2020–21
Departmental Results Report

Patented Medicine Prices Review Board

The Honourable Jean-Yves Duclos
Minister of Health

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From the Chairperson

I am pleased to present the 2020-21 Departmental Results Report 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* (the "Act"). The PMPRB is a consumer protection agency with a dual regulatory and reporting mandate. Its regulatory mandate is to ensure that the prices of patented medicines sold in Canada are not excessive. Its reporting mandate is to provide stakeholders with pharmaceutical trends information to help them make informed choices.

2020-21 was a very challenging year. The COVID 19 pandemic wreaked havoc with the daily activities of the world. The PMPRB, like all organizations had to quickly shift to a virtual workplace. Because of its excellent IT infrastructure and forward thinking, the PMPRB was able to continue to fulfil its regulatory and reporting mandate without interruption, a testament to the hard work, adaptability, and dedication of its staff.

Over the past year, the PMPRB worked with stakeholders and interested members of the public to ensure a fully operational set of Guidelines was ready for implementation. During this period, the PMPRB completed consultations on its regulatory framework and issued not one, but two drafts of the new Guidelines. The new Guidelines, which give effect to the amended *Patented Medicines Regulations,* and were scheduled to come into force on January 1, 2021, were further delayed. The new date for their coming into force is January 1, 2022. The final Guidelines include transitional measures, which provide patentees with sufficient time to take the necessary steps to come into voluntary compliance with the relevant pricing ceilings for both new and existing patented medicines.

Having consolidated the additional resources made available to us as part of the Government's commitment to improve the affordability, accessibility and appropriate prescribing of prescription drugs in Budget 2017, the PMPRB is ready and eager to begin applying its new regulatory framework January 1, 2022 when the amended Regulations come into force. Our efforts to provide patentees with the information and knowledge they need to comply with the new framework began in earnest soon after the release of the new Guidelines in October 2020 and will continue up to and beyond the coming into force date. Staff have worked tirelessly to make the necessary changes to our online filing and data management systems so that the transition to the new filing requirements is as seamless as possible come July, and will work diligently to fix any bugs in those systems should they arise in the ensuing months.

In parallel to continued patentee outreach sessions on the Guidelines, the PMPRB hosted multiple consultation sessions for its stakeholder community on our Guidelines Monitoring and Evaluation Plan (GMEP) in the first half of 2021. The first such session was a workshop with the PMPRB's government partners on January 19, 2021. Its purpose was to seek feedback on research questions and metrics of particular interest to federal, provincial, and territorial (F/P/T) health ministries, as well as health technology assessment bodies and other pan-Canadian health organizations.

In late 2020-early 2021 the PMPRB held its first virtual public hearing in the matter of the price of the patented medicine cysteamine bitartrate, sold under the trade name "Procysbi" by Horizon Therapeutics Canada. The purpose of this hearing was to determine whether the medicine has been or is being sold in any market in Canada at a price that, in the Board's opinion, is or was excessive; and, if so, what order, if any, should be made to remedy the excessive pricing. A decision on the matter is pending.

As a member of the Health Portfolio, the PMPRB plays an important role in advancing the broader objective of improving the health of Canadians through a responsible, accessible and sustainable health system. Over the past year, we worked closely with our F/P/T health partners to align and optimize our respective processes in the context of the new regulatory framework and other ongoing reforms to improve access and affordability. We continued to provide analytical support and expertise to our health partners under our National Prescription Drug Utilization Information System (NPDUIS) reporting mandate, in efforts to advance policy work on pan-Canadian initiatives to improve the pricing and reimbursement of pharmaceuticals in Canada.

In November of this year, my second and final term as a PMPRB Board member, and my tenure as its Chairperson, will come to an end. It has been an honour and a privilege to serve as a Board member and to lead the PMPRB through such a transformative and pivotal period in its long and storied history. I would like to thank the Minister for having afforded me this opportunity and for the confidence placed in the PMPRB's ability to contribute more meaningfully to the Government's efforts to safeguard Canada's public health system, one of our most treasured assets. Finally, I would like to express my reverence and regard for the public servants on the PMPRB staff that I've had the honour and pleasure of working alongside during my two terms on the Board. People may come and go but the commitment of staff at the PMPRB to the very highest ideals of public service is unwavering and I am confident it will endure long after my term as Chairperson comes to an end.

