‘What We Learned’ Report

Patented Medicine Prices Review Board

Policy Roundtable held December 5th and 6th, 2023, in Ottawa

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1. Introduction

Phoenix Strategic Perspectives Inc. (Phoenix SPI) was commissioned by the Patented Medicine Prices Review Board (PMPRB) to facilitate a consultation with stakeholders, a Policy Roundtable, and to write a report on the presentations and discussions. This report presents a summary of what was learned from the Policy Roundtable.

1.1 Background

The PMPRB is a quasi-judicial administrative agency with a dual price review and reporting mandate. Through its price review mandate, the PMBRB ensures that the prices of patented medicines sold in Canada are not excessive. Changes to the PMPRB's Guidelines are now necessary to implement regulatory amendments, and to give effect to the Board's commitment to modernize and simplify its administrative framework.

On November 10, 2023, the PMPRB released the Scoping Paper[1] for the consultations on the Board's Guidelines which outlines themes and questions to inform the upcoming industry consultation on the development of new Guidelines. Interested stakeholders were invited to participate in a Policy Roundtable and/or prepare submissions in response to the themes and questions raised.

The Policy Roundtable was held December 5th and 6th, 2023, in Ottawa. Stakeholders from across the country participated in the two-day (in person and virtual) consultation hosted by the PMPRB. While in-person attendance was limited, all interested stakeholders were able to register to participate online. The purpose of the consultation was to engage stakeholders in a face-to-face session to explore themes important and relevant to the development of a new set of PMPRB Guidelines. Participating stakeholders included representatives from Rights Holders and Industry Associations, patient groups, pharmacies and distributors, civil society, academia, and a research funding organization, as well as a health practitioner and an individual.

In addition to the Policy Roundtable sessions, stakeholders were also invited to submit written submissions on any of the questions raised in the Scoping Paper as well as on any other topics they considered to be relevant to the discussion. The closing date for submissions was December 20th, 2023.

[1] The scoping paper may be accessed at: Scoping paper for the consultations on the Board's Guidelines - Canada.ca or Document d'orientation aux fins de consultation sur les Lignes directrices - Canada.ca.

The PMPRB received 70 written submissions from a range of stakeholders. Most submissions were put forth by Rights Holders and Industry Associations (n=36, 51%), followed by patient advocacy groups (n=15, 21%) and pharmacy and distributors (n=7, 10%). The remaining submissions (n=12) were from civil society / unions (n=2), a private payer (n=2), pan-Canadian health agencies which includes the federal and provincial/territorial governments, Canadian Agency for Drugs and Technologies in Health (CADTH) and the pan-Canadian Pharmaceutical Alliance (pCPA) (n=4), a provider/physician (n=1), an academic / policy researcher (n=1), and two individuals (n=2). The submissions can be found at the following links: English and French.

The report does not include any analysis on the written submissions; the PMPRB will be reviewing these separately.

1.2 The consultation

The event was structured as a roundtable and designed to allow stakeholders to voice opinions and concerns regarding the Guidelines and the consultation process. Parties interested in taking part in the event were invited to complete and submit a registration form by November 24th, 2023. In advance of the event, the PMPRB circulated a Scoping Paper outlining themes and specific questions on which the PMPRB was seeking feedback.

The sessions were held in-person and virtually. Presentations could focus on any of the questions raised in the Scoping Paper as well as on any other topics considered to be relevant to the discussion. One session was conducted in English and one in French. The English session took place on December 5th and continued during the second part of the morning session and during the afternoon session on December 6th. The French session took place during the first part of the morning session on December 6th.

All parties who wished to make a presentation were given the opportunity to do so. In total, 34 stakeholder presentations were made over the course of the two-day consultation. Presenters represented a diverse group of stakeholders.

Stakeholder Group	Number of Presentations
Rights holder, Industry, Industry Association	15
Patient, Patient Advocacy	5
Distributor, Pharmacy, Pharmacy Association	5
Civil Society, Union	3
Academia	3
Health Practitioner	1
Individual	1
Research funding organization	1
Total	**34**

The time allotted for each presentation, including questions and comments from members of the PMPRB, was 15 minutes.

2. What was learned

Over the course of the two-day consultation, stakeholders discussed a range of issues, expressed a variety of opinions, and made numerous recommendations, both general and specific, related to themes and questions considered relevant and important to a discussion about Guidelines and the consultation process. Issues, opinions, and recommendations identified by stakeholders routinely dealt with the following topics:

- The PMPRB mandate
- Assessing excessive pricing
- Considerations for PMPRB Guidelines
- Understanding the life sciences ecosystem
- Alignment of PMPRB Guidelines with broader government initiatives
- Stakeholder engagement

What was learned from stakeholder input regarding each of these topics is presented below.

