December 5, 2022

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

PMPRB 2022 Draft Guidelines Consultation

Summary: Core positions and recommendations

The Best Medicines Coalition (BMC), a national alliance of 29 patient organizations, has endeavoured to understand and evaluate how the proposed Guidelines will ultimately impact patient care and outcomes and offers the following positions and recommendations:

1. ***Addressing dual goals of affordability and timely availability of medicines***

   To move forward, the Guidelines must both address affordability in the context of excessive pricing and contribute to an environment where new medicines are available in a timely manner and where patients with critical unmet needs are able to access clinical trials.

2. ***Alignment with policy intent to avoid unintended consequences***

   There is uncertainty whether the draft Guidelines align 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.

3. ***Comprehensive impact assessment with focus on patient care***

   The Guidelines should not move forward without a rigorous impact assessment before implementation followed by monitoring and analysis regularly at established intervals, and definitive evidence that the proposals do not carry risk to current and future patients. PMPRB staff should provide case studies for public discussion before implementation.

4. ***Moving forward with good faith engagement***

   Health Canada and the PMPRB must reconsider and proceed with a period of meaningful discussion, engaging all stakeholders in good faith. Policy makers and regulators have an obligation and responsibility to understand and integrate values and goals as defined by those who represent the interests of patients and as such patient voices must be integrated into the ongoing work of the PMPRB.

Introduction:

The BMC has continued as an active participant in consultations on pharmaceutical pricing regulation reform and the Patented Medicines Pricing Review Board (PMPRB). This current submission follows previous input, including on proposed Guideline revisions related to Gap medicines, comparator countries and international price tests in August 2021; on the proposed Guideline Monitoring and Evaluation Plan (GMEP) in June 2021; on draft Guidelines in August and February 2020; on proposed reforms in February 2018 and June 2017; and on Health Canada's *PMPRB Guidelines Modernization Discussion Paper,* in October 2016. In addition, BMC has provided additional input through correspondence and participation in stakeholder briefing sessions.

This submission was developed with the participation of BMC member organizations, specifically the BMC Drug Pricing Regulation Working Group and other members. Statements and positions expressed within this submission reflect areas of consensus among BMC member organizations.

Draft Guidelines: BMC positions and considerations

1. Addressing dual goals of affordability and timely availability of medicines

Canada needs an integrated approach to how medications are managed and provided to patients, encompassing various bodies such as the PMPRB, and with a shared focus on improving patient care and outcomes. Ensuring affordability is critical. Of equal importance, all policies, including regarding pricing regulations and enabling Guidelines, must support the timely introduction of a comprehensive range of new medicines and reduce barriers for clinical trials to be conducted in Canada.

Discussion:

- The BMC's primary focus in considering pricing regulations and related Guidelines is ensuring that patients have access to the medicines they need when they are needed, especially for patients with unmet needs who await new or yet to be discovered treatments.

- In keeping with this principle, the BMC fully supports policy and regulatory reforms which make medicines more affordable, including regarding the PMPRB and its mandate to address excessive pricing within the context of potential abuse of patent protection. Many patients and their families are burdened with significant prescription drug costs in addition to the considerable personal and financial stress related to living with or caring for an individual with a serious health condition or disability. Likewise, the absence of a safe and effective treatment increases costs and overall burden borne by the patient and their family.

- While excessive prices must be addressed, all measures including regulations and implementation Guidelines must encourage, and not deter, timely introduction of new medicines and vaccines plus clinical trials sponsored by drug developers, giving patients who volunteer for early access to promising new therapies. Put simply, patients in Canada need effective and balanced policies aimed at sustaining and improving the health and wellbeing of current and future patients.

- Given the need to address the goals of affordability and timely availability, the BMC urged the government to proceed with a new basket of comparator countries but pause the more controversial economic factors. We welcomed the announcement by the Honourable Jean-

Yves Duclos, Minister of Health on April 14, 2022 to proceed in this direction. We hoped this would resolve most controversies and uncertainties.

