Submission to Patented Medicine Prices Review Board (PMPRB) regarding Guideline Monitoring & Evaluation Plan (GMEP) 2021

June 21, 2021

On behalf of the signatories to this submission, we present the analysis and Recommendation for the Guideline Monitoring & Evaluation Plan (GMEP) 2021 proposed by PMPRB in June 2021.

1. Foundational Principles Regulating PMPRB

1.1. Legal Obligations of the PMPRB

The PMPRB is a quasi-judicial agency of the federal government created under *the Patent Act.*[1] It reports in through Health Canada for purposes of the drug pricing Regulations while other parts of the *Act* report in through the Minister of Innovation, Science and Economic Development. It is responsible to determine whether the price being proposed for the sale of a drug or other treatment in Canada is excessive. If the price is deemed to be excessive based on the criteria set out in the Regulations to the *Patent Act*, the manufacturer must lower the price to meet these criteria or will not be permitted to sell the product in Canada.

Quasi-judicial bodies including Agencies, Boards, and Tribunals, make decisions on behalf of the government, when it is impractical or inappropriate for the government to do so itself. They must behave impartially in their decision-making process.[2]

Quasi-judicial bodies are under a duty to act in accordance with the rules of natural justice, giving persons specially affected by the decision a reasonable opportunity of presenting their case, listening fairly to both sides and reaching a decision untainted by bias.[3] They also have the right to engage specific expertise to assist in providing needed advice and input.[2]

The rules of natural justice apply to all decision makers and those advising them, *e.g.,* the Board of Directors, the staff of PMPRB and any advisors on whom they rely.

Since these bodies are created to move tasks, in whole or in part, out of the traditional parliamentary and Cabinet processes, the agency itself should opt for public involvement in the decision-making process.[4]

1.2. Government Policy Obligations of the PMPRB

In conducting its role as the decision maker regarding excessive drug pricing in Canada, the PMPRB reports in through Health Canada. Public engagement activities by the PMPRB should therefore align with the principles outlined in the Health Canada (HC) and the Public Health Agency of Canada (PHAC) Guidelines on Public Engagement, published November 2019.[5]

These Guidelines recognize the importance of public engagement as an important part of the democratic process and allows Health Canada and the Public Health Agency of Canada to fulfill key responsibilities, including the following:

- "Foster information exchange and knowledge sharing to improve the understanding of health issues and build relationships among interested and affected parties"[5]
- "Facilitate discussions between HC and PHAC and individuals, groups and organizations, external to the Government of Canada, to provide opportunities to shape government policies, programs, services and regulatory initiatives" [5]

- "Consider the feedback and perspectives of individuals and groups in the development or assessment of government policies, programs, services and regulatory initiatives in order to inform decisions"[5]
- "Enable informed decision-making that ultimately fulfills the mandates of HC and PHAC and improves the health and safety of Canadians"[5]

The Guidelines define public engagement as planned two-way discussions with individuals, organizations, or groups, external to the Government of Canada, designed to gather input, clarify information and foster understanding among those interested and affected by an issue, decision or action and to better inform HC and PHAC's decision-making. Public engagement activities should include key stakeholders directly impacted, namely patients and patient groups, Indigenous Peoples and groups, caregivers, people with disabilities and health care providers.[5]

The Guidelines are based on the following fundamental principles of meaningful public engagement:

- **Openness and Inclusiveness**
    - Designed and promoted to provide opportunity to all interested participants to provide input.
    - Engagement activities available through variety of formats to remove barriers to participation.
- **Timeliness and Transparency**
    - Purpose, scope and objectives are clearly communicated and planned.
    - Provide sufficient time for interested stakeholders to participate.
- **Relevance and Responsiveness**
    - Engagement activities are participant-focussed.
    - Materials designed to facilitate engagement activities and to meet engagement objectives.

It is important to note that "public engagement" has a broader meaning than "consultation," reflecting a wider variety of interactions and outcomes ranging from informing the public to engaging in dialogue. It can consist of one or more activities depending on the complexity of the issue, the potential impact, and the diversity of impacted stakeholders. The greater the potential impact on affected and interested participants, the higher the level of engagement and reporting back should be. Additionally, highly technical issues of narrow relevance require a focused and detailed public engagement approach at the dialogue level, while issues potentially impacting a broad range of stakeholders with diverging points of interest requires larger engagement activities to inform, listen and discuss.[5] Examples of public engagement approaches are presented in **Table 1**.

Table 1. Common Approaches to Public Engagement. Adapted from Health Canada and the Public Health Agency of Canada Guidelines for Public Engagement, 2019.[5]

Approach	Description	Benefits	Challenges
In-person discussion sessions	• Participants attend a group session involving presentations and/or discussions.	• Opportunity for open dialogue among participants and decision-makers. • Effective for gathering input on preliminary options or ideas.	• More costly and time-consuming than alternatives. • Subject to availability of participants at a specific time and location
Online interactive platform	• Participants join an online discussion forum to discuss issues and share their views with others.	• Opportunity to gain perspectives from participants from regional or remote areas at their convenience. • Flexible approach which can be designed and adapted based on objectives and adjusted throughout the engagement.	• Time consuming to design, implement, moderate, and monitor. • Requires planning and resources to summarize and analyze feedback.
Online questionnaire	• Opportunity to participate is posted online or emailed to targeted participants with a link to the questionnaire. • Participants complete the questionnaire and submit it directly online.	• Opportunity to gain perspectives from participants from regional or remote areas at their convenience. • Flexible approach which can be designed and adapted based on objectives.	• Time consuming to design, deliver and monitor. • Participants cannot benefit from hearing the different perspectives of others. • Requires planning and resources to summarize and analyze feedback collected.
Request for feedback	• A draft document or proposal is posted online or emailed to target audience and participants are asked to provide general feedback by email.	• Cost-effective way to receive detailed, meaningful feedback on drafts or proposals. • Specific information can be obtained in a controlled manner.	• Participants cannot benefit from hearing the different perspectives of others. • Requires planning and resources to summarize and analyze feedback

When an appropriate public engagement activity is chosen and designed, the initiative can be launched, and the process and outcomes of the engagement initiative should be evaluated to determine its success and allow for continuous improvement.