Dr. Mitchell Levine

Results at a glance

Priority 1 – Implement new pricing framework and begin evaluating its impact

The PMPRB took advantage of the original delay in the implementation of the Regulations from July 1, 2020 to January 1, 2021 and extended the period for stakeholders to comment on the June 2020 draft of the Guidelines. Consequently, in October 2020, the PMPRB issued new Guidelines. The Guidelines, which are non-binding, implement the amendments to the *Patented Medicines Regulations*, which come into force January 1, 2022 and formalize the PMPRB's move to a more risk-based approach to ensuring that prices of patented medicines are not excessive.

The PMPRB also developed a GMEP to monitor and analyze trends in the pharmaceutical market before and after the implementation of the PMPRB's new Guidelines to assess whether they are working as intended, and to inform the need for any future adjustments. The PMPRB invited stakeholders to help shape the development of this plan by providing comments on the proposed GMEP by June 21, 2021. Stakeholders were also invited to participate in a public webinar held on May 31, 2021.

In addition, the PMPRB held three Research Webinars: Research Webinar 1 offered insight into spending on expensive drugs for rare diseases and market size of patented medicines in Canada; Research Webinar 2 looked at drug pricing and its impact on R&D investments, clinical trials and availability of medicines in Canada; and, Research Webinar 3 looked at drug shortages in Canada.

Priority 2 –Support the Government's high-level priorities for the future of pharmaceutical management in Canada.

The PMPRB continues to work with F/P/T health partners to align and optimize their respective processes in the context of the new framework and other recent or ongoing reforms that impact pricing and reimbursement.

In addition, the PMPRB also continues to provide analytical support and expertise to health partners, as appropriate, in efforts to advance policy work relating to the foundational elements of national pharmacare and other pan-Canadian initiatives to improve the pricing and reimbursement of pharmaceuticals in Canada.

Furthermore, the PMPRB continues to leverage its resources and expertise to optimize its ability to protect consumers from excessive prices and maximize its value proposition to its F/P/T health partners and the health system as a whole.

For more information on the PMPRB's plans, priorities and results achieved, see the "Results: what we achieved" section of this report.

Results: what we achieved

Core responsibility

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.

Results:

In June 2020, the PMPRB released draft Guidelines for consultation with its stakeholders. To this end, the PMPRB held two online public consultations; one with representatives from the pharmaceutical industry, the other with all interested stakeholders. In addition, by invitation, the PMPRB held two, dedicated sessions with its health partners and three Research Webinars on topics of interest: Research Webinar 1 offered insight into spending on expensive drugs for rare diseases and market size of patented medicines in Canada; Research Webinar 2 looked at drug pricing and its impact on R&D investments, clinical trials and availability of medicines in Canada; and, Research Webinar 3 looked at drug shortages in Canada.

Also, in June 2020, the Federal Court issued its decision in respect of Innovative Medicines Canada's application for judicial review of the recent amendments to the Patented Medicines Regulations. The new section 85(1) excessive pricing factors and new comparator countries was upheld but amendments relating to the calculation of net prices, subsection 3(4) of the Amended Regulations, were deemed outside the PMPRB's jurisdiction. The Quebec Superior Court issued a similar decision. Considering these decisions, the PMPRB extended its deadline for comments on the June 2020 draft Guidelines and published new Guidelines in October 2020. The new Guidelines, which give effect to the amended *Patented Medicines Regulations*, were scheduled to come into force on January 1, 2021, but were further delayed. The new date for their coming into force is January 1, 2022.

The PMPRB saw a decrease in the rate of compliance with its Guidelines, from 88.4% in 2019-20, to 86.3% in 2020-21, well below the 95% target. In recent years, patentees have been more apt to challenge the price ceilings applied under the PMPRB's pricing Guidelines to the latest generation of very high cost medicines that is coming to dominate the market. In 2020-21, the PMPRB accepted four Voluntary Compliance Undertakings (VCU), which resulted in a price reduction for five DINs[i] and recovered $228,510.21[ii] in excess revenues through payments to the Government of Canada.

