Medicines Access Coalition - BC

June 21, 2021

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

Submitted by email to: pmprb.consultations.cepmb@pmprb-cepmb.gc.ca

SUBMISSION ON PMPRB GMEP

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 to share feedback on the Patented Medicine Prices Review Board (PMPRB) Guideline Monitoring and Evaluation Plan. We also put forward requests for considerations in how this plan is carried out and implemented.

We recognize the importance of maintaining and ensuring fair prices for medicines which are affordable for Canadians. 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 these PMPRB Updated Draft Guidelines which may be

different from those who are regulators, create policies, plan budgets or are employed by for-profit corporations. We draw your attention to a number of areas which we highlight so you may consider and engage.

We would like to express that with the recent internal information that has come to light with respect to PMPRBs communication plan to manage the dissemination of information by patient organizations negatively impacts our view of PMPRB. Furthermore, these actions and the allocation of public funds to actively oppose patient organizations through a communications plan involving social media rather than engage in meaningful consultation and discussion causes PMPRB to lose its credibility as an unbiased quasi-judicial agency set up to look out for the best interests of Canadians, in particular the patients.

FEEDBACK AND SUGGESTIONS FOR CONSIDERATION

1. **Transparency and accountability**

There continues to be concern around the lack of transparency and that there is too much discretion and subjectivity given to the PMPRB Staff. A monitoring plan must assess these subjective decisions and ensure a level of transparency. For example, with respect to investigations where no board members are involved, staff have a great deal of discretion. As described in Section B, item 94, the PMPRB staff are given significant freedom to *"utilize any of the tests described in the Guidelines and modifications or variations of those tests (e.g., MIP instead of HIP or median as opposed to the top of the dTCC) depending what it believes most appropriate to the factual circumstances surrounding the price of the patented medicine under investigation".* This essentially allows complete modification or variation of tests at the staff's discretion, essentially allowing interpretation and subjectivity to play a role in how tests are applied and conducted in these investigations, which seems inappropriate and lack transparency.

The GMEP does not outline how these subjective activities will be monitored and assessed for appropriateness, nor how they will be made transparent and how the staff will be accountable for such decisions. Details around who is responsible and accountable have been conspicuously limited, as well as the metrics and performance indicators which are to be monitored and measured.

2. **Monitoring of the impact of PMPRB changes should be done with built-in early warning signals**

A comprehensive, robust, and accurate monitoring plan in combination with a monitoring process and details describing the sources of data and definitions is extremely important and must be robust on ongoing. A transparent and comprehensive post-implementation surveillance plan and process, including ongoing monitoring and independent evaluation, with active and respected participation from patient organizations or patient representatives who are focused on the impact to patients.

The evaluation process must be broad in scope and rigorous, evaluating the impact on Canadians as it relates to market entry and access to new drugs. Building on the areas outlined in the Updated Draft Guidelines background document provided, we request the incorporation of metrics specifically focused on patient care outcomes, including the availability of new therapeutic options for treating people in Canada in comparison with those in other countries. This consists of the following measures:

a) number of new drugs submitted for approval,
b) number of new drugs approved for marketing (NOC),
c) delay in time to launch in Canada compared to first launch in the world,
d) time to availability on market when it can be used for treating patients,
e) number of new drugs listed on public formularies,
f) number of drugs and patients going through the Special Access Programme,
g) number of patients being sent to USA and other countries for treatments not available in Canada, and
h) other measures which are directly or indirectly impacted by the PMPRB Guideline changes.

The number of clinical trials of new drugs, the respective drug trial phases, the number of subjects enrolled, the number of study sites, and other measures directly or indirectly impacted by the PMPRB changes should be measured and compared to historical numbers in Canada as well as other countries to identify trends and forecast impact to Canadians. Negative effects should be identified early, and corrective measure must take place as soon as possible to avoid further harm to Canadians.

A plan that adopts an early warning mechanism is needed to identify and provoke early action, decisions, and changes should the impact of these PMPRB Guidelines appear to show a negative trend compromising the care or treatment of Canadians compared to historical numbers or compared to similar countries. One of the core measures includes the appropriate monitoring and comparison of the number and time to new medicine launches in Canada and the number of drugs and the time it takes before a Canadian patient can be prescribed and treated with the therapy. During the preparation of this submission, we have reviewed discrepant reports on the number of clinical trials in Canada since the announcement of the PMPRB Draft Guidelines, the number of drug launches in Canada, and the number of new drugs to which patients have received access. The numbers and trends should be the same as these seem to be clearly defined measures, but it appears to be rather complex and open to interpretation since the conclusions from different sources of data are in stark opposition to one another. Involvement of patient organizations and patient representatives would help to resolve discrepancies as they are more likely to seek the true impact on the patients rather than uphold their organizational objectives and goals, which might explain the differences seen in the presentations.

In addition, the evaluation plan must include analysis of the net real savings or expenditures (further investments in the process), including the health system costs, PMPRB Staff budgets, and legal and associated litigation costs that arise from these PMPRB changes. It may be prudent to also monitor the number and costs related to legal conflicts which arise directly and indirectly from these PMPRB changes which diminishes the public funds available to improve the access to medicines and the health and wellbeing of Canadians. There is a human cost to delayed or non-access to breakthrough

medicines and a mechanism to fairly identify this as early as possible must be incorporated within the new framework and Guidelines.

To maintain balance and improve the transparency of the mechanisms and processes used for monitoring and evaluating the metrics and performance indicators, these must be developed with the participation of stakeholders including patients and patient organizations. Measurements should be made and reported to the public regularly, with early indicators to provoke quick intervention before there is further and significant harm to Canadians. A monitoring process must be undertaken early and not wait until after years of implementation where harm can continue unnoticed and unaddressed. It is suggested that the evaluation is conducted within 12 months of implementation of the Updated Guidelines and as part of the PMPRB's annual reporting for the first five years following implementation and regularly moving forward. Monitoring and evaluation processes must address these fundamental questions (as also put forth by the Best Medicines Coalition):

- What has been the impact on the range of medicines made available, compared to previous levels of Canadian new medicine introductions and other countries, the timing of introductions, types of medicines, and the number and types of clinical trials conducted in Canada?
- Do the new regulatory framework and Guidelines reduce duplication, improve efficiency, and contribute to healthcare system sustainability?
- Is the new regulatory framework flexible enough to ensure that new medications to address unmet needs are expedited?
- Do the new regulations ensure that existing medicines and older medicines do not incur price increases that reduce net savings?
- How will patient organizations engage and identify issues and difficulties of accessing breakthrough medicines which may be a direct impact of new regulations?
- Does the new framework contribute to improved patient care and outcomes and, if so, to what extent?

These monitoring and evaluation processes must encompass high standards of transparency, independence, and accountability, with thorough reporting. All