Patented Medicine Prices
Review Board

Scoping Paper
for the
Consultations
on the
Board's Guidelines

November 2023

Patented Medicine Prices Review Board Canada
Conseil d'examen du prix des médicaments brevetés Canada
Canada

Introduction

The Patented Medicine Prices Review Board (PMPRB), established by Parliament in 1987 under the *Patent Act* (the Act), is a quasi-judicial administrative agency with a dual price review and reporting mandate. Through its price review mandate, it ensures that the prices of patented medicines sold in Canada are not excessive.

The amendments to the *Patented Medicines Regulations* ("Regulations"), published in the Canada Gazette, Part II, came into force on July 1, 2022, and resulted in an updated schedule of eleven comparator countries ("PMPRB11")[1] and reduced reporting requirements for medicines believed to be at the lowest risk of excessive pricing. Changes to the PMPRB's Guidelines are now necessary to implement the regulatory amendments, and to give effect to the Board's commitment to modernize and simplify its administrative framework.

This Scoping Paper is intended to serve as a catalyst for a more informed, focused, and productive consultation process in developing new Guidelines by outlining themes and specific questions the PMPRB is seeking feedback on. This paper is for discussion purposes only, and it is not intended as a definitive articulation of the PMPRB's position on these issues.

[1] The countries listed in the Regulations include Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom.

Participation in the Consultation

The PMPRB is launching the first phase of consultations on its new Guidelines by inviting stakeholders to participate in a Policy Roundtable scheduled for December 5 (English session) and December 6 (French session). Both sessions will be held in person and virtually. The intent of these meetings is to foster a productive conversation, where all parties can voice their opinions and concerns regarding future Guidelines.

Activity	Key Dates
Policy Roundtable – English Session	December 5, 2023
Policy Roundtable – French Session	December 6, 2023
Deadline for registration to participate in the Roundtable	November 24, 2023
Deadline for Written Submissions	December 20, 2023
What we Heard Report	Early 2024

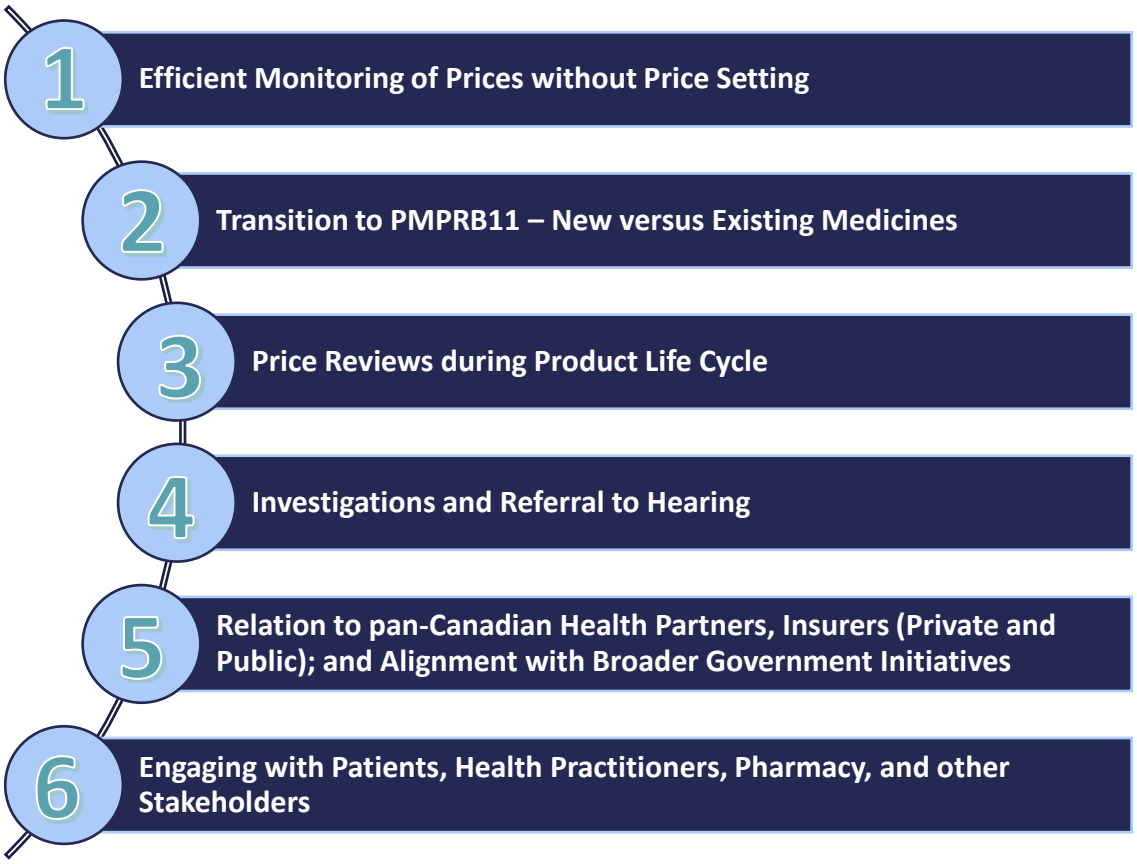
Interested parties are invited to make presentations to the PMPRB and/or submit written submissions on any of the questions raised in this Scoping Paper as well as on any other topics they consider to be relevant to the discussion.

