

BEST MEDICINES COALITION

COALITION POUR DE MEILLEURS MÉDICAMENTS

Input on the Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines



September 11, 2024

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Introduction

The Best Medicines Coalition (BMC), a national alliance of 30 patient organizations, welcomes the opportunity to provide input to the Patented Medicine Prices Review Board (PMPRB) regarding the *Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines*, and thanks the Board for its consideration.

As its mission, the BMC seeks timely access to a comprehensive range of medically necessary, safe, and effective drugs and other treatments, informed by patient-driven evidence and values, and delivered equitably and affordably to all patients in Canada. The following standing goals drive the BMC's advocacy and inform its positions:

- Effective models for meaningful, proactive and impactful patient engagement in health and pharmaceutical policy development, recommendations and decision making, where patients and patient organizations are recognized as legitimate and integral contributors and patient-informed evidence is valued and incorporated.
- Drug programs which deliver higher standards of equitable and consistent access to a comprehensive range of safe, effective and affordable medicines for all patients in a timely manner.
- Streamlined, transparent and accountable health policy and regulatory frameworks which uphold patient-driven principles, invest in both incremental and breakthrough advancements, provide improved pathways to timely access to all medically necessary medications, protect patient safety and ensure ongoing secure drug supply.

The BMC has been an active participant in consultations on pharmaceutical pricing regulation reform since modernization efforts were initiated by Health Canada in 2016. The BMC has provided input on the following: the development of new Guidelines in December 2023; the Draft Guidelines consultation in December 2022; the proposed Guideline revisions related to Gap medicines, comparator countries and international price tests in August 2021; the proposed Guideline Monitoring and Evaluation Plan in June 2021; the draft Guidelines in August and February 2020; the proposed reforms in February 2018 and June 2017; Health Canada's PMPRB Guidelines Modernization Discussion Paper in October 2016; and two separate studies conducted by the House of Commons Standing Committee on Health.

The positions expressed in this submission, as in all previous submissions, were developed with the participation of BMC member organizations and all statements and positions expressed reflect areas of consensus.

Core Positions on Drug Pricing Regulations

The BMC takes this opportunity to reiterate core positions regarding drug pricing regulations, as follows:

- BMC supports the goal of improving the affordability of medicines, both for individual patients, health care systems and public and private insurance. Patients and their families, and those who pay on their behalf, bear the burden of excessive prescription medicine costs with significant impact, and we support efforts to address this, particularly in relation to appropriate international comparators.

- Of equal importance, patients need timely access to new medicines which address unmet or inadequately met needs. There must be confidence, based on best available evidence, that regulatory frameworks and guidelines will facilitate and not discourage or deter rapid introduction of a comprehensive range of medicines and vaccines as well as clinical trials which provide willing patients early access to promising new therapies.

BMC has supported a balanced and nuanced approach regarding drug pricing regulations. Specifically, BMC has called for the application of the new basket of comparator countries immediately but urged the government to not pursue controversial elements of the proposed regulatory package. In April 2022, the government announced it would proceed with implementing the new basket of comparator countries, but in light of court judgements not with regulations related to the new factors on prices or with certain filing requirements, and these changes were welcomed by the BMC.

Considerations regarding the Discussion Guide:

The BMC stands by its ongoing core positions, summarized above and expressed in submissions on previous related consultations. Regarding the **Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines**, the BMC offers input on the four themes below, followed by discussion points:

- ***Supporting accessible engagement.***
- ***Impact assessment to enable evaluation.***
- ***Inclusive approaches to pricing complaints.***
- ***Certainty regarding availability and access.***

Discussion points:

Supporting accessible engagement

We challenge the PMPRB to understand, recognize and embrace the value and contribution that patients and the organizations that represent them can provide to the PMPRB as it develops and refines guiding principles, policies and processes. We believe that the patient voice has a rightful place in informing the direction of the PMPRB about patent medicines and thus is incumbent on the PMPRB to ensure that patients and the organizations that represent them can effectively participate and contribute.

We note that in the Discussion Guide, under section, *4. Valued Insights: Addressing Important Topics Beyond PMPRB's Decision-Making Authority*, the following is stated regarding patient engagement:

Unfortunately, despite the compelling personal stories shared with the Board by numerous patient advocates, direct involvement in PMPRB decision making around individual medicines is neither supported by s.85(1), nor is it feasible given the confidential nature of communications between Rights Holders and Board Staff.

While this position may be warranted, it overlooks a multitude of additional avenues the PMPRB has at its disposal to improve engagement with the patient community, and we ask that the PMPRB give this careful consideration.

The BMC recognizes the measures that the PMPRB has taken recently to engage with the patient community, including the patient group round table held in early 2024, and the prospect of similar ongoing forums is welcomed.

Broadly, the BMC seeks information from the PMPRB on its strategy to engage the patient community. Specifically, we seek answers to the following questions: how will patients share views and insights on an ongoing basis? How will the patient community be informed about decisions? What will be the ongoing point of contact for the patient community at the PMPRB?

