Patented Medicine Prices Review Board

2021–22

Departmental Plan

Patty Hajdu
Minister of Health

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Table of contents

From the Chairperson

I am pleased to present the 2021-22 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* (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.

The PMPRB has been on a reform track for the better part of five years. In that time, we have left no stone unturned in our efforts to modernize the organization and reaffirm its relevance. From our senior leadership, our relationships with partners and stakeholders, our office space and IT network, even our legal framework, nothing is as it was five years ago. Despite or perhaps because of all these changes, we've seen consistent, across the board improvement in all our public service survey results since 2014, and strikingly so in the areas of employee engagement, leadership and workplace well being. This is a testament to the character of the organization and bodes well for our future success in turbulent times.

With the recent issuance of our new pricing Guidelines and the coming into force of the amended *Patented Medicine Regulations* slated for July of this year, the PMPRB is eager to turn the page on this lengthy chapter of much needed change and rededicate itself to the vitally important work of protecting Canadian consumers from excessive prices in era marked by increasingly high cost 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 later this year 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 and will continue in the lead up to the coming into force date and beyond. 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.

The coming into force of the new framework does not mean that policy development will now take a backseat to our regulatory work, as this year will see the development and roll out of a comprehensive Guidelines Monitoring and Evaluation Plan (GMEP) to assess any changes in

relevant trends following implementation of the Guidelines and inform any future adjustments to ensure that they are working properly. As currently envisaged, the GMEP will consist of four key areas of focus: prices, access, ecosystem and PMPRB processes, each with multiple research objectives. Each area of focus will be monitored and evaluated by comparing trends prior to and post implementation of the new regulatory framework. During the consultation process on the Guidelines, multiple stakeholders expressed a desire to be involved in the development and implementation of the GMEP. Accordingly, we will be seeking input in due course from the stakeholder community on the scope and methods to be used in the GMEP.

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. This year and going forward we will work closely with our federal, provincial and territorial (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. Under our National Prescription Drug Utilization Information System (NPDUIS) reporting mandate, we will continue to provide analytical support and expertise to our health partners, as appropriate, 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 she has 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

Plans at a glance

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

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 July 1, 2021, and formalize the PMPRB's move to a more risk-based approach to ensuring that prices of patented medicines are not excessive. To ensure that the transition to the PMPRB's new regulatory framework is as seamless as possible, the PMPRB will:

- continue its outreach strategy so that patentees understand the content of the new Guidelines and the tools available to help them comply with them; and

- develop and implement a comprehensive Guidelines Monitoring and Evaluation Plan (GMEP) to assess changes in trends following implementation of the new pricing framework and inform any future adjustments to ensure the Guidelines are working as intended.

The implementation of the PMPRB's new Guidelines is the final step in a multi-year effort to give effect to the Government of Canada's commitment to make prescription drugs affordable and accessible for Canadians.

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

This priority reflects ongoing work to better align and integrate the roles, responsibilities and processes of the various participants in the pan-Canadian pharmaceutical pricing and reimbursement system with a view to improving the affordability, accessibility and appropriate prescribing of medicines in Canada. These efforts include analytical and policy work to support the establishment of foundational elements of national universal pharmacare, including the potential establishment of a Canadian drug agency, a national formulary and a rare disease drug strategy. To help achieve this priority, the PMPRB will:

- Work with Federal/Provincial/Territory (F/P/T) health partners to align and optimize our respective processes in the context of its new regulatory framework and other recent or ongoing reforms that impact pricing and reimbursement;

- Provide analytical support and expertise to F/P/T 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; and

- Focus reporting efforts on key areas for achieving greater savings for the Canadian health care systems in an era where very high cost medicines pose an increasing threat to sustainable growth.

In the course of carrying out its regulatory and reporting mandate, the PMPRB has developed considerable policy and analytical capacity and is frequently used as a resource to support broader efforts by the federal health portfolio and pan-Canadian partners to foster a modern and sustainable health system. At a time of unprecedented change in the Canadian pharmaceutical ecosystem, the PMPRB will continue 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 planned results, see the "Core responsibilities: planned results and resources, and key risks" section of this report.