The introduction, of new, extremely high-priced patented medicines has been a major driver of sales growth in recent years. High cost medicines now account for close to 50 percent of all patented medicine sales in Canada yet cover less than two percent of claimants.

Gender-based analysis plus

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.

Since the price of a medicine does not vary for the sex or gender of the user, the PMPRB's price review process does not take explicit account of the diversity of user groups or their economic situation. Lower medicine prices, and associated savings for all payers, will benefit all 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.

Experimentation

The PMPRB is developing a GMEP to monitor and evaluate trends in the pharmaceutical market that may impact the patentees, as well as consumers, patients, and payers that it is mandated to protect. The GMEP will analyze trends before and after the implementation of the PMPRB's new framework to assess whether it is working as intended, and to inform the need for any future adjustments.

Based on the nature of the changes contained in the new Guidelines and in response to the feedback received from its stakeholders during the consultation process that led to those changes, the PMPRB is proposing a GMEP that will assess four key areas of focus: I. prices of medicines; II. access to medicines; III. the pharmaceutical ecosystem; and IV. PMPRB processes.

For each of these four areas, the PMPRB, in consultation with its stakeholders, will identify relevant indicators to monitor. Baseline results (benchmarks) will be generated based on the years immediately preceding the coming-into-force of the amended Regulations. Starting with 2022, changes will be monitored on an ongoing basis and compared to the benchmarks to identify and evaluate any relevant changes in the trends in the data.

Under the extraordinary circumstances of the Covid19 pandemic, the PMPRB, based on case law and other administrative tribunal best practices, put in place the infrastructure, processes and systems needed for a virtual and online hearing, including public access using YouTube. All parties, including panel members, the public, hearing participants and counsel, were well served and found this experience to be highly successful.

Results achieved

Departmental results	Performance indicators	Target	Date to achieve target	2018–19 Actual results	2019–20 Actual results	2020–21 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, 2021	57.1%	56.9%	58.2%[b]
	% of patented medicine price in Canada within the thresholds set out in the Guidelines	95%[c]	March 31, 2021	90.5%	88.4[d]	86.3%[e]

[a] This performance indicator was introduced in 2016-17. Operating under the premise that the PMPRB would continue to conduct its price reviews without significant changes in its regulatory framework, the PMPRB established a target of 50% of patented medicine prices being below the median price. 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.

[b] The 58.2% of patented medicine prices in Canada reported as being below the median international price includes a significant number of patented medicines being sold in fewer than five countries and therefore are not being compared to the actual median international price. Of the 1,272 patented medicines sold in Canada in 2020, only 746 were sold in five or more countries. Of this 746, only 353 patented medicines (47.3%) had a Canadian price below the median price. This is a significant difference from the reported 58.2%.

[c] This percentage, based on the number of price reviews completed by March 31 of 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 number of patented medicines for which the price review was completed at March 31 of the fiscal year.

[d] Because of an adjustment to the calculation of the denominator this number does not match the number reported in the 2019-20 DRR.

[e] As of March 31,2021, 54 patented medicines were still under review, and 166 were under investigation, two were the subject of a hearing and one was subject to a Stay Order.

Budgetary financial resources (dollars)

2020–21 Main Estimates	2020–21 Planned spending	2020–21 Total authorities available for use	2020–21 Actual spending (authorities used)	2020–21 Difference (Actual spending minus Planned spending)
14,728,961	14,728,961	13,888,037	10,858,873	(3,870,088)

Human resources (full-time equivalents)

2020–21 Planned full-time equivalents	2020–21 Actual full-time equivalents	2020–21 Difference (Actual full-time equivalents minus Planned full-time equivalents)
65	57	(8)

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

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:

- Acquisition Management Services
- Communication Services
- Financial Management Services
- Human Resources Management Services
- Information Management Services
- Information Technology Services
- Legal Services
- Material Management Services
- Management and Oversight Services
- Real Property Management Services

Results:

In 2020-21 working in collaboration with Public Services and Procurement Canada, the PMPRB completed work on the construction of its dedicated hearing room. The hearing room is equipped and ready for use when normal daily activities can resume. In the meantime, the PMPRB successfully conducted its first virtual hearing, made by possible by its excellent IT infrastructure.

