	**51.0**	**60.5**	**61.5**
Internal Services	18.6	19.3	18.5	21.0	21.5	21.5
Total	**62.5**	**63.7**	**61.0**	**72.0**	**82.0**	**83.0**

The increase in planned FTEs for 2018-19 and beyond is a result of the additional funding received in the 2017 Budget.

Estimates by vote

For information on the PMPRB's organizational appropriations, consult the 2018–19 Main Estimates.[vii]

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[viii] 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 ended March 31, 2019 (dollars)

Financial information	2017–18 Forecast results	2018–19 Planned results	Difference (2018–19 Planned results minus 2017–18 Forecast results)
Total expenses	11,475,716	16,107,128	4,631,412
Total revenues	456	-	(456)
Net cost of operations before government funding and transfers	11,475,260	16,107,128	4,631,868

Supplementary 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 (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.

Raison d'être, mandate and role

"Raison d'être, mandate and role: who we are and what we do" is available on the PMPRB's website.[xi]

Operating context and key risks

Information on operating context and key risks is available on the PMPRB's website.[xii]

Reporting framework

The PMPRB's Departmental Results Framework and Program Inventory of record for 2018–19 are shown below:

<table>
<tr><td rowspan="4">Departmental Results Framework</td><td colspan="2">Core Responsibility: Regulate Patented Medicine Prices</td><td rowspan="5">Internal Services</td></tr>
<tr><td rowspan="3">Departmental Result: Affordable patented drug prices</td><td>Indicator 1: % of patented drug prices in Canada are below the median price of the PMPRB's comparator countries</td></tr>
<tr><td>Indicator 2: % of patented drug prices in Canada within the thresholds set out in the Guidelines</td></tr>
<tr><td rowspan="2">Program Inventory</td><td colspan="2">Patented Medicine Price Regulation Program</td></tr>
<tr><td colspan="2">Pharmaceutical Trends Program</td></tr>
</table>

Concordance between the Departmental Results Framework and the Program Inventory, 2018–19, and the Program Alignment Architecture, 2017–18

2018–19 Core Responsibilities and Program Inventory	2017–18 Lowest-level program of the Program Alignment Architecture	Percentage of lowest-level Program Alignment Architecture program (dollars) corresponding to the program in the Program Inventory
Core Responsibility 1: Regulate Patented Medicine Prices		
Patented Medicine Price Regulation Program	Patented Medicine Prices Regulation Program	100%
Pharmaceutical Trends Program	Pharmaceutical Trends Program	100%

Under the Program Alignment Architecture, the PMPRB had one, two-fold Strategic Outcome: "Canadians are protected from excessive prices for patented medicines sold in Canada and stakeholders are informed on pharmaceutical trends"; and two supporting programs and internal services. With the Departmental Results Framework the PMPRB has one core responsibility: "Regulate patented medicine prices" this is because in large part, the reports on pharmaceutical trends demonstrate the effectiveness, or lack thereof, of price regulation and/or identify trends that may require attention. The programs under both reporting structures are the same.

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.[xiii]

Supplementary information tables

The following supplementary information tables are available on the PMPRB's website

- Departmental Sustainable Development Strategy[xiv]
- Gender-based Analysis Plus[xv]

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.[xvi] 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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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 appropriated departments over a three-year period. Departmental Plans are tabled in Parliament each spring.

Departmental Result (résultat ministériel)

Any 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 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.

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 2018–19 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 in which two or more federal organizations, through an approved funding agreement, work toward achieving clearly defined shared outcomes, and which has been designated (by Cabinet, a central agency, etc.) as a horizontal initiative for managing and reporting purposes.

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 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 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.

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.

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 Alignment Architecture (architecture d'alignement des programmes)[1]
A structured inventory of an organization's programs depicting the hierarchical relationship between programs and the Strategic Outcome(s) to which they contribute.

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.

1. Under the Policy on Results, the Program Alignment Architecture has been replaced by the Program Inventory.

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. PMPRB Guidelines Scoping Paper – High Level Overview of Potential New Framework, http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1341&lang=EN

ii. The seven countries to which Canada compares itself under the Patented Medicines Regulations are France, Germany, Italy, Sweden, Switzerland, the UK and the US – also known as the "PMPRB7")

iii. 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.

iv. 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 are either 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 taken into consideration 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.

v. See the PMPRB's Compendium of Policies, Guidelines and Procedures, Schedule 5 – Median International Price Comparison Test,

1.3 When the new patented drug product is sold in fewer than five countries at the time it is first sold in Canada, the median international price will be calculated on an interim basis. At the end of three years or when the same patented drug product with the same strength and dosage form is sold in at least five countries, whichever occurs first, Board Staff will re-determine the median international price.

http://www.pmprb-cepmb.gc.ca/view.asp?ccid=492&lang=EN

vi. GC InfoBase, https://www.tbs-sct.gc.ca/ems-sgd/edb-bdd/index-eng.html#start

vii. 2017–18 Main Estimates, https://www.canada.ca/en/treasury-board-secretariat/services/planned-government-spending/government-expenditure-plan-main-estimates.html

viii. PMPRB's Future-oriented Statement of Operations: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1345&lang=en

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

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

xi. Raison d'être, http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1005&lang=en

xii. Operating Context and Key Risks, -http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1357&lang=en

xiii. GC InfoBase, https://www.tbs-sct.gc.ca/ems-sgd/edb-bdd/index-eng.html#start

xiv. Departmental Sustainable Development Strategy: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1359&lang=en

xv. Gender-based Analysis Plus: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1360&lang=en

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