Core responsibilities: planned results and resources, and key risks

This section contains detailed information on the department's planned results and resources for each of its core responsibilities. It also contains information on key risks related to achieving those results.

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

On October 23, 2020, the PMPRB published its new Guidelines. In July 2021, the amended *Patented Medicines Regulations* (the "Regulations") come into force. Together, these two instruments strengthen and modernize Canada's pricing framework for patented medicines so that the PMPRB can continue to fulfill its statutory mandate to protect Canadian consumers from excessive prices in an era where high-cost medicines account for a rapidly growing share of public and private spending on pharmaceuticals. These reforms have the potential to save Canadians billions of dollars over the next decade.

The Guidelines explain the steps that will typically be taken by staff at the PMPRB in assessing whether a patented medicine appears to be priced excessively in Canada. The Guidelines also explain how the information patent-holding pharmaceutical companies must provide to the PMPRB pursuant to the Regulations is used to enable that assessment. 2021 will be a challenging year from a regulatory administration standpoint in that data filings by patentees for the first six months of the year will be based on the old regulatory framework and filings for the second six months will be based on the new Guidelines and amended Regulations.

To ensure the PMPRB's new Guidelines are fair, functional and fit for their purpose, the PMPRB has committed to developing and implementing a comprehensive GMEP to assess changes in trends following implementation of the new Guidelines and inform future adjustments as necessary to ensure they are working as intended.

As currently envisaged, the GMEP will focus on four key trendlines:

1. **Changes in prices** - This will include both list and net prices, and their corresponding ceilings, as well as any changes in the prices of drugs not directly affected by the reforms.

2. **Changes in access** - This will consider the access continuum, from the development of medicines (clinical trials), to medicine approval and availability, Health Technology

Assessment (HTA), pan-Canadian Pharmaceutical Alliance (pCPA) negotiations and formulary listings.

3. **Changes in the ecosystem** - This will focus on research, development and economic footprint, drug spending, and the supply chain.

4. **Changes in PMPRB processes** - This will look at the operational aspects of the price assessment, scientific review of medicines, administrative burden in terms of compliance activities, and outreach activities (specifically the number of engagement activities the PMPRB is undertaking to assist patentees in understanding the Guidelines and their application).

Each area of focus will be monitored and evaluated by comparing trends prior to and post implementation of the PMPRB's new regulatory framework. Baseline results (benchmarks) will be generated for the trends under the Guidelines as they were up to and including 2020. Given that the new Guidelines will come into force mid-2021, starting in 2022, the trends under the new Guidelines will be monitored on an ongoing basis and compared against the established benchmarks.

The PMPRB's Compliance Information Management System ("CIMS") is a web-based database application used to assist the review and analysis of data filed by patentees. The PMPRB has made enhancements to CIMS so that it could accept and process the additional information patentees must provide under the new Regulations. In July 2021, when the PMPRB begins receiving data via the enhanced CIMS system it will monitor and evaluate how well the system is functioning and make any necessary adjustments.

Under the National Prescription Drug Utilization Information System (NPDUIS) reporting mandate, the PMPRB continues to provide decision makers with critical information and intelligence on price, utilization, and cost trends, so that Canada's healthcare system has more comprehensive and accurate information on how medicines are being used and on sources of cost pressures.

The PMPRB supports and strengthens its NPDUIS engagement activities by regularly consulting with the NPDUIS Advisory Committee, participating in conferences and seminars, and organizing information sessions with interested stakeholders to share the results of the analytical studies. In 2021-22, NPDUIS plans to publish the results of several analyses as annual publications, report series, and chartbooks.

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 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.

The PMPRB has not planned any experimentation. Over the past several years, the primary focus of the organization has been to reform and modernize its regulatory framework. To that end, it has conducted the most extensive and far reaching public consultations in its more than three decades long history. This process has been an all-hands-on deck effort. As the PMPRB switches gears from policy development of the new framework to its implementation, we will be experimenting, in a sense, with an entirely new legal regime. The PMPRB lacks the human or financial resources at this time to take on any additional experimental initiatives.