2.1 The PMPRB mandate

In identifying and discussing topics or issues considered important and relevant, stakeholders often referred to the PMPRB's statutory mandate. While the PMPRB has a dual mandate[2], the focus was usually on its regulatory role. The Board's mandate to protect against misuse of market exclusivity through excessive pricing was routinely noted, with stakeholders emphasizing that PMPRB deliberations and Guidelines should be aligned with this mandate. Two apprehensions were voiced by stakeholders in relation to the PMPRB carrying out its regulatory mandate: the PMPRB exceeding the scope of its mandate, and the PMPRB falling short of its mandate.

Stakeholders who focused on the PMPRB exceeding its mandate emphasized that the PMPRB mandate is narrow and specific. Consequently, the Board would be exceeding its mandate by engaging in consumer protection, price setting, price regulation, price control, or any activity with the purpose of lowering drug prices. Such activities were described as beyond the jurisdiction of the PMPRB because pricing control and regulations fall under the constitutional

[2] The PMPRB has a dual mandate: in its regulatory role, it protects consumers by ensuring that the prices of patented medicines are not excessive; in its reporting role, it provides information on pricing trends in the pharmaceutical industry via its Annual Reports.

authority of provincial and territorial governments.[3] On the other hand, there were expressions of concern from stakeholders about the PMPRB not doing enough to limit or control the price of drugs in Canada. By not taking steps to ensure the prices of patented medicines are not excessive, these stakeholders said the PMPRB would be falling short of its mandate.

2.2 Excessive pricing

Highest international price or median international price

There was agreement that the PMPRB's mandate is to protect against excessive pricing, but there were differences of opinion about how to interpret 'excessive'. In particular, there were different points of view concerning the threshold for reviewing prices. Using international pricing as their point of reference, specifically the 11 comparator countries[4] identified in the amendments to the *Patented Medicines Regulations* (*Regulations*), stakeholders were divided about which price should constitute the basic reference point, or triage measure, for price reviews: the highest international price or the median international price.

Advocacy for using the highest international price as the initial triage measure was based on the perception that it is the reference point most consistent with the PMPRB's mandate. From this standpoint, prices equivalent to, or lower than, the prices of comparative countries in the *Regulations* should be deemed compliant and not be subject to pricing review. Stakeholders cautioned the PMPRB about using the median international price as a reference point because this goes beyond the regulation of excessive pricing and into price setting, which exceeds the Board's mandate.

Advocacy for using the median international price as the initial triage measure was based on the view that international trends within the 11 comparative countries should be used to determine excessive pricing. If international prices are trending downward and Canadian prices are stable or increasing, then Canadian prices could be considered excessive relative to international prices. From this perspective, drugs in Canada with prices above the median international price could be subject to price reviews.

In addition to the question of what price level should be used as the initial triage measure, stakeholders routinely commented on two other pricing-related issues: the distinction

[3] As exercised, for example, through pCPA and the Institut national d'excellence en santé et services sociaux (INESSS) in Quebec.

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

between 'new' and 'existing' medicines and the categorization of drugs by therapeutic level of improvement.

New vs. existing medicines

Stakeholders held differing views on whether PMPRB Guidelines should distinguish between medicines that existed as of July 2022 (existing medicines) and medicines introduced after this date (new medicines). The basic consideration is whether products should be assessed based on the pricing regime under which they were launched. Both positions would have potential implications for pricing. If this distinction was accepted, prices of existing patented medicines deemed to be non-excessive under the previous pricing regime could continue to be accepted as compliant under any subsequent regime. If the distinction was not accepted, existing medicines could be subject to pricing reviews based on the new regime.

Therapeutic level of improvement

Among stakeholders who raised the issue of categorizing drugs according to therapeutic improvement, there was general agreement that this practice should continue, with the implication being that the price of drugs could be increased *or* decreased based on their level of improvement. Stakeholders emphasized that such assessments should be made by independent agencies, and that any price adjustments consider the nature and degree of improvement.

2.3 Considerations for PMPRB Guidelines

Certain expressions were used repeatedly by stakeholders to identify features considered to be of fundamental importance to any future PMPRB Guidelines. These included 'predictability', 'stability', 'clarity', 'transparency', and 'consistency'. They tended to be used to convey the message that what is needed in terms of compliance expectations and requirements is as much certainty as is reasonably possible over the entire lifecycle of patented products. Stakeholders considered certainty important to help achieve the following:

- Make Canada an attractive place for companies in the life sciences industry to invest, build a presence and undertake research and development.
- Create an environment that will allow the Canadian health care system to be an early beneficiary of new medical innovations and product launches.
- Support better business planning by pharmacies which will facilitate their ability to provide a stable access of products to patients.