Over the past fiscal year, the PMPRB continued the work on implementation of the Automatic Classification and Metadata Enhancements (ACME) Project to reduce the manual information end-users are required to input into the Electronic Document and Records Management System (EDRMS). The ACME will automate processes such as classification, metadata generation and tagging, and information governance, which is intended to make information management more user-friendly.

The PMPRB's Compliance Information Management System ("CIMS") is a web-based application used to review and analyze data filed by patentees and assess patentees' compliance. The PMPRB is making several enhancements to CIMS so that it can accept and process the additional information patentees must provide under the new Regulations and Guidelines. While modernization of the online filling tool is complete, updating price tests for new medicine reviews and upgrading several data management components of the application is ongoing.

Modernization of the CIMS application will fully integrate the new regulatory framework into the existing system to ensure that the Regulatory Affairs and Outreach (RA&O) branch can continue to manage information filed by patentees as well as monitor compliance.

Budgetary financial resources (dollars)

2020–21 Main Estimates	2020–21 Planned spending	2020–21 Total authorities available for use	2020–21 Actual spending (authorities used)	2020–21 Difference (Actual spending minus Planned spending)
3,075,439	3,075,439	4,502,892	4,400,210	1,324,771

Human resources (full-time equivalents)

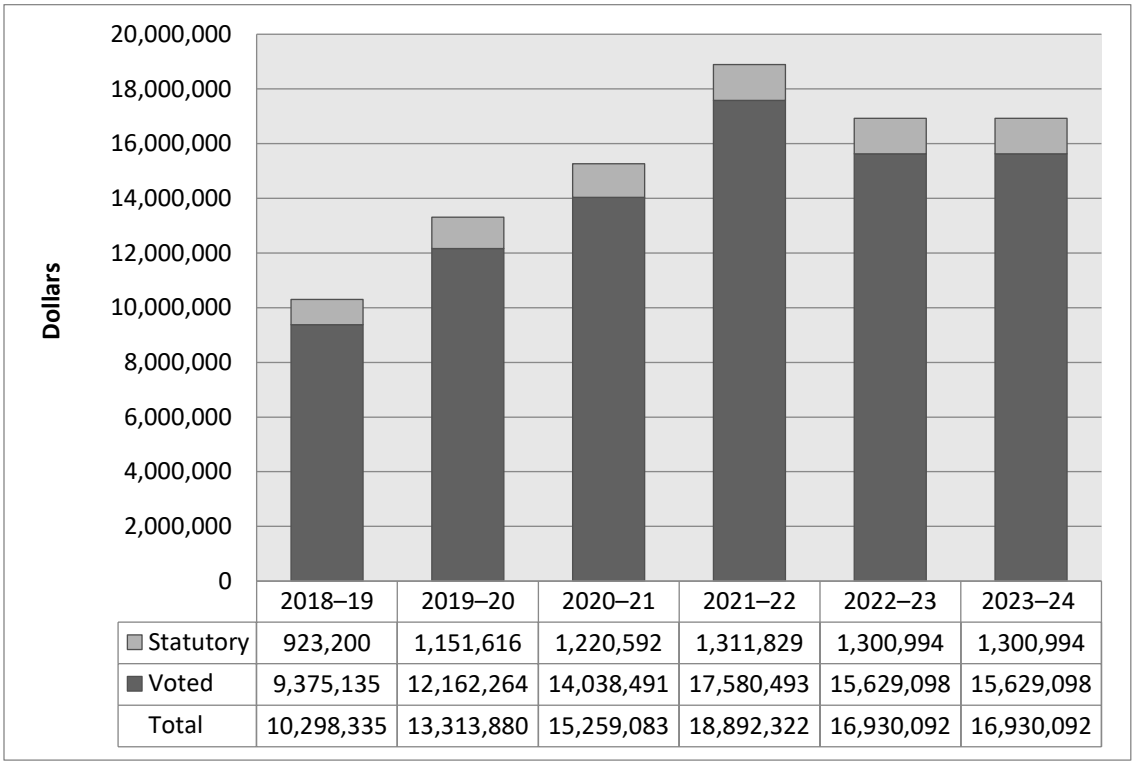
2020–21 Planned full-time equivalents	2020–21 Actual full-time equivalents	2020–21 Difference (Actual full-time equivalents minus Planned full-time equivalents)
22	23	1