Key risks

The PMPRB has identified five potential risks to the achievement of results for its Core Responsibility. The first risk is that coming into force of the new Regulations will be further delayed because of the COVID-19 pandemic. The PMPRB has no control over the timing of coming into force as this is a decision of the Minister of Health and the Governor in Council. However, in the event of further delay the PMPRB will continue to conduct price reviews under the old Guidelines and Regulations to achieve the best possible result for Canadians. It will also continue to focus its enforcement resources on cases that are most relevant to consumers.

The second risk is that implementation of the new regulatory framework mid year may cause confusion for patentees about what data to file and how and when that data will be used for

ceiling price calculation and compliance purposes. To mitigate this risk, the PMPRB has implemented an outreach strategy so that patentees understand the new Guidelines and has developed tools to help them comply. In addition, under subsection 98(4) of the Act, the Board may provide advance guidance to a patentee on its price if there is enough information to do so.

The third risk is that the new regulatory framework may have unintended consequences on patient access to innovative new medicines or clinical trial activity in Canada. While the data does not support claims by opponents of the reforms that this is already happening, the PMPRB will implement a comprehensive plan for monitoring and evaluating their effect on price, access, research and development in Canada, and on the PMPRB's processes so that corrective action can be taken quickly if warranted. However, the expectation and intent is that the cost savings achieved by public and private drug plans as a consequence of these reforms will enable public and private drug plans to pay for new, innovative medicines that might otherwise not be affordable given current budget constraints.

The fourth risk is that voluntary compliance with the PMPRB's non-binding Guidelines may decline initially as patentees test the boundaries of the new regime. This may result in more investigations and potentially more hearings into the prices of patented medicines. Through Budget 2017, the PMPRB received additional funding which it has used to ensure it will have enough resources to implement the new framework and contend with any corresponding increase in contested pricing matters. The recently completed construction of the PMPRB's own dedicated hearing facilities will ensure that it has the capacity to accommodate multiple parallel hearings, if necessary.

The fifth and final risk is that legal challenges to the new Regulations and Guidelines brought by patentees will result in court decisions that affect some or all of the legislative changes. The PMPRB is working with the federal Attorney General to ensure that any such challenges are properly defended, and the risk of an adverse judgement(s) is mitigated.

Planned results for Regulate Patented Medicine Prices

Departmental result	Departmental result indicator	Target	Date to achieve target	2017–18 actual result	2018–19 actual result	2019–20 actual result
Affordable patented medicine prices	% of patented medicine prices in Canada are below the median of the PMPRB's comparator countries	50%[a]	March 31, 2022	56.4%	57.1%	56.9%[a]
	% of patented medicine prices in Canada within the thresholds set out in the Guidelines	95%[a]	March 31, 2022	91.0%	90.5%	85.9%[a]

[a] 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, primarily as a result of voluntary compliance with the non-binding Guidelines by patentees. 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 56.9% 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 1,348 patented medicines sold in Canada in 2019, only 778 were sold in five or more countries. Of this 778, only 365 patented medicines (47%) had a Canadian price below the median price. This is a significant difference from the reported 56.9%.

[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] As of March 31, 2020, 60 patented medicines were still under review, and 128 were under investigation, two were the subject of a hearing and one was subject to a Stay Order.

Financial, human resources and performance information for the PMPRB's program inventory is available in the GC InfoBase.[i]

Planned budgetary financial resources for Regulate Patented Medicine Prices

2021–22 budgetary spending (as indicated in Main Estimates)	2021–22 planned spending	2022–23 planned spending	2023–24 planned spending
15,805,187	15,805,187	13,857,783	13,847,783

Financial, human resources and performance information for the PMPRB's program inventory is available in the GC InfoBase.[ii]

Planned human resources for Regulate Patented Medicine Prices

2021–22 planned full-time equivalents	2022–23 planned full-time equivalents	2023–24 planned full-time equivalents
61	60	60

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

Internal Services: planned results

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

Planning highlights

The PMPRB will continue initiatives to make the PMPRB a employer of choice through improvements to its onboarding process like creating special forums for new recruits to engage with senior management, and enhancements to its wellness program, which is aimed at helping employees look after their mental and physical well-being.

