



HEALTH COALITION OF ALBERTA

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Patented Medicine Prices Review Board
333 Laurier Ave. West, Suite 1400
Ottawa, Ont. K1P 1C1
Email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

RE: PMPRB Guidelines Consultation Input

To Whom it May Concern:

Thank you for the opportunity to provide feedback on the six topics for discussion as outlined in the *Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines* document released earlier this year. The Health Coalition of Alberta (HCA) has reviewed this document and attended the stakeholder webinar last month. We will use learnings from these sessions to respond to the latest discussion guide.

Who We Are:

The Health Coalition of Alberta is an alliance of more than 120 health charities, patient groups, non-profit organizations and individuals driven by a unified purpose. Through the strength of our membership, we have voice and influence into public health decisions that impact the health of Albertans. We use a collaborative, solution-focused approach to engage with governments, health policy decision-makers and other stakeholders to achieve our goals.

The Health Coalition of Alberta advocates for the adoption of a relational model of care that is centered on patient needs to achieve their full health potential. We support shared decision-making between the health care team and educated and informed patients in order to make choices that will have the most impact on not only the health but also the emotional and social needs of each individual.

We achieve our purpose by: advocating on key health care issues; educating our members and the public so they can engage effectively with the health care system; and, by raising awareness and stimulating dialogue around health care policy and service changes that impact Albertans.

Patient Engagement:

The HCA has encouraged the PMPRB to adopt a process that is transparent, clear, evidence-based and engages patients. We appreciate the new focus on patient engagement that has been demonstrated in recent months. We participated in inaugural consultative discussion group with the Chairman of the PMPRB Board in the spring and look forward to continuing the discussion about patient priorities, how to co-create an effective patient advisory committee and how to ensure patient perspectives are embedded into the work of PMPRB.

It is our firm belief that a successful approach to providing affordable and accessible medications to Canadians can only be achieved through collaborative efforts with all stakeholders as equal partners. Recognizing and incorporating patients' lived experiences is essential for making ethical decisions and assessing the impact on care in Canada. These perspectives must be central to any decisions made by the PMPRB.

To ensure that impactful decisions are made with the highest level of engagement, the Health Coalition of Alberta recommends the following:

1. **Entrenchment of Patient Perspectives:** We advocate for the formal entrenchment of patient perspectives within the PMPRB. This includes the equal representation of patient members on the Board of Directors to ensure that Canadian values are reflected in PMPRB's objectives.
2. **Formalization of the Patient Advisory Panel:** We recommend the formalization of the proposed Patient Advisory Panel, ensuring it is co-created with patients. This panel should have the authority to assess PMPRB projects, investigations, or decisions through a societal lens.
3. **Learning from Existing Frameworks:** We encourage the PMPRB to explore and adopt best practices from established patient engagement frameworks both in Canada and internationally. Examples include Canada's Drug Agency's patient engagement framework and the guidelines from the International Association for Public Participation. Additionally, the Health Coalition of Alberta has developed its own patient engagement guide and would be pleased to share this with the PMPRB.

We believe that these steps will significantly enhance the PMPRB's ability to integrate patient perspectives effectively and make well-rounded decisions that reflect the needs and values of Canadians.

Topic Feedback:

The HCA appreciates the clear messages about the role of the PMPRB, the process used to determine excessive pricing, the role of Board vs. staff and answers to past questions in the newest discussion guide. Of particular importance is the statement identifying the two main objectives for the Guidelines: "a) enhance the Board's administrative efficiency, and b) provide transparency and predictability to Rights Holders regarding the process typically engaged in by

PMPRB staff (“Staff”) in identifying patented medicine that may be at a greater risk for excessive pricing for an in-depth review or a potential hearing”.

Unfortunately, we are not convinced these Guidelines will achieve either objective. We are once again asking for evidence that demonstrates this is the best approach to ensure that the prices of patented medicines sold in Canada are not excessive and price assessments are being conducted fairly, transparently, consistently, and, without any detrimental impact on the health of Canadians first. We also recommended that PMPRB monitors the process and conducts a thorough assessment to gauge both the financial savings achieved as well as determine its impact on Canadians’ ability to access new medications and improved health outcomes.

We also want to highlight that the questions in the discussion guide seem to be primarily designed for manufacturers rather than patients. The high level of specificity and depth related to pricing limit the ability of patients and their representatives to provide meaningful feedback. It is our recommendation that the PMPRB host a patient-specific event to gather further societal perspectives if there are gaps left from this submission process.

However, we will provide some specific feedback on applicable topics listed below:

Topic 1: We agree with previous comments that support using the highest international price among the PMPRB11 countries as the benchmark for determining excessive pricing. These countries were chosen by the PMPRB as appropriate comparators, and their prices should be used to set the threshold for excessive pricing. Before considering any expansion of the definition of excessive pricing, we recommend that the PMPRB first focus on reducing the current rate of “32% of all patented medicines having Canadian list prices higher than the highest international price (HIP) of the PMPRB11 in 2023” to zero.

Topic 2: We would like to see evidence that including existing medications into this process will not trigger unintended consequences or create health inequities in Canada.

Topic 3: We are unclear about the impact of both the proposed annual reviews and the increases based on CPI criteria. We request evidence demonstrating that both mechanisms are necessary to prevent excessive pricing.

Topic 4: To ensure fairness in the process, we recommend Option 1: restricting complaints to the Federal Minister of Health or their Provincial or Territorial counterparts. This approach allows all stakeholders, including patients, to raise concerns with their respective Ministers of Health, fostering a more inclusive and equitable environment.

Topic 5: At first glance, these options appear to raise equity concerns. However, a deeper explanation is needed to understand the rationale behind the Board's potential exemptions for biosimilars and/or vaccines.

Topic 6 and Topic 7: We suggest that the PMPRB does not duplicate scientific and evidence reviews that are already conducted by other agencies within the pharmaceutical landscape. A

more efficient process could be to utilize reviews conducted by Health Canada, Canada's Drug Agency and others to answer these questions. We do believe that for Topic 6, Option 2: each comparator will be assigned a level of similarity, is a method to account for incremental improvement that frequently occurs in the development of new medications. However, this may be a prime example of how agencies can leverage combined expertise and streamline review processes to produce guidance that will also ensure consistency when identifying comparator medications, etc.

In conclusion, we appreciate the opportunity to provide input on the PMPRB's Guidelines Consultation. The Health Coalition of Alberta values the ongoing efforts to enhance transparency, efficiency, and patient engagement in the pricing process for patented medicines. Our feedback reflects our commitment to ensuring that the guidelines effectively address excessive pricing while considering the diverse perspectives and needs of patients. We believe that by incorporating patient perspectives, avoiding duplication of existing reviews, and carefully evaluating the impact of proposed changes, the PMPRB can achieve its objectives of administrative efficiency and transparency. We look forward to continued collaboration to ensure that the final guidelines align with the best interests of Canadians and foster a fair and effective pricing system.

Thank you for considering our recommendations. If you have any questions about this submission, please contact the Health Coalition of Alberta at director@healthcoalitionab.ca

Sincerely,

A handwritten signature in black ink that reads "B. Kidd". The signature is written in a cursive, slightly slanted style.

Beth Kidd
Executive Director