Please complete the Policy Roundtable Registration Form to indicate your interest in participating in the Roundtable. While there are a limited number of available spots to register for in-person attendance, all interested persons can register to participate online. Also, please note that the number of available spots to give presentations is limited. Presenters will be chosen in a way that ensures contributions reflect a diversity of opinions.

Stakeholders can voice their opinions at the sessions as well as through written submissions by **December 20, 2023**. A What We Heard document will be released in early 2024.

Themes for Discussion

The PMPRB is interested in hearing stakeholders' views on the following themes to inform the development of final PMPRB Guidelines. Comments on other related issues are also welcome.



Theme 1: Efficient Monitoring of Prices without Price Setting

The purpose of the Guidelines is to explain the procedures used by staff at the PMPRB when monitoring the prices of patented medicines. In particular, the Guidelines explain the criteria staff will consider in determining whether the price of a patented medicine warrants a more in-depth review in the form of an investigation. As recently reiterated by the Courts, while the Board has the power to order that the price of a medicine be reduced to a non-excessive level following a public hearing, the Board does not set or mandate prices for patented medicines and Guidelines are not intended to be read as pricing guidelines. Board orders on excessive pricing can only be issued after a public hearing.

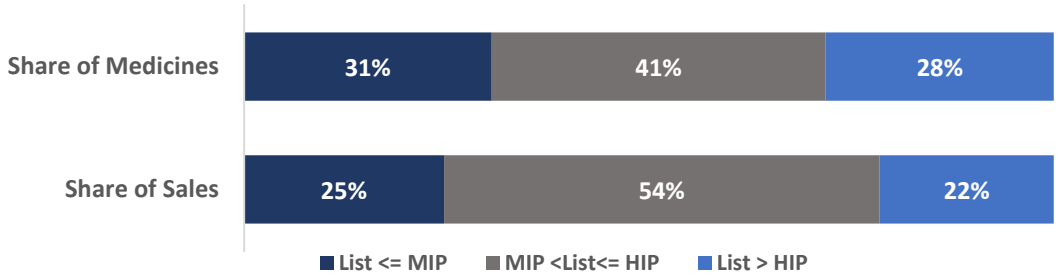
The PMPRB does not have the capacity nor the need to conduct hearings for each patented medicine under its jurisdiction. Therefore, the PMPRB seeks to develop an administrative review system that allows for the most efficient monitoring of cases of potential excessive pricing. The aim is to provide the transparent guidance sought by rights holders during this administrative review while clearly delineating the respective roles and responsibilities of the Board and staff. In particular, rights holders should be provided with sufficient information to allow them to evaluate their risk of being subject to a hearing by explaining how staff analyses price information and makes recommendations to the Chairperson regarding whether an investigation should be closed, closed subject to an undertaking, or lead to a Notice of Hearing.