Analysis of trends in spending and human resources

Actual expenditures

Departmental spending trend graph

The following graph presents planned (voted and statutory spending) over time.



	2018–19	2019–20	2020–21	2021–22	2022–23	2023–24
Statutory	923,200	1,151,616	1,220,592	1,311,829	1,300,994	1,300,994
Voted	9,375,135	12,162,264	14,038,491	17,580,493	15,629,098	15,629,098
Total	10,298,335	13,313,880	15,259,083	18,892,322	16,930,092	16,930,092

As announced in Budget 2017, 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 Employee Benefits Payments (EBP) and increased funding for the Special Purpose Allotment (SPA).

Voted spending in 2019-20 was higher than voted spending in 2018-19 due to increased funding received through Budget 2017, which was used to hire additional regulatory officers, health economists, data analysts, and legal counsel, as well as for work on the Workplace 2.0 fit-up and additional funding for the SPA. Voted spending in 2020-21 was higher than voted spending in 2019-20 largely due to hearing costs in the matter of the price of "Procysbi" by Horizon Therapeutics Canada, as well as the construction costs for the PMPRB's dedicated hearing facilities.

For purposes of forecasting Planned Spending for 2021-22 and future years, it is necessary to assume that the entire SPA funding for hearings will be spent 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 2021-22 is $6,206,486; for 2022-23 and beyond, the amount of the SPA is $4,463,361. This is the primary reason for declined planned spending in 2022-23.

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

Core responsibilities and Internal Services	2020–21 Main Estimates	2020–21 Planned spending	2021–22 Planned spending	2022–23 Planned spending	2020–21 Total authorities available for use	2018–19 Actual spending (authorities used)	2019–20 Actual spending (authorities used)	2020–21 Actual spending (authorities used)
Affordable patented medicine prices	14,728,961	14,728,961	15,805,187	13,857,783	13,888,037	9,336,597	7,343,076	10,858,873
Subtotal	**14,728,961**	**14,728,961**	**15,805,187**	**13,857,783**	**13,888,037**	**9,336,597**	**7,343,076**	**10,858,873**
Internal Services	3,075,439	3.075,439	3,087,135	3,072,309	4,502,892	2,955,259	3,977,283	4,400,210
Total	**17,804,400**	**17,804,400**	**18,892,322**	**16,930,092**	**18,390,929**	**10,298,335**	**13,313,880**	**15,259,083**

Planned spending in 2020-21 was higher than Actual spending largely due to a lapse of funding for the Special Purpose Allotment (SPA) to conduct Public Hearings. The SPA can only be used to cover the costs of public hearings, such as external legal counsel and expert witnesses, etc. For purposes of forecasting Planned Spending, it is necessary to assume that the entire SPA funding will be spent because these expenditures are dependent on the number of hearings, and the length and complexity of the hearings held, which are difficult to predict. In 2020-21, the SPA was $5,257,786 and the PMPRB only spent $2,482,717, a difference of $2,775,069. Any unspent amount is returned to the Consolidated Revenue Fund.

Planned spending in 2021-22 is higher than planned spending on 2020-21 because of increased funding received through Budget 2017. This additional funding will be reduced in 2022-23 and beyond by approximately $2M, which explains the decrease in planned spending for 2022-23.

