December 20, 2023

Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Input to the PMPRB regarding development of new Guidelines

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 development of Guidelines as outlined in its scoping document, 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. Most recently, the BMC participated in the PMPRB's December 5, 2023 consultation session, represented by Kim Steele, Vice-Chair of BMC's Board of Directors.

Previously, BMC provided input as follows: 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, in addition to 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 positions regarding drug pricing 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:

- 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 a significant burden of prescription medicine costs, 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 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 balanced approach regarding drug pricing regulations. Specifically, BMC has called for the application of the new basket of comparator countries immediately but urged that the Government forgo the originally proposed regulatory package which included problematic economic factors, an approach adopted by the Federal Government in April 2022.

Considerations regarding the development of new Guidelines
As the Board embarks on the development of new Guidelines, the BMC provides input exploring the following themes:

> ***Effective engagement.*** Ensuring that patients and the organizations that represent them can effectively participate and contribute to the consultation process.
>
> ***Supporting patient-driven positions.*** Ensuring that the PMPRB Guidelines are informed by patient-driven positions, including those of the BMC.

Effective engagement: Considerations to move forward
Moving forward, we challenge the PMPRB to better understand what patient organizations do, how we operate and recognize the capabilities and how we can bring value to policy deliberations. In addition, to ensure a respectful and cooperative process, we request that the PMPRB seek to understand and consider the ethical guidelines patient organizations have in place to protect the independence of our work.

Patient organizations, including the BMC and its members, are involved in price regulation reform considerations with the goal of improving the health outcomes of the patients we represent and ensuring that health systems can sustainably support patients.

While most representatives of patient organizations do not have the expertise or capacity to assess highly technical aspects, there is an opportunity to engage patient organizations on the outputs and outcomes the PMPRB aims to achieve with the Guidelines. To enable this, we recommend that the following steps be taken by the PMPRB in this iteration of the Guideline development and consultation process. These recommendations support an overall improved consultation process and Guidelines which will meet the mutually beneficial objectives of patients and payers:

1. As part of its process in drafting new guidelines, the PMPRB must provide information that is appropriate and meaningful to patient organizations about the outcomes the PMPRB intends to achieve. This must be done in plain language and in accessible formats.

2. The PMPRB must undertake an impact assessment of the draft guidelines and then make this assessment publicly available. This assessment would address whether patients in Canada will continue to have access to medicines in line with comparable countries, along with other important measures.

3. The PMPRB must provide opportunities for patient organizations to review and provide meaningful feedback to the PMPRB on both the guideline objectives and the impact assessment conducted by the PMPRB. There must be full assurance that the Guidelines meet mutually beneficial objectives for patients and payers, and that there are no unintended impacts that do not serve the delicate balance of appropriate price and access to necessary medicines.

4. We believe patient organizations do have an important, necessary voice, and that the PMPRB – and other apparatuses of government – must do a better job to give patient organizations the space and proper information to meaningfully provide feedback on planned outcomes, recognizing the expertise and capacity patient organizations have.

Supporting patient-driven positions: considerations to move forward

As stated previously, Canada needs effective and balanced Guidelines which contribute to sustaining and improving the health and wellbeing of current and future patients. We believe the Guidelines must achieve the following:

1. Improve the affordability of medicines, for individual patients, health care systems, and public and private payers. Patients, their families, and public and private payers bear a significant burden of prescription medicine costs. We support efforts to address this, particularly in relation to appropriate international comparators.

2. Ensure timely access to new medicines that address unmet needs. There must be confidence, based on best available evidence, that regulatory frameworks and the guidelines that support them 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.

3. Finally, we believe any adopted guidelines should also seek to improve the Board's transparency and embed greater accountability through rigorous monitoring and evaluation, conducted independently. This will ensure that the objectives of the guidelines are met and that there are no unintended consequences to patient access to medications.

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 patient organizations, one that acknowledges our expertise and why we exist: to serve and represent Canada's patient community. We urge you to adopt patient needs and improvement of patient outcomes as a fundamental objective.

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 involve 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 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 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