Question 1.1:	What elements of the 2010 Guidelines should be retained? Which ones and why?
Question 1.2:	Should new Guidelines continue to categorize medicines by therapeutic class comparator characteristics such as the Level of Therapeutic Improvement?
Question 1.3:	Should the Board accord more weight to one or more of the factors set out in s. 85 of the Act in designing the Guidelines?

In accordance with s. 85(1)(c) of the *Patent Act*, the PMPRB evaluates and compares the pricing of patented medicines in Canada with other international markets. International price comparisons are often the simplest and earliest type of price review that the PMPRB can perform, since all of the relevant information is provided by rights holders in their semi-annual filings, and no additional external information (e.g., scientific reviews, public prices of other medicines) is needed.

Box 1: Canadian list prices of patented medicines within the PMPRB11.

- **28%** of all patented medicines had Canadian list prices higher than the highest international price (HIP) of the PMPRB11 in 2022, representing **22%** of the total sales.
- **69%** of all patented medicines had Canadian list prices higher than the median international price (MIP) of the PMPRB11 in 2022, representing **75%** of the total sales.



Note: Values may not add to totals due to rounding.

Source: PMPRB 2022 including all the patented medicines with both Canadian and PMPRB11 prices available (N=880 Drug Identification Numbers (DINs) representing 78% of total Canadian patented DINs and 93% of the total patented sales in 2022).

Question 1.4: If international prices are used as the initial triage measure for commencing investigations, what price levels within the PMPRB11 should be used as the triage measure? (e.g. HIP or MIP?)

Question 1.5: How should the PMPRB conduct an initial review and monitor the prices of patented medicines that have few or no international prices?

Question 1.6 Would an expedited price review (e.g., within 90 days after initial Form 2 submission) of a new medicine based solely on international prices being below the MIP accelerate introduction of innovative medicines?

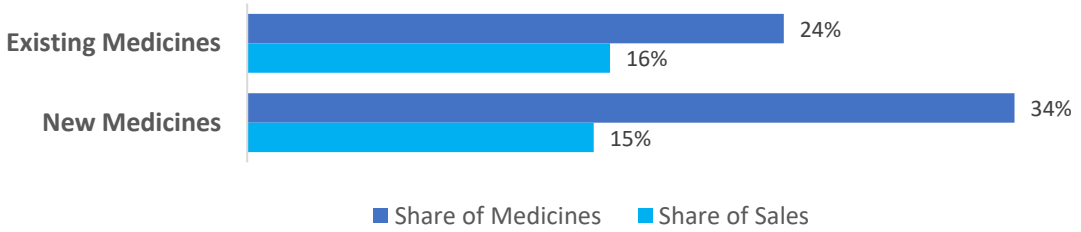
i. How soon after an expedited review should a full price review take place?

Theme 2: Transition to PMPRB11 – New versus Existing Medicines

In July of 2022, the Schedule of comparator countries in the Regulations changed from the PMPRB7 to the PMPRB11. The change did not include any grandfathering clauses; thus, all information has to be filed using the PMPRB11, regardless of the original date of introduction of the medicine.

Box 2: Respective shares of Existing medicines versus New medicines with their Canadian List Prices below or equal to the Median International Price (MIP) of the PMPRB11 in January to June 2023.

- **24%** of existing patented medicines had Canadian list prices below or equal to the MIP of the PMPRB11 in January to June 2023, representing **16%** of the total existing medicine sales.
- **34%** of new patented medicines had Canadian list prices below or equal to the MIP of the PMPRB11 in January to June 2023, representing **15%** of the total new medicine sales.



Note: Values may not add to totals due to rounding.

Source: PMPRB January to June 2023, including all the patented medicines with both Canadian and PMPRB11 prices available (N= 812 DINs, representing 78% of total Canadian patented DINs and 96% of the total patented sales in January to June 2023; out of these 812 DINs, 68 were New DINs and 744 were Existing DINs.).

Question 2.1:	Should the Guidelines distinguish between medicines that existed as of July 2022 (existing medicines) and medicines introduced afterwards (new medicines)?
Question 2.2:	What approach should the Board take with respect to existing medicines with prices above the HIP of the PMPRB11? Should the Board review these prices, and if so, how soon?