The fundamental importance stakeholders assigned to ensuring a reasonable degree of certainty informed advocacy for the two pricing recommendations identified above, one related to new medications and the other related to existing medications.

- The recommendation to use the highest international price as the reference price for new medications included the argument that it is clear, easy to apply, and provides a predictable maximum non-excessive price over the lifecycle of a patented product. By contrast there are significant predictability concerns about using the median international price given that, in the context of a basket that consists of 11 countries, the median can fluctuate greatly over the lifecycle of a patented product.
- The recommendation that existing patented medicines should continue to be accepted as compliant included the argument that patentees and other supply chain stakeholders made investment decisions and/or executed business plans under the previous Guidelines regime. To subject them to the new pricing regime could be destabilizing, e.g. jeopardize existing product listing agreements (PLAs), and disrupt access to and/or availability of medications.

2.4 The life sciences ecosystem

The life sciences environment in Canada was often described by stakeholders as an ecosystem characterized by a multiplicity of constituents and a complex regulatory framework that includes different levels of government and different agencies, each with their respective roles, responsibilities, and mandates. As with any ecosystem, what happens in any part of it can affect the whole.

Stakeholders noted that the PMPRB needs to understand and consider the potential impacts and repercussions of its Guidelines throughout the life sciences ecosystem because unintended consequences can reverberate both 'upstream' and 'downstream' in this ecosystem. The main message from stakeholders was that PMPRB Guidelines and decisions can affect the life sciences ecosystem in Canada both positively and negatively, particularly in relation to the following:

- Development of the life sciences sector, e.g., investment, innovation, clinical trials, research and development, commercialization of products, and product launches.
- Service to consumers and patient care including the security of drug supply chains.
- Access to, and the availability of, existing and new drugs.

Considering the impact of PMPRB Guidelines and decisions also includes looking at their impact on the lives of Canadians. In assessing these impacts, stakeholders emphasized both affordability and availability as important considerations. The focus on affordability drew

attention to the high cost of medications in Canada and the real-life consequences that follow from this. The focus on availability also highlighted real-life consequences, with stakeholders noting that timely access to new medicines has life changing consequences and reduces health care costs. Stakeholders contended that both issues should be taken into consideration because a singular focus on one can have unintended and potentially adverse effects on the other.

2.5 Alignment with broader government initiatives

Aligning PMPRB Guidelines with broader government of Canada initiatives and priorities with the goal of nurturing and supporting a vibrant and sustainable life sciences and biomanufacturing sector was explicitly endorsed by some stakeholders. This included alignment with the government of Canada's *Biomanufacturing and Life Sciences Strategy*, *National Strategy for Drugs for Rare Diseases*, and the national pharmacare strategy.

At the same time, a cautionary approach was recommended when considering the alignment of PMPRB Guidelines with broader government of Canada initiatives and priorities. Stakeholders suggested that in probing relations between the PMPRB and pan-Canadian health agencies, particularly related to coordinating decisions and timelines with other actors in the Canadian pharmaceutical landscape, the board should be mindful that such considerations might take it beyond its mandate. In this regard, it was also noted that the regulatory landscape is complicated and that the mandates of various agencies are separate and distinct.[5] Consequently, the view of stakeholders was that the PMPRB should carry out its specific mandate irrespective of other agencies but that it should be attuned to what other agencies are doing and recognize that efficiencies can be made in this regard.

2.6 Stakeholder engagement

Going forward, meaningful stakeholder engagement is considered essential. Stakeholders advised that such engagement includes soliciting input *from* them, consulting and collaborating *with* them, and making information and resources available *to* them. Engagement comprises a broad range of activities that includes recognizing and taking advantage of stakeholder knowledge and expertise, providing meaningful access to such knowledge and expertise, understanding what stakeholder organizations do and how they operate, and engaging with members of groups represented by organizations via appropriate communication channels to gain insight into their lived experience.

[5] For example, pricing is the purview of pCPA and therapeutic referencing is the purview of CADTH and *INESSS*.

Concrete examples of meaningful engagement offered by stakeholders included:

- Creating working or advisory groups that consider both technical expertise and lived experience.
- Conducting impact analyses and case studies, making them available, and meeting with stakeholders to discuss them.
- Monitoring performance of the PMPRB in meeting stakeholder needs.
- Engaging in effective knowledge translation and mobilization by providing information and resources that are appropriate and meaningful, in clear language and accessible formats.
- Auditing for discriminatory ideas and practices in the functioning and/or assumptions of the PMPRB.

While meaningful engagement with stakeholders is considered essential, stakeholders also emphasized that the PMPRB must maintain its independence, be mindful of its mandate, and be vigilant in avoiding any possibility of conflict of interest, as this could adversely affect its credibility.