Actual human resources

Human resources summary for core responsibilities and Internal Services

Core responsibilities and Internal Services	2018–19 Actual full-time equivalents	2019–20 Actual full-time equivalents	2020–21 Planned full-time equivalents	2020–21 Actual full-time equivalents	2021–22 Planned full-time equivalents	2022–23 Planned full-time equivalents
Affordable patented medicine prices	47	58	65	57	61	60
Subtotal	**47**	**58**	**65**	**57**	**61**	**60**
Internal Services	18	19	22	23	24	24
Total	**60**	**65**	**87**	**80**	**85**	**84**

The increase in planned FTEs for 2019-20 and beyond is a result of the additional funding received in the 2017 Budget and the need for additional staff and expertise to address the requirements of framework modernization. These additional resources will make the PMPRB a more relevant and effective price regulator, with more legal capacity to manage a greater number of hearings, more expertise in health economics, epidemiology and financial accounting and more modern and user-friendly IT infrastructure.

Actual FTEs in 2020-21 is lower than planned FTEs as a result of departures and staffing delays.

Expenditures by vote

For information on the PMPRB's organizational voted and statutory expenditures, consult the Public Accounts of Canada 2020–2021.[iv]

Government of Canada spending and activities

Information on the alignment of the PMPRB's spending with the Government of Canada's spending and activities is available in GC InfoBase.[v]

Financial statements and financial statements highlights

Financial statements

The PMPRB's financial statements[vi] (unaudited) for the year ended March 31, 2021, are available on the departmental website.

Financial statement highlights

Condensed Statement of Operations (unaudited) for the year ended March 31, 2021 (dollars)

Financial information	2020–21 Planned results	2020–21 Actual results	2019–20 Actual results	Difference (2020–21 Actual results minus 2020–21 Planned results)	Difference (2020–21 Actual results minus 2019–20 Actual results)
Total expenses	19,613,907	17,106,372	14,905,203	(2,507,535)	2,201,169
Total revenues	0	3,689	1,551	(3,689)	2,138
Net cost of operations before government funding and transfers	19,613,907	17,102,683	14,903,652	(2,511,224)	2,199,031

Condensed Statement of Financial Position (unaudited) as of March 31, 2021 (dollars)

Financial information	2020–21	2019–20	Difference (2020–21 minus 2019–20)
Total net liabilities	2,786,048	2,639,317	146,731
Total net financial assets	1,759,658	1,878,279	(118,621)
Departmental net debt	1,026,390	761,038	265,352
Total non-financial assets	93,060	144,385	(51,325)
Departmental net financial position	(933,330)	(616,653)	(316,677)

Corporate Information

Organizational profile

Appropriate minister[s]: The Honourable Jean-Yves Duclos

Institutional head: Dr. Mitchell Levine, Chairperson

Ministerial portfolio: Health

Enabling instrument[s]: *Patent Act*[vii] and *Patented Medicines Regulations*[viii]

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[ix].

For more information on the department's organizational mandate letter commitments, see the Minister's mandate letter[x].

Operating context

Information on the operating context is available on the PMPRB's website[xi].

Reporting framework

The PMPRB's Departmental Results Framework and Program Inventory of record for 2020–21 are shown below.

<table>
<tr><td rowspan="3">Departmental Results Framework</td><td colspan="2">Core Responsibility: Regulate Patented Medicine Prices</td><td rowspan="5">Internal Services</td></tr>
<tr><td rowspan="2">Departmental Result:
Affordable drug medicine 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 threshold 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>

Supporting information on the program inventory

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

Supplementary information tables

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

- Reporting on Green Procurement[xiii]
- Gender-based analysis plus[xiv]

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.[xv] 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 and GBA+ of tax expenditures.

Organizational contact information

The Patented Medicine Prices Review Board
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Suite 1400
Ottawa, Ontario K1P 1C1

Toll-free no.: 1-877-861-2350
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TTY: (613) 288-9654

Email: PMPRB.Information-Renseignements.CEPMB@pmprb-cepmb.gc.ca
Web address: https://www.canada.ca/en/patented-medicine-prices-review.html[xvi]

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 3-year period. Departmental Plans are usually tabled in Parliament each spring.

departmental priority *(priorité)*

A plan or project that a department 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.

departmental result *(résultat ministériel)*

A consequence or outcome that a department seeks to achieve. 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 quantitative measure of progress on a departmental result.

departmental results framework *(cadre ministériel des résultats)*

A framework that connects the department's core responsibilities to its departmental results and departmental result indicators.

