



August 31, 2021

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

Input to PMPRB regarding proposed Guideline revisions related to Gap medicines, comparator countries and international price tests

Introduction:

The Best Medicines Coalition (BMC) is a national alliance of patient organizations which together represent millions of patients in Canada. This latest submission to the PMPRB follows input the BMC provided on a series of PMPRB consultation periods, including 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 input through various correspondences and participation in stakeholder briefing sessions. As with previous submissions, this document is based on standing BMC positions and recommendations that reflect areas of consensus amongst our member organizations.

We note for the record that the BMC did not provide a submission to the March 2021 PMPRB consultation on the definition of Gap medicines and the timeline for compliance given the technical nature of the subject matter. We clarify this here since PMPRB referenced the BMC in their decision on the definition of Gap medicines and the timeline for compliance. As a result, the BMC subsequently wrote to the PMPRB requesting the removal of reference to the BMC on a matter for which our organization did not take a position, and the PMPRB responded regarding this inaccuracy, and we accepted the apology of the Executive Director.

Outstanding issues:

We will take this opportunity to acknowledge that the BMC awaits a fulsome and meaningful response from the PMPRB regarding statements made about the BMC and other patient groups with respect to our positions and activities in an internal document. In this document, which was made public through an Access to Information request, the PMPRB disparaged the BMC in tone and content and stated that patient groups are involved in disseminating disinformation and that the BMC has aggressive public relations strategies. These statements are inaccurate. We have corresponded with the PMPRB refuting these assertions and requesting evidence to substantiate these claims or a withdrawal of unsubstantiated claims.

To date, the PMPRB has not provided proof, nor has it apologized for these assertions against our organization and the patients we represent. We again request that the PMPRB provide an appropriate and comprehensive response immediately.

Input regarding proposed Guidelines:

Despite the context outlined above, the BMC provides this brief submission to the PMPRB highlighting our stance on the latest notice and comment period about a revised version of the Guidelines, whereby the PMPRB is proposing a further change to the definition of Gap medicines, the references to the comparator countries and the international price tests for grandfathered/grandparented medicines and their line extensions.

BMC Position: Do not proceed without full impact assessment

The BMC is unable to support the proposed Guidelines and revisions without a full and credible impact assessment which would provide evidence that the changes will not have a negative impact on patient care, specifically the ability of patients in Canada to access medications they need.

Discussion:

The explanation the PMPRB posted of the proposed changes lacked sufficient detail, and more notably, failed to outline both the objectives and the anticipated outcomes of the proposal. Our focus as a patient organization is to understand the beneficial or detrimental outcomes to the patient community of proposed changes in this space. Without such reflection, moving forward with these guidelines carries significant risk to patients.

The BMC is requesting clarification on both the planned objectives and anticipated outcomes but cannot provide any comment or feedback at this stage given the limited information and analysis released by the PMPRB. As such, until a comprehensive impact assessment is completed and shared, BMC does not support implementation of the revised proposed Guidelines. Quite simply, we would be extremely concerned if the PMPRB decided to move forward with this new Guideline change without such detailed impact assessment and the ability for patients to reflect and provide comment.

Additional issues and discussion:

- **BMC's Standing Core Position:**

The BMC is steadfast in our support of the following nuanced position: the immediate implementation of the new basket of comparator countries in the Regulations to lower list prices, and the delay of the proposed economic factors to allow for extensive review, impact monitoring and evaluation. At this time, the BMC does not have a position on how the newly proposed re-benchmarking provision of the Guidelines aligns with our core positions, and without further detail from the PMPRB, cannot provide comment.

- **PMPRB Third-Party Audit:**

We recommend that the federal government ensure a truly independent evaluation of the impact of the Patent Act regulations and PMPRB proposed Guidelines by engaging a third-party entity at arms length to Health Canada and the PMPRB to undertake fulsome consultations with all stakeholders. These consultations should strive to understand and ultimately address the multitude of concerns regarding Government and PMPRB's actions associated with these regulations and guidelines. We are continuously concerned that feedback and recommendations from the numerous PMPRB consultations have yet to be acknowledged or implemented by the PMPRB. The need for this rigorous oversight is compounded by recent revelations of the PMPRB's framing of patient organizations such as the BMC, and by the PMPRB proceeding with proposed Guideline changes containing little information on objectives or outcomes.

Summary:

As stated in our May 28, 2021 letter to the Prime Minister, given the PMPRB's perspectives on the feedback brought forward by patient groups, we do not believe that the PMPRB has the capacity and impartiality to self-monitor and self-evaluate, nor to move forward with these new proposed Guideline changes. Furthermore, as stated in our June 8, 2021 letter to the PMPRB Board Chair, we hope that the PMPRB can come together with all stakeholders to develop a consensus on research methods and evidence standards, specifically regarding patient access, as part of monitoring and evaluation strategies.

Given the ongoing federal election and the substantive issues raised regarding the PMPRB, the BMC recommends against proceeding with these Guidelines as revised as well as the initiation of an independent evaluation of the PMPRB and its activities, as well as a comprehensive impact assessment. These would be welcome first steps by the Government and PMPRB towards mending relationships with affected stakeholders and respecting the PMPRB duty to be impartial.

As we stated in our June 8, 2021 letter to the PMPRB Board Chair, all our concerns expressed stem from a core belief that it is of critical importance that the PMPRB operate in such a way that all concerns, constructive criticisms, and opportunities for improvement, can be expressed and are acknowledged respectfully. We offer this input regarding the proposed revised Guidelines in this spirit and request that our perspectives and concerns will be given full and careful consideration.



About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of patient organizations, together representing millions of patients, with a shared goal of equitable, timely and consistent access for all Canadians to safe and effective medicines that improve patient outcomes. 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 building, planning 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.



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
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