



March 18, 2025

Input on Patented Medicine Prices Review Board Draft Guidelines

Introduction:

The Best Medicines Coalition (BMC), a national alliance of 32 patient organizations, welcomes the opportunity to provide input to the Patented Medicine Prices Review Board (PMPRB) regarding the ***Draft Guidelines for PMPRB Staff*** issued for consultation in December 2024.

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 actively participated in pricing regulation reform deliberations since modernization efforts began in 2016, providing the following input: Guideline discussion guide, September 2024; new Guideline development, December 2023; Draft Guidelines, December 2022; Guidelines on gap medicines, comparator countries and international price tests, August 2021; Guideline Monitoring and Evaluation Plan, June 2021; Guidelines, August and February 2020; proposed reforms, February 2018 and June 2017; Health Canada's Modernization Discussion Paper, October 2016; and two separate House of Commons Standing Committee on Health studies.

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:

- The BMC supports the goal of improving the affordability of medicines, both for individual patients and health care systems including public and private payors. 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 safe and effective 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. In previous consultations, the BMC called for application of the new basket of comparator countries but urged the government to not pursue controversial elements of the then proposed regulatory package. In April 2022, a decision was announced that application of the new basket of comparator countries would proceed but not elements related to the new factors on prices or with certain additional filing requirements, and BMC welcomed this approach.

Considerations regarding the Draft Guidelines:

The BMC stands by its ongoing core positions, summarized above and expressed in previous submissions. For the current Draft Guidelines consultation, the BMC offers input on three themes, below, followed by brief discussion points:

1. ***Strengthening stability and predictability in uncertain times***
2. ***Supporting ongoing meaningful patient engagement***
3. ***Impact assessment to enable evaluation***

Discussion points:

1. Strengthening stability and predictability in uncertain times

The evolving United States' tariff and trade situation has intensified concerns regarding availability and access to necessary medications, including for patients who are vulnerable to any supply interruptions or price fluctuations. In the interest of protecting patient care, the BMC calls for exemptions of drugs and related treatments from tariffs and other trade measures. Any effect on prices or supply must be carefully assessed, managed and addressed so that access is not further restricted in response to pricing or other trade pressures.

In this context, the BMC urges the PMPRB to fully adopt market predictability and stability as core objectives and to ensure that these Guidelines contribute to this end point. The BMC supports Guideline revisions which would increase long term certainty regarding prices for existing medicines such as those introduced under previous frameworks and regulations.

2. Supporting meaningful ongoing patient engagement

The BMC welcomes recent efforts by the PMPRB to engage with patient organizations, including round table discussions hosted by PMPRB leadership. In addition, the simplified overview section in consultation material contributes to transparency and accessibility. We appreciate this openness and encourage the PMPRB to continue these important efforts.

Moving forward, we again challenge the PMPRB to recognize the value and contribution that patients and the organizations that represent them can provide outside of confidential discussions with rights holders. As stated previously, we believe that the patient voice has a rightful place in informing the direction of the PMPRB and it is incumbent on the PMPRB to ensure that patients and the organizations that represent them can effectively participate and contribute.

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.

3. Impact assessment to enable evaluation

We continue to urge the PMPRB to fully commit to rigorous impact assessment and to engage all stakeholders in development and execution. Importantly, impact assessment reports must be made publicly available in a timely fashion and presented in accessible plain language.

The patient community seeks to fully understand outcomes as the Guidelines are applied. Simply put, the BMC seeks assessment and analysis which would address whether patients in Canada will continue to have access to best-available medicines in line with comparable countries, or if access has diminished, along with other important measures.

Conclusion:

Thank you for the opportunity to participate in this consultation and we thank the Board for its careful consideration. The BMC looks forward to working with the PMPRB to develop approaches to meaningfully and appropriately engage the patient community, acknowledging goals and perspectives.



About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of 32 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
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