Departmental Results Report *(rapport sur les résultats ministériels)*

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

experimentation *(expérimentation)*

The conducting of activities that seek to first explore, then test and compare the effects and impacts of policies and interventions in order to inform evidence-based decision-making, and improve outcomes for Canadians, by learning what works, for whom and in what circumstances.

Experimentation is related to, but distinct from innovation (the trying of new things), because it involves a rigorous comparison of results. For example, using a new website to communicate with Canadians can be an innovation; systematically testing the new website against existing outreach tools or an old website to see which one leads to more engagement, is experimentation.

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. For a particular position, the full-time equivalent figure is the ratio of number of hours the person actually works divided by the standard number of hours set out in the person's collective agreement.

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

An analytical process used to assess how diverse groups of women, men, and gender-diverse people experience policies, programs and services based on multiple factors including race ethnicity, religion, age, and mental or physical disability.

government-wide priorities *(priorités pangouvernementales)*

For the purpose of the 2019–20 Departmental Results Report, those high-level themes outlining the government's agenda in the 2019 Speech from the Throne, namely: Fighting climate change; Strengthening the Middle Class; Walking the road of reconciliation; Keeping Canadians safe and healthy; and Positioning Canada for success in an uncertain world.

horizontal initiative *(initiative horizontale)*

An initiative where two or more federal organizations 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 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 to the expected result.

planned spending *(dépenses prévues)*

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

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 the department's programs and describes how resources are organized to contribute to the department's core responsibilities and results.

result *(résultat)*

A 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.

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 Drug Identification Number (DIN) is assigned to each strength of each individual dosage form of each patented medicine at the time it is approved by Health Canada. A medicine name may have more than one DIN (DINs).

[ii] This amount does not include a payment of $75,844.49 received in 2020-21 for a VCU that was signed in January 2020 even though the payment was received in 2020-21 because it was reported in the 2019-20 amount. It does include an additional amount received in October 2020 for a VCU that was accepted in 2019 because this payment was not previously reported.

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

[iv] Public Accounts of Canada, http://www.tpsgc-pwgsc.gc.ca/recgen/cpc-pac/index-eng.html

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

[vi] The PMPRB's financial statements (unaudited) for the year endng March 31, 2021 are available at, https://www.canada.ca/en/patented-medicine-prices-review/corporate/transparency/departmental-results-report/2020-21-departmental-financial-statements.html

[vii] The *Patent Act*, https://laws-lois.justice.gc.ca/eng/acts/P-4/page-1.html

[viii] The *Patented Medicines Regulations* and amendments, https://laws-lois.justice.gc.ca/eng/regulations/SOR-94-688/nifnev.html

[ix] The PMPRB's raison d'être, mandate and role: who we are and what we do": http://www.pmprb-cepmb.gc.ca/about-us/mandate-and-jurisdiction/

[x] Minister of Health Mandate Letter: https://pm.gc.ca/en/mandate-letters/2019/12/13/minister-health-mandate-letter

[xi] Information on the operating context is available at, https://www.canada.ca/en/patented-medicine-prices-review/corporate/transparency/departmental-results-report/2020-21-operating-context.html

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

[xiii] Reporting on Green Procurement, https://www.canada.ca/en/patented-medicine-prices-review/corporate/transparency/departmental-results-report/reporting-green-procurement-2020-21.html

[xiv] Gender-based analysis plus, https://www.canada.ca/en/patented-medicine-prices-review/corporate/transparency/departmental-results-report/gender-based-analysis-2020-21.html

[xv] Report on Federal Tax Expenditures, https://www.canada.ca/en/department-finance/services/publications/federal-tax-expenditures.html

[xvi] PMPRB website, https://www.canada.ca/en/patented-medicine-prices-review.html