Medicines Access Coalition - BC

February 15, 2021

Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
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Submitted to: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

SUBMISSION ON: The change to the definition of Gap medicines and the timeline for compliance

BACKGROUND

Medicines Access Coalition – BC (formerly The Better Pharmacare Coalition) has been effectively advocating for appropriate and timely access to evidence-based prescription medications through the BC PharmaCare program and federal agencies since 1997. With a renewal of the Coalition in 2020 and a new name which more effectively reflects our mandate, we aim to be the leader in advocating for better access to medicines in BC by providing a unified voice of many patient care organizations. We are now known as MedAccessBC and have expanded our scope and activities to more effectively meet the needs of our coalition members and improve the health of British Columbians which often requires us to take action at a federal level, such as feedback and submissions we have provided to CADTH and its programs and services, PMPRB, and other national organizations.

MedAccessBC's current member organizations represent more than two million BC patients, caregivers and advocates. We achieve our mandate by providing education and awareness, interacting with stakeholders who participate or influence the decisions directly affecting the access to medicines including, policy makers, government, researchers, health practitioners, public and private health payers, benefit managers/consultants, pharmaceutical manufacturers, and others who play a role in the access to medicines.

On behalf of the members of MedAccessBC, we welcome the opportunity to provide a written submission sharing our views on the **change to the definition of Gap medicines and the timeline for compliance** by the Patented Medicine Prices Review Board (PMPRB) in response to the request for comments.

We recognize the importance of maintaining and ensuring fair prices for medicines which are affordable for Canadians and hope to see the reduction in prices of medicines in Canada soon. However, we also emphasize the importance of ensuring a healthcare landscape that ensures Canadians have consistent access to new and breakthrough medicines as well as participate and

gain benefit from clinical trials involving new drug therapies. Early access to innovative and life-saving medicines in parity with the rest of the world ensures Canadians are able to achieve a high level of quality of life and life expectancy, contributing to the success of Canada as a whole. Patients and patient organizations who focus on the health and well-being of people and Canadians as a first priority have perspectives on changes to policies and guidelines which affect the current and future access to medicines for Canadians.

VIEWS AND CONSIDERATIONS

We believe that a delay in the implementation of the updated PMPRB Draft Guidelines may give stakeholders involved more time to prepare and adjust to these changes and possibly due to the impact of the COVID pandemic, it is curious as to why a phased approach of the changes could not be implemented beginning with a change in the basket of countries as comparators to begin with.

With respect to this request to comment we provide our view on the change in definition of Gap Medicines and the change in timelines. The change in the definition of Gap Medicines to medications first sold prior to July 1, 2021 seems to be entirely appropriate with the delay in guideline implementations. However, this is not to endorse the updated guidelines overall. For this, please see our letter submitted August 4, 2021 (see: https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/submission-received/june2020/June%202020%20submission_Medicines%20Access%20Coalition-BC%20(MedAccessBC)_EN.pdf)

With respect to the change in timelines, it seems there is a reduction in the timeline for a patentee to comply with the MLP. We are in favour of lower prices sooner, however, not at the expense of a potential future loss of new medicine launches in Canada or few clinical trials carried out and conducted in Canada. The main concern of regarding these changes and changes in general is the potential to reduce the inclusion of Canada as a top tier country for pharmaceutical manufacturers to launch new therapies and carry out clinical trials in Canada.

Patient and patient organizations such as our members would like to draw PMPRB's attention to its approach and process that it makes changes, they should be done in such a way as to genuinely consider the impact or unintended consequences which may result in fewer needed innovative medicines being made available to Canadians in comparison to other developed countries.

Our core concerns are ensuring that medicines are accessible to the people who need them for the treatment of medical conditions, and that:

- choices of treatments are available to appropriately treat the diversity of individuals in Canada with chronic conditions,
- medicines are priced fairly and affordable for Canadians,
- Canada continues or improves on the number of new and useful medicines launched
- Canadians benefit from research of new medicines,
- new medicines are available in Canada early, and that Canada is one of the first countries to have access in the world,
- the processes of controlling or limiting prices is conducted through a transparent process,
- price control measures are done with accountability and responsibility to Canadians,

- patients and patient organizations are genuinely and meaningfully engaged when it comes to health regulations, processes and policies which impact the health and well-being of Canadians.

Requiring patentees to comply with MLP within 1 reporting period rather than the original 2 reporting periods for grandfathered and gap medicines has implications which are unclear as no rationale or reasons have been stated by PMPRB as to why these changes are being made. At this point, we do not have any reasons to endorse or oppose these changes.

In the future, it would be particularly helpful if the department or agency making updates and changes to government guidance and policies which are put forward for review and request comment and submission, provide rationale and explanation as to the reasons such changes are being made together with some description of the potential short-term and long-term impact.

Patient organizations are especially stretched thin this past year with the pandemic and fundraising challenges and each review and submission requires resources and effort to respond. We welcome the opportunity for comment and consultation, and request that these requests are done with further background and details provided and in particular with explanations and justifications provided for changes being made.

Summary

The Medicines Access Coalition – BC (MedAccessBC) would like to refer readers to the submission on the PMPRB Updated Guideline changes submitted August 4, 2020 ((see: https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/submission-received/june2020/June%202020%20submission_Medicines%20Access%20Coalition-BC%20(MedAccessBC)_EN.pdf). We request that the PMPRB refrain from making frequent changes which reduce the predictability of the healthcare ecosystem which may result in reduced access to medicines or further increases challenges to accessing medicines. We encouraged a phased implementation beginning with the application of the new PMPRB11 and measure its impact and savings, gathering more knowledge on impacts before proceeding to other more complex Guideline implementations. Comprehensive monitoring of the impact of the PMPRB Guideline changes must be undertaken to identify detrimental effects early so any harm to Canadians resulting from reduced access to medicines is avoided. Increased transparency and accountability by the PMPRB are needed as additional complexities are introduced to the review process.

Patient representatives and patient organizations should be engaged to provide valuable input and insight in an unbiased manner to help steer the process, especially where the decisions may be largely subjective. We would be pleased to be involved in the development and implementation of mechanisms to monitor and evaluate these changes as they are implemented.

We are grateful for the opportunity to provide this submission and are open to further dialogue.

Sincerely,

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See list of coalition members on following page.

Members of Medicines Access Coalition – BC (formerly Better Pharmacare Coalition)

aHUS Canada
BC Coalition of Osteoporosis Physicians
BC Lung Association
BC Schizophrenia Society
Canadian Cancer Survivor Network
Canadian PKU and Allied Disorders
Canadian Psoriasis Network
Canadian Pulmonary Fibrosis Foundation
Canadian Skin Patient Alliance
Canadian Society of Intestinal Research
Canadian Spondylitis Association
Crohn's and Colitis Canada
Diabetes Canada
Gastrointestinal Society
HeartLife Foundation
Hep C BC
Kidney Cancer Canada
Kidney Foundation of Canada
Mood Disorders/Lookout Society
MS Society
Obesity Canada
Osteoporosis Canada
Pacific Hepatitis Network
Pain BC
Parkinson Society British Columbia
Prostate Cancer Foundation BC
Save Your Skin Foundation
Women's Health Initiative Network