Theme 3: Price Reviews during Product Life Cycle

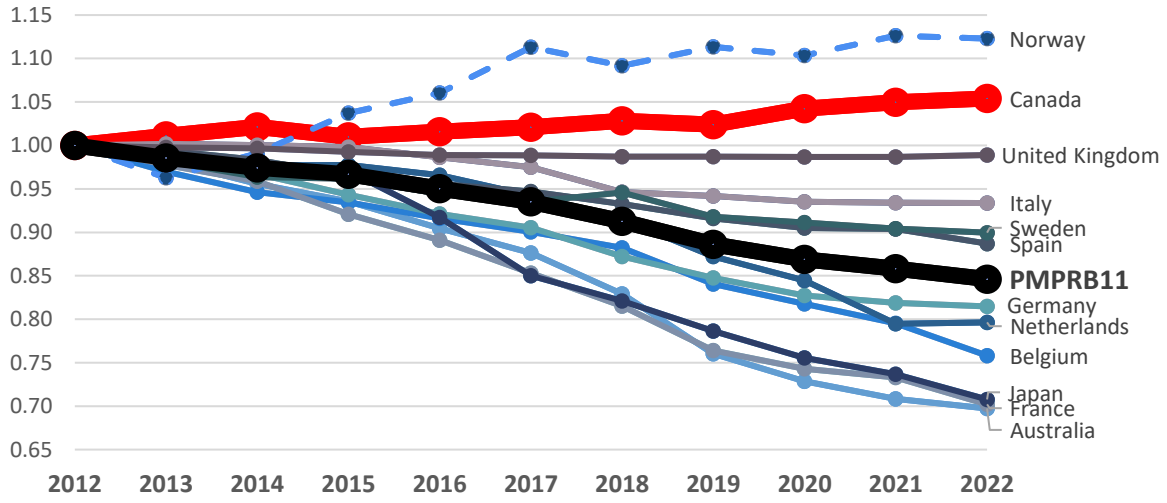
According to the *Patent Act*, the PMPRB's duty to monitor excessive pricing extends during the duration of the patent[2] or certificate of supplementary protection.

It is common in many countries for the list prices of medicines to decrease over time. Canadian list prices, on the other hand, tend to remain static or increase. The combination of these trends leads Canadian prices to increase relative to their foreign counterparts, towards the higher end of the PMPRB11 basket over time. As reported in the PMRPB Annual Report, in 2021, Canadian list prices of patented medicines were the third highest in the Organisation for Economic Co-operation and Development (OECD), behind only the US and Switzerland.

Box 3: Pricing trends in Canada versus the PMPRB11

Over the 2012 to 2022 period, list prices of patented medicines increased slightly by **5**% in Canada, while the prices decreased by **15**%, on average in the PMPRB11.

Patented Medicine Price Index, 2012-2022



Note: This price index measures the average year-over-year change in prices of patented medicines sold in Canada using a sales-weighted average of price changes at the level of individual medicines. This index is based on list price and sales information from the MIDAS® database.

Data source: PMPRB; MIDAS® database, 2012-2022, IQVIA (all rights reserved)

[2] Once the patent is granted, the PMPRB's jurisdiction over the price at which the medicine was sold extends to the pre-grant period, as the party selling the medicine derives the benefit of the patent during this period and so is a "patentee", pursuant to subsection 79(1) of the Act.

As the pharmaceutical landscape continues to evolve, it is important to consider how the Guidelines and its associated price reviews remain relevant at all stages of a medicine's life cycle. Finding a balance that allows for ongoing monitoring without undue administrative burden while maintaining predictability is essential.

Question 3.1: How often should price reviews be conducted? (1-5 years).

i. Should they be different for small molecules (average 10-year exclusivity period) versus biologics (average 20+ year exclusivity period)? Should they be different for medicines for rare diseases?

Question 3.2: What criteria besides time should be used to trigger a price review?

i. Approval of a significant new indication?

ii. Significant change to the therapeutic class comparators? Availability of new/stronger evidence related to benefit vis-à-vis therapeutic class comparators?

iii. Departure from identified pricing thresholds?