We urge the PMPRB to consider a progressive and meaningful approach to embedding a diverse range of voices in policy setting and direction, including perspectives of equity-deserving populations, the patient community and others. Regarding patient perspectives, examples of how to do this include patient representation on the Board itself and designating a patient officer or patient ombudsman. The BMC is available to assist in the development of strategies and proposals, as are other patient organizations.

There are various ways the PMPRB can improve engagement from an educational, knowledge transfer standpoint. For example, educational webinars designed for and with the patient community, improving the web site user experience for laypeople, and utilizing a knowledge translation specialist with experience in the patient space are all options worthy of consideration, we submit.

Impact assessment to enable evaluation.

As part of its process in drafting and consulting on new Guidelines, we urge the PMPRB to provide information about intended outcomes and to conduct and publish preliminary impact assessments so that all elements can be evaluated meaningfully. Impact assessments must be made publicly available in a timely fashion and presented in plain language which is accessible.

Currently, we find it extremely challenging to grasp the ramifications of each option presented in the Discussion Guide without an impact assessment of what can be expected to result from each option. Without detailed expected outcomes for each option, evaluations cannot be evidence based.

The patient community wishes to understand desired outcomes and seeks reassurance that outcomes will be achieved. Broadly, the BMC seeks impact assessments which would address whether patients in Canada will continue to have access to best-available medicines in line with comparable countries, along with other important measures.

Inclusive approaches to pricing complaints.

In the interests of inclusivity and accountability, the BMC supports the notion that there are no limits or restrictions (Option 4) on which individuals or organizations can lodge a complaint about an excessive price, including patients, patient groups or any other interested party.

The BMC supports the notation of treating all parties equally to ensure the broadest range of complaints. A potential high volume of complaints should be accommodated with appropriate processes put in place, followed by assessment and revisions to the framework and guidelines as necessary.

Certainty regarding availability and access.

Every effort must be made by the PMPRB to ensure that the application of regulations do not lead to pricing fluctuations which may impact predictability, availability and access. Just as patients value and need timely access to new medications, they also rely on a secure ongoing supply of currently used medications. Interruptions in availability and access, such as because of a temporary drug shortage, an ongoing supply challenge or a discontinuation, have negative implications for patient care and outcomes. The BMC does not support the application of new pricing frameworks retroactively on existing medicines reviewed prior to July 2022, the period before the application of the new Guidelines. We reiterate the need for impact assessments before this idea to increase the scope of PMPRB oversight is implemented.

Conclusion

Thank you for the opportunity to participate in this consultation. The BMC looks forward to working with the PMPRB to develop an approach that meaningfully and appropriately engages the patient community, one that acknowledges our goals and motivation to serve and represent patients and values our expertise. Likewise, we urge you to conduct rigorous impact assessments on any proposed options and to present and adopt measures which serve principles of availability, inclusivity and accountability, such as accepting complaints from all without limits or restrictions and applying Guidelines only on new medications.



About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of 30 patient organizations. The BMC seeks timely access to a comprehensive range of medically necessary, safe, and effective drugs and related treatments, informed by patient-driven evidence and values, and delivered equitably and affordably to all patients in Canada. The BMC's areas of interest include drug approval, assessment, and reimbursement, as well as patient safety and supply issues. As an important aspect of its work, the BMC strives to ensure that Canadian patients have a voice and are meaningful participants in health policy development, specifically regarding pharmaceutical care. The BMC's core activities include issue education, consensus-based position development, and advocacy, making certain that patient-driven positions are communicated to decision makers and other stakeholders. The BMC was formed in 2002 as a grassroots alliance of patient advocates. In 2012, the BMC was registered under the federal Not-for-profit Corporations Act and operates under the direction of a Board of Directors comprised of representatives of member organizations and elected annually.



Alliance for Access to Psychiatric Medications
 Asthma Canada
 Brain Tumour Foundation of Canada
 Canadian Arthritis Patient Alliance
 Canadian Breast Cancer Network
 Canadian Cancer Survivor Network
 Canadian Council of the Blind
 Canadian Cystic Fibrosis Treatment Society
 Canadian Epilepsy Alliance
 Canadian Hemophilia Society
 Canadian PKU & Allied Disorders
 Canadian Skin Patient Alliance
 Canadian Spondyloarthritis Association
 CanCertainty
 Crohn's and Colitis Canada

Cystic Fibrosis Canada
 Eczema Society of Canada
 Fighting Blindness Canada
 Health Coalition of Alberta
 Huntington Society of Canada
 Kidney Cancer Canada
 Lymphoma Canada
 Medical Cannabis Canada
 Medicines Access Coalition – BC
 Migraine Canada
 Millions Missing Canada
 Ovarian Cancer Canada
 Parkinson Canada
 Psoriasis Canada
 the cancer collaborative