Also, in 2021-22, the PMPRB will begin a review of its Departmental Results Framework (DRF). In particular, the PMPRB will examine the reasonableness and appropriateness of its performance indicators, modifying them if need be, to ensure they are the best indicators. The DRF is the structure against which departments report financial and non-financial performance information for estimates and parliamentary reporting. Since the PMPRB has undergone major changes to its regulatory framework, it is important that the DRF reflect this.

Planned budgetary financial resources for Internal Services

2021–22 budgetary spending (as indicated in Main Estimates)	2021–22 planned spending	2022–23 planned spending	2023–24 planned spending
3,087,135	3,087,135	3,072,309	3,072,309

Planned human resources for Internal Services

2021–22 planned full-time equivalents	2022–23 planned full-time equivalents	2023–24 planned full-time equivalents
24	24	24

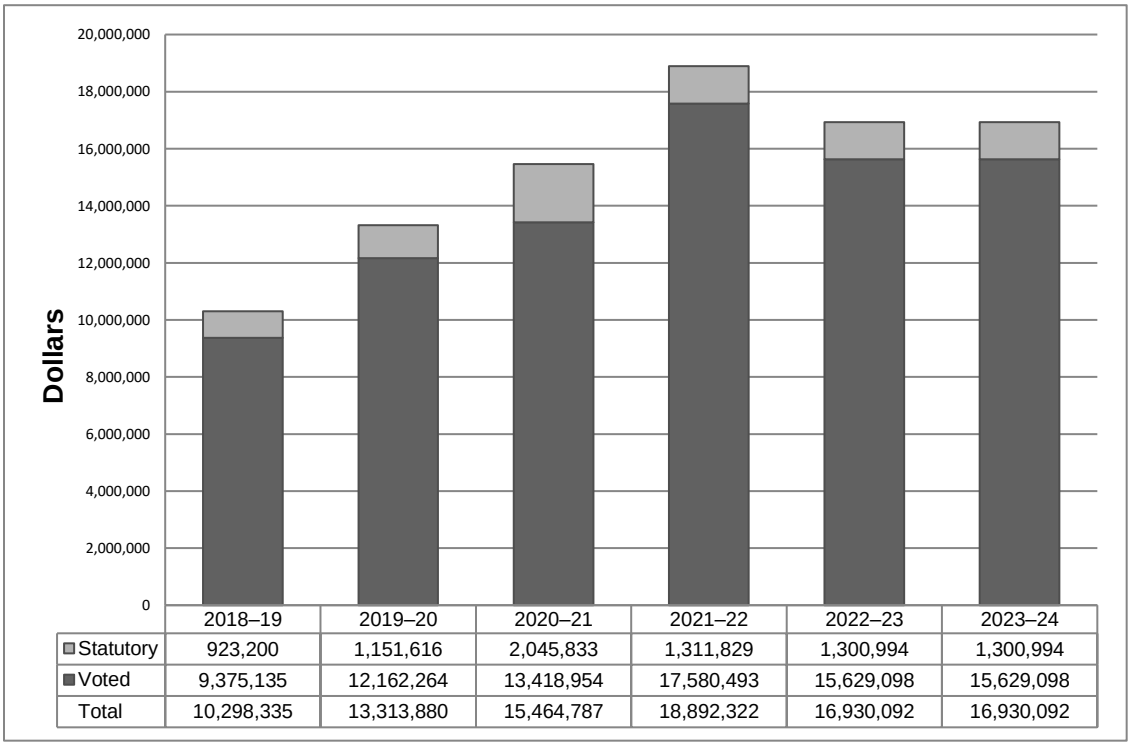
Spending and human resources

This section provides an overview of the department's planned spending and human resources for the next three consecutive fiscal years and compares planned spending for the upcoming year with the current and previous years' actual spending.

