



**BEST
MEDICINES COALITION**
COALITION POUR DE
MEILLEURS MÉDICAMENTS

**Submission to the Standing Committee on Health:
Patented Medicine Prices Review Board**

Best Medicines Coalition



April 25, 2023

Standing Committee on Health: Patented Medicine Prices Review Board

Introduction:

- The Best Medicines Coalition (BMC), a national alliance of 29 patient organizations together representing millions of patients, welcomes the opportunity to provide input to the Standing Committee on Health as it considers the Patented Medicine Prices Review Board (PMPRB), and thanks the committee for its consideration.
- The BMC has been an active participant in consultations on pharmaceutical pricing regulation reform and the PMPRB since modernization efforts were initiated by Health Canada in 2016. This submission follows previous input into the Standing Committee on Health as part of its PMPRB study in late 2020. In addition, BMC has submitted as part of PMPRB consultations, including the following: 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 (GMEP) in June 2021; the draft Guidelines in August and February 2020; the proposed reforms in February 2018 and June 2017; and Health Canada's PMPRB Guidelines Modernization Discussion Paper, in October 2016.
- This submission was developed with the participation of BMC member organizations and all statements and positions expressed within this submission reflect areas of consensus.

Core Positions on Drug Pricing:

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

- Canada needs effective and balanced pharmaceutical pricing regulations which contribute to sustaining and improving the health and wellbeing of current and future patients. Regulations must achieve the following:
 - **Improve the affordability of medicines**, for individual patients, health care systems, and public and private insurance. Patients and their families, and public and private payers who pay on their behalf, bear a significant burden of prescription medicine costs, and we support efforts to address this, particularly in relation to appropriate international comparators.
 - **Ensure timely access to new medicines which address unmet needs.** There must be confidence, based on best available evidence, that regulatory frameworks 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 nuanced and balanced 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 refrain from proceeding with the originally proposed regulatory package which included controversial and problematic economic factors.

- **Given the need to address the dual goals of affordability and timely availability, the BMC welcomed and fully supported the announcement by the Honourable Jean-Yves Duclos, Minister of Health on April 14, 2022** to proceed with applying the new basket of comparator countries while putting other aspects, including economic factors, on hold.
- In BMC's December 2022 submission regarding draft Guidelines, concerns were expressed that the proposed Guidelines were not aligned with the government's ongoing policy intent on pricing regulation and broader policy objectives, and therefore should not be considered final without fulsome review, integration, and alignment.

Moving Forward Effectively:

The BMC takes this opportunity to reiterate positions regarding appropriate regulatory frameworks, accountability, and the related issue of inclusive consultation:

1. Adopt effective and efficient frameworks and systems to support patient care

The broad regulation of pharmaceuticals, including regarding pricing, must be efficient and not duplicative and prolonged due to redundant and overlapping mandates. Every effort must be made to ensure that all elements are the best use of limited resources with the goal of improving patient care.

- At this critical juncture, there is an opportunity to review existing functions of not just the PMPRB, but a range of agencies, given the context of the proposed new Canadian Drug Agency and potential development of legislation related to the concept of national pharmacare.
- Reflecting on the necessary functions of Health Canada, PMPRB, CADTH and any other bodies involved in the drug review and implementation processes is an important step to streamline approvals, support patient access and build a resilient and sustainable drug system. Any duplication and unnecessary processes which potentially complicate and delay access to medicines for patients in Canada must be avoided.

2. Implement meaningful and respectful patient engagement practices

The extended and arduous process of drug pricing reform and related consultations experienced over the past several years has highlighted the critical need for renewal, including collaborative leadership which values and has demonstrated expertise in respectfully and meaningfully engaging all stakeholders, including the patient communities.

- The PMPRB's consultation processes, often characterized as adversarial, have not reflected genuine collaborative engagement with stakeholders, including the patient community.
- Moving forward, the emphasis must be on strengthening and building relationships so that the PMPRB and stakeholders can work together effectively and productively. Patient-informed approaches to policy development and decision making, including fulsome discussion, must be adopted moving forward.
- Leadership at the PMPRB, and indeed all agencies involved in critical healthcare policy, must commit to understanding and prioritizing patient needs and recognize the value that patients and their representatives bring to deliberations regarding drafting and supporting health policy.

- A holistic and value-based approach to patient engagement must be adopted, with opportunities for input and involvement embedded in the structure and processes of the PMPRB and any other agency involved in shaping health care systems and delivering care to patients.

3. Build accountability through rigorous, independent monitoring and evaluation

Throughout the reform consultation process, diverse stakeholders have called for measures to improve the Board's transparency and embed greater accountability through rigorous monitoring and evaluation, conducted independently.

- As reforms progress and are implemented, there must be rigorous impact analysis to ensure that regulations will have a positive impact and not hinder access to necessary medicines and that they contribute to the best possible care and outcomes. The BMC continues to call for an evaluation process to ascertain if there has been a positive or negative outcome followed by course corrections if needed. It is critical that monitoring, analysis, and evaluation be conducted independently and at arm's length from the PMPRB itself.
- Evaluation processes must be conducted independently and be clear and transparent with a focus on the impact to patients, not just program budgets. A key marker of effectiveness is whether medicines – particularly those which address unmet needs – will be available to Canadians affordably and in a timely manner.
- Independent monitoring and evaluation must be transparent and rigorous including analysis of real savings and costs related to possible treatment delays in the short or long term, with mechanisms in place to trigger adjustments. Consideration should also be given to the impact on access for all patients, including underrecognized populations such as Indigenous and racialized groups. Importantly, public reporting must be entrenched, and made public in a more timely manner than current PMPRB practice.

Key Recommendations:

The BMC thanks the committee for its review and consideration of these important issues. As the committee conducts its study and develops its report to Parliament, we ask that members considers the following recommendations on how the Government and the PMPRB should move forward:

1. Adopt effective and efficient frameworks and systems to support patient care.
2. Implement meaningful and respectful patient engagement.
3. Build accountability through rigorous, independent monitoring and evaluation.



About the Best Medicines Coalition

The Best Medicines Coalition (BMC) is a national alliance of 29 patient organizations which 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. With interests in drug approval and oversight, assessment, and reimbursement, as well as safety and supply issues, core activities include member issue education, consensus position development and advocacy.

As an important aspect of its work, the BMC strives to ensure that patients and the organizations that represent them have a voice and are meaningful participants in health policy development, specifically regarding pharmaceutical care. The BMC was formed in 2002 as a grassroots alliance and in 2012 it was registered under the federal Not-for-profit Corporations Act, governed by a Board of Directors elected from member organizations.

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 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 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.

Member organizations:

Alliance for Access to Psychiatric Medications
Asthma Canada
Brain Tumour Foundation of Canada
Canadian Arthritis Patient Alliance
Canadian Association of Psoriasis Patients
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 Psoriasis Network
Canadian Skin Patient Alliance
Canadian Spondylitis Association

CanCertainty
Crohn's and Colitis Canada
Cystic Fibrosis 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