2. The Guideline Monitoring & Evaluation Plan (GMEP)

2.1. Implications of the Nature and Scope of GMEP

The PMPRB proposes to do an analysis in 4 key areas, the first 3 of which are drug pricing, access to treatments and the pharmaceutical ecosystem.

These are extremely complex health economic areas. They also hold the highest significance for people living in Canada. There is no greater potential impact on affected and interested participants than government decisions impacting access to live saving and quality of life enhancing medications. As such, the highest level of public engagement is warranted. In addition, technical advisors must display a history of unbiased, evidence-based analysis in this area.

The PMPRB has recognized this to some extent by indicating that it will identify relevant indicators to monitor **in consultation with its stakeholders**.

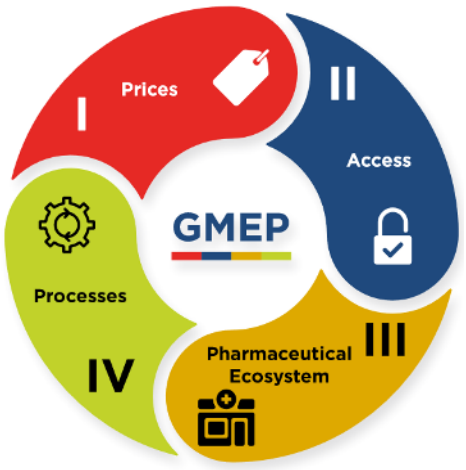

Figure 1. Diagram of the 4 key areas of the PMPRB Guideline Monitoring & Evaluation Plan. Copied from PMPRB GMEP 2021 consultation document.[1]

The indicators that the PMPRB proposes to monitor and assess in the Prices, Access and Pharmaceutical Ecosystem areas require interpretation in the context of the health policy environment in Canada and internationally. The PMPRB does not have such expertise in-house. In fact, much of this information is only available through specific stakeholders who can help with the collection, analysis and interpretation of key indicators.

The causal links between PMPRB Guidelines and Prices, Access and Pharmaceutical Ecosystem indicators, including clinical trial intensity, availability of new medicines, system coordination, drug spending, research and development and economic footprint, are of immense complexity. Therefore, the monitoring and evaluation committee must include expertise from diverse stakeholder groups that can provide context on the forces that are driving changes in those indicators based on an understanding of the entire healthcare environment and its dynamic nature.

We submit that by the quasi-judicial nature of the PMPRB, the duty to hold the highest level of public engagement in its proceedings, and its unilateral decision to select technical advisors without any stakeholder consultation clearly demonstrate the need for a GMEP that is transparent, evidence-based and impartial, and with multistakeholder membership.

While the technical advisors selected may well have expertise in this area, the public pronouncements of some members violate the duty of impartiality required by the PMPRB.* Thus, a full review of this decision must be undertaken and a transparent selection process, including opportunity for stakeholder engagement must be implemented. Patient group stakeholders and no doubt other stakeholders as well will be more than willing to offer suggestions about experts that have a history of unbiased technical expertise for your consideration.

Recommendation

Health Canada should exercise its responsibility to evaluate the PMPRB's policies, processes and plans to ensure PMPRB compliance with its legal and government policy obligations in the area of drug pricing, as set out above. A public report back should be made available by Health Canada on its findings.

In alignment with the principle of continuous improvement, Health Canada should direct PMPRB to make appropriate modifications based on the findings from the evaluation.

This process should be undertaken by Health Canada whenever the PMPRB is making changes to its Guidelines and other planning processes.

3. Conclusions

Based on the analysis of the legal and government policy obligations of the PMPRB in relation to public engagement and the conduct of its mandate, the GMEP must be entirely re-designed in accordance with recommendation above.

4. Signatories

Kathleen Barnard, Founder and President, Save Your Skin Foundation

Martine Elias, Executive Director, Myeloma Canada

CONECTed, a network of national patient oncology organizations

Filomena Servidio-Italiano, President and CEO, Colorectal Cancer Resource & Action Network

Jackie Herman, President, Canadian Neuroendocrine Tumour Society (CNETS)

MJ DeCoteau, Founder and Executive Director, Rethink Breast Cancer

*It is clear from the public stances expressed by a number of the technical advisors that they have inherent biases with regard to particular stakeholder groups, namely patients, patient representatives and pharmaceutical industry.

John-Peter Bradford, Chief Executive Officer, Life-Saving Therapies Network (LSTN)

Cheryl-Anne Simoneau, B.A. (Phil. & Soc.), Founder and Board Member, The Chronic Myelogenous Leukemia (CML) Society of Canada

Stephanie Michaud, President and CEO, BioCanRx

Antonella Scali, Executive Director, Canadian Psoriasis Network (CPN)

5. References

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