Position:
To move forward, proposed Guidelines must both effectively address affordability in the context of excessive pricing and contribute to an environment where new medicines are available in a timely manner and where patients with critical unmet needs are able to access clinical trials.

2. *Alignment with policy intent to avoid unintended consequences*

The proposed Guidelines must reflect the intended impact of the new regulations as well as broader policy objectives. In his April 2022 statement, the federal Minister of Health cited the important goals of improving access to medicines and generating savings while supporting innovation and investment in the pharmaceutical sector. In addition, longer term considerations such as regarding rare disease strategy, national pharmacare options and a national drug agency are still in development.

Discussion:

- The BMC supports a modernized regulatory framework that addresses excessive prices within the context of potential abuse of patent protection to levels which will allow for the timely introduction of new medicines, as is the government's stated intent. However, there are indications that the proposed draft Guidelines will deliver prices well below this original intent with potentially negative implications for patient access to new medicines.

- There are indications the Guidelines, in taking a new approach from past practice, will introduce significant market uncertainty stemming from a general lack of clarity, vague discretionary investigative powers and potential for price reductions which go beyond the stated policy intent with unintended consequences. Specifically, we are concerned about the impact on global corporate decisions regarding timely launches of new medicines in Canada and drug developer funding of clinical trials in Canada and how this will increase the burden on patients, especially those with significant unmet needs, and their families.

Position:
There is uncertainty whether the draft Guidelines align 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.

3. ***Need for comprehensive impact assessment now***

As an organization representing the interests of patients, the BMC's fundamental role in this consultation is to endeavour to understand and evaluate how the proposed Guidelines will ultimately impact patient care and outcomes and to evaluate the proposal from this lens.

Discussion:

- Comprehensive and credible analysis of immediate and long-term implications to patient access and outcomes of the new regulatory framework and Guidelines is imperative. A comprehensive impact assessment would include immediate case-by-case evaluation of impact regarding specific medicines and scenarios along with a plan for ongoing regular tracking of new medication launches with international comparisons.

- It is the obligation and responsibility of Health Canada and the PMPRB to work together with all stakeholders, including the pharmaceutical industry, the patient community, and

others, to develop a framework for immediate and ongoing impact analysis which is meaningful and credible. We note that in previous consultation periods through the reform process, patient organizations took on some of this evaluation work to fill this ongoing void.

- We understand that tracking and analysis can be challenging, involving monitoring activity in Canada and other countries, and then identifying if launches take place in Canada and timing and comparing to other markets, and undertaking this work regularly and transparently. Ideally, the focus would be on new drugs which meet unmet needs. An additional and complementary approach would be to work with the patient community to identify specific drugs which are being anticipated and actively track them in Canada and compare.

Position:
The Guidelines should not move forward without a rigorous impact assessment before implementation followed by monitoring and analysis regularly at established intervals, and definitive evidence that the proposals do not carry significant risk to current and future patients. PMPRB staff should provide case studies for public discussion before implementation.

Summary: Moving forward with good faith engagement

The proposed Guidelines do not reflect fundamental policy intentions specific to pharmaceutical pricing regulatory reform or broader policy objectives as articulated by Minister Duclos. Furthermore, without comprehensive impact analysis it is not possible to be confident that the Guidelines will not result in negative implications for patients in Canada.

Health Canada and the PMPRB must reconsider and proceed with a period of meaningful discussion, engaging all stakeholders in good faith. In addition to private and public payers, fulsome consultation would include the pharmaceutical industry which while informed by commercial objectives is most credibly able to evaluate market impact and the realities of global decision making.

Equally important, the patient community must be brought into discussions fully and meaningfully. Policy makers and regulators have an obligation and responsibility to understand and integrate values and goals as defined by those who represent the interests of patients and as such patient voices must be integrated into the ongoing work of the PMPRB. Other stakeholders, such as health system professionals, specialists who work on the front lines of healthcare delivery, and academics, must also be involved. Rigorous and meaningful engagement must be initiated immediately and ultimately embedded in all aspects of policy development and reviews.

BEST MEDICINES COALITION
COALITION POUR DE MEILLEURS MÉDICAMENTS

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.

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