Planned spending

Departmental spending 2018–19 to 2023–24

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	2,045,833	1,311,829	1,300,994	1,300,994
Voted	9,375,135	12,162,264	13,418,954	17,580,493	15,629,098	15,629,098
Total	10,298,335	13,313,880	15,464,787	18,892,322	16,930,092	16,930,092

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 Special Purpose Allotment (SPA).

Forecasted spending for 2020-21 is significantly higher than actual spending in 2019-20 because of increased funding and hiring of new staff to prepare for implementation of the new Guidelines. Planned spending for 2021-22 increases significantly from 2020-21 due to continued funding increases related to the enforcement of the new regulatory framework. Planned spending in 2022-23 and beyond decreases because of a reduction in funding for the SPA.

Budgetary planning summary for core responsibilities and Internal Services (dollars)

The following table shows actual, forecast and planned spending for each of PMPRB's core responsibilities and to Internal Services for the years relevant to the current planning year.

Core responsibilities and Internal Services	2018–19 expenditures	2019–20 expenditures	2020–21 forecast spending	2021–22 budgetary spending (as indicated in Main Estimates)	2021–22 planned spending	2022–23 planned spending	2023–24 planned spending
Regulate Patented Medicine Prices	7,343,076	9,336,597	11,126,955	15,805,187	15,805,187	13,857,783	13,857,783
Subtotal	**7,343,076**	**9,336,597**	**11,126,955**	**15,805,187**	**15,805,187**	**13,857,783**	**13,857,783**
Internal Services	2,955,259	3,977,283	4,337,832	3,087,135	3,087,135	3,072,309	3,072,309
Total	**10,298,335**	**13,313,880**	**15,464,787**	**18,892,322**	**18,892,322**	**16,930,092**	**16,930,092**

The forecast spending for 2020-21 is based on actual spending and anticipated spending to year end, which does not anticipate full spending of the Special Purpose Allotment (SPA). At the time of preparing this report, forecasted spending of the SPA amounted to $1,527,224. This and an anticipated surplus in the salary and O&M spending account for the variance in 2020-21 forecast spending and 2021-22 planned spending.

For purposes of forecasting Planned Spending for 2021-22 and future years, the PMPRB assumes 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 2021-22 is $6,206,486; and, for 2022-23 and beyond the amount of the SPA is $4,463,361. The SPA amount was reduced because the new Guidelines were originally expected to come into force in January 2019, and it was anticipated that, by 2022-23, Staff and patentees would have a better understanding of the how to apply the new Guidelines and there would be fewer contested pricing matters.

Planned human resources

The following table shows actual, forecast and planned full-time equivalents (FTEs) for each core responsibility in PMPRB's departmental results framework and to Internal Services for the years relevant to the current planning year.

Human resources planning 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 forecast full-time equivalents	2021–22 planned full-time equivalents	2022–23 planned full-time equivalents	2023–24 planned full-time equivalents
Regulate Patented Medicine Prices	47	58	59	61	60	60
Subtotal	**47**	**58**	59	**61**	**60**	60
Internal Services	19	21	23	24	24	24
Total	**66**	**79**	82	**85**	**84**	84

The increase in actual FTEs in 2019-20 and forecasted and planned FTEs in 2020-21 and beyond is because of the additional funding provided in Budget 2017 and a need for additional staff and expertise to address the PMPRB's framework modernization and implementation.

Estimates by vote

Information on the PMPRB's organizational appropriations is available in the 2021–22 Main Estimates.[iv]

Future-oriented Condensed statement of operations

The future-oriented condensed statement of operations provides an overview of the PMPRB's operations for 2020–21 to 2021–22.

The amounts for forecast and planned results in this statement of operations were prepared on an accrual basis. The amounts for forecast and planned spending presented in other sections of the Departmental Plan were prepared on an expenditure basis. Amounts may therefore differ.