Question 3.3: Should the relative weighting given to different section 85 (*Patent Act*) factors change over the lifecycle of a medicine?

Question 3.4: How should the PMPRB treat the allowable Consumer Price Index increase in the context where international list prices are decreasing?

Question 3.5: What is the ideal timing for scientific review and therapeutic comparator identification? At what price review stage(s) should scientific review be applied?

Theme 4: Investigations and Referral to Hearing

Investigations are an administrative process that consists of an in-depth review of the information provided by the rights holders and any relevant information obtained from other sources. The purpose of these administrative investigations is to prioritize cases that may be brought to the attention of the Chairperson and could potentially lead to a hearing. Staff will recommend to the Chairperson that a hearing be commenced, or to close the investigation. The Chairperson makes the final decision to send a case to a hearing.

The Board previously used a combination of Guidelines price ceilings along with additional criteria to determine whether an investigation should be opened. The publication of these criteria in the Guidelines improved transparency and provided rights holders with greater certainty as to their risk of being considered for a hearing. For example, investigations were only triggered where prices exceeded the Guidelines ceiling by a set percentage, where potential excess revenues were above a set amount, or where complaints were received.

As previously mentioned, the PMPRB does not have the capacity to conduct hearings for each patented medicine under its jurisdiction. As a result, the PMPRB has historically relied on voluntary action by rights holders by providing them an opportunity to take remedial action (e.g., voluntary price reductions and repayment of potential excess revenues) that could result in the closure of an investigation instead of being sent to a hearing.

Since 1993, over $210 million has been collected through Voluntary Undertakings (VCUs), settlements, and Board Orders through payments to the Government of Canada.

- → 162 VCUs have been accepted.
- → 31 notices of hearing have been issued, 14 of which were resolved through settlements prior to the hearing on the merits and 17 of which were subject to a full public hearing on the merits (10 related to allegations of excessive pricing and 7 related to allegations of failure to file).

Box 4: Patented medicines for human use sold in 2012 to 2021 – Status of price review as of March 31 in the following reported year.

- Over the past decade, the vast majority of patented medicines were within Guidelines thresholds.
- Over the last 5 years, on average, approximately 11% of patented medicines reported to the PMPRB were subject to investigation (2017-2021). During this period, on average, only 0.9% of patented medicines were brought before a Hearing.

	2012	2013	2014	2015	2016[1]	2017	2018	2019	2020	2021
Total	1328	1343	1363	1359	1435	1391	1403	1364	1289	1177
Within Guidelines Thresholds	1090	1098	1038	960	901	950	968	948	892	783
Under Review	7	2	34	30	66	25	51	60	54	43
Does Not Trigger Investigation	139	164	227	265	267	239	232	205	169	165
Under Investigation	59	66	61	93	101	122	128	128	166	169
VCU	31	13	2	10	60	54	21	19	5	12
Hearing	2	0	1	1	1	1	2	2	2	4
Subject to Price Reduction Order (Stayed)	-	-	-	-	-	-	1	1	1	1

[1] The compliance status was not reported for 39 DINs as of 2016.

Source: Annual Report 2012- 2021.

Question 4.1:	Are the criteria published in the 2010 Guidelines for commencing an investigation still appropriate (assuming adjustment to PMPRB11)?
Question 4.2:	How much detail should the Guidelines set out regarding what happens once an investigation is opened?
Question 4.3:	Should the PMPRB continue to use Undertakings as an investigation closure mechanism?

Theme 5: Relation to pan-Canadian Health Partners, Insurers (Private and Public); and Alignment with Broader Government Initiatives

The PMPRB strives to align with and complement the priorities and objectives of other health partners in the Canadian pharmaceutical landscape including broader healthcare and innovation objectives.

The PMPRB's role is part of a larger complex system that governs how medicines are approved, regulated, and distributed to Canadians across the country. The development of new guidelines presents an opportunity for the PMPRB to reduce the uncertainty of the path to market for innovators, and to coordinate with and offer better support to existing regulatory and pricing bodies, as well as support initiatives of federal, provincial, and territorial activities within the pharmaceutical sector.

Question 5.1:	What efficiencies could be gained by co-ordinating decisions and timelines of the PMPRB with those of the Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et services sociaux (INESSS) and pan-Canadian Pharmaceutical Alliance (pCPA) or insurers (public and private)?
Question 5.2:	How can the PMPRB optimize its presence within the Canadian bio/pharmaceutical ecosystem to support a whole of government approach to issues relating to patented medicines?

Theme 6: Engaging with Patients, Health Practitioners, Pharmacy, and other Stakeholders

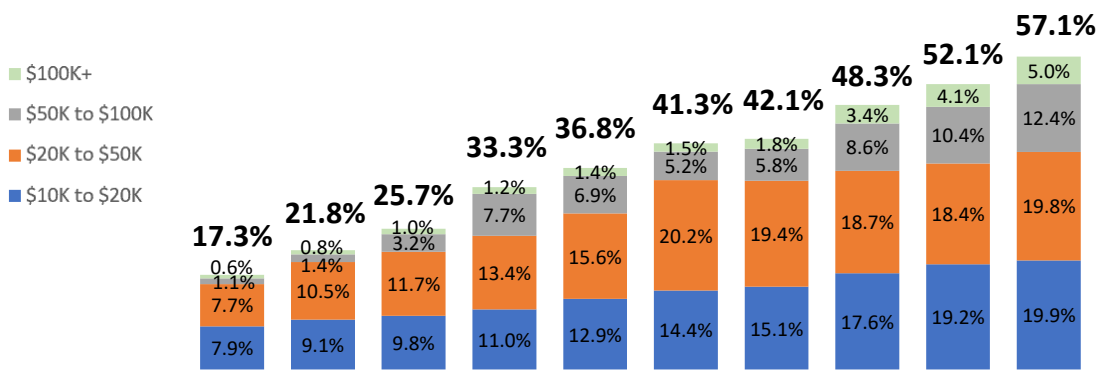
The objective is to seek feedback from stakeholders who are not rights holders.

The PMPRB acknowledges the importance of soliciting input from a range of non-industry and non-institutional stakeholders who represent diverse voices in the broader consumer community that is affected by the PMPRB. This discussion is essential for gaining insight into public perspectives on patented medicines and their pricing, especially in the context of rare diseases and evolving clinical evidence.

Box 5: High-cost medicines dominate the pharmaceutical landscape.

- High-cost medicines represent an increasing share of the total sales of patented medicines, rising from 17.3% in 2012 to 57.1% in 2021.
- Despite accounting for over half of all sales in 2021, less than 1% of the population use these medicines.

Share of Sales for High-Cost Patented Medicines by Annual Treatment Cost, 2012 to 2021



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Total no. of medicines	92	105	116	129	143	150	162	172	189	201
Estimated treatment population (thousands)	136.9	167.2	186.9	222.4	254.1	284.8	285.8	331.3	349.8	370.3
Share of total Cdn population	0.39%	0.48%	0.53%	0.62%	0.70%	0.77%	0.78%	0.88%	0.92%	0.97%

Note: The methodology for this analysis was revised in 2018, and as such, historical results may not match those reported in earlier editions.

Source: Modified from Figure 10 of the 2021 Annual Report. PMPRB; IQVIA Private Pay Direct Drug Plan database, 2012–2021

Question 6.1:	What is your experience with innovative medicines and their list prices in Canada?
Question 6.2:	What role do the PMPRB Guidelines play in your decision-making process in Canada and globally (if applicable)?
Question 6.3:	Canada and the world are facing a generation of new high-priced drugs for the treatment of rare diseases. i. Should the PMPRB view the question of whether the prices of these medicines are "excessive" through a different lens than other types of medicines? ii. What quality of evidence should the Board consider when conducting its scientific review of these medicines?
Question 6.4:	How can the PMPRB better engage with you?

Conclusion and Follow-Up

The PMPRB thanks all parties for their interest and engagement with this Policy Roundtable.

It is our ambition to finalize new Guidelines during 2024, again following an appropriate consultation process.