A more detailed future-oriented statement of operations and associated notes[v], 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, 2022 (dollars)

Financial information	2020–21 forecast results	2021–22 planned results	Difference (2021–22 planned results minus 2020–21 forecast results)
Total expenses	16,378,583	20,583,155	4,204,572
Total revenues	295	-	(295)
Net cost of operations before government funding and transfers	16,678,288	20,583,155	4,204,867

The PMPRB is projecting $20.6M in expenses based on 2021-22 Main Estimates and accrued information. This amount does not include future supplementary estimates. It represents an increase of $4.2M from 2020-21 projections, primarily attributable to a lapse in SPA funding for hearings. The PMPRB assumes 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 2021-22 planned expenses by core responsibility are as follows:

- Regulate Patented Medicine Prices $17.1M; and,
- Internal Services $3.5M.

PMPRB receives most of its funding through annual Parliamentary appropriations.

Corporate information

Organizational profile

Appropriate minister(s): The Honourable Patty Hajdu

Institutional head: Dr. Mitchell Levine, Chairperson

Ministerial portfolio: Health

Enabling instrument(s): *Patent Act*[vi] and *Patented Medicines Regulations*[vii]

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[viii].

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

Operating context

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

Reporting framework

The PMPRB's approved departmental results framework and program inventory for 2020–21 are as follows.

<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="2">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>

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.[xi]

Supplementary information tables

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

- Departmental Sustainable Development Strategy[xii]
- Gender-based analysis plus[xiii]

Federal tax expenditures

PMPRB's Departmental Plan does not include information on tax expenditures that relate to its planned results for 2021–22.

Tax expenditures are the responsibility of the Minister of Finance, and the Department of Finance Canada publishes cost estimates and projections for government-wide tax expenditures each year in the Report on Federal Tax Expenditures.[xiv] This report provides detailed information on tax expenditures, including objectives, historical background 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 solely the responsibility of the Minister of Finance.

Organizational contact information

Mailing address

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Web site: 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 a department over a 3-year period. Departmental Plans are tabled in Parliament each spring.

departmental priority (priorité ministérielle)

A plan or project that a department has chosen to focus and report on during the planning period. Departmental 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 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)

A framework that consists of the department's core responsibilities, 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 and what doesn't. Experimentation is related to, but distinct form 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. 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 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 2021–22 Departmental Plan, government-wide priorities refers to those high-level themes outlining the government's agenda in the 2020 Speech from the Throne, namely: Protecting Canadians from COVID-19; Helping Canadians through the pandemic; Building back better – a resiliency agenda for the middle class; The Canada we're fighting for.

horizontal initiative (initiative horizontale)
An initiative in which 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 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.

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.

strategic outcome (résultat stratégique)
A long-term and enduring benefit to Canadians that is linked to the organization's mandate, vision and core functions.

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

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

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

iv. 2019–20 Main Estimates, https://www.canada.ca/en/treasury-board-secretariat/services/planned-government-spending/government-expenditure-plan-main-estimates.html

v Future-oriented Financial Statements: https://www.canada.ca/en/patented-medicine-prices-review/corporate/transparency/departmental-plan/2021-22-future-oriented-statement-operations.html

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

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

viii PMPRB's Raison d'être: http://www.pmprb-cepmb.gc.ca/about-us/mandate-and-jurisdiction

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

x Information on the operating context is available on the PMPRB's website: https://www.canada.ca/en/patented-medicine-prices-review/corporate/transparency/departmental-plan/2021-22-operating-context.html

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

xii Departmental sustainable development strategy: https://www.canada.ca/en/patented-medicine-prices-review/corporate/transparency/departmental-plan/2021-22-departmental-sustainable-development-strategy.html

xiii Gender-based analysis plus: https://www.canada.ca/en/patented-medicine-prices-review/corporate/transparency/departmental-plan/2021-22-gender-based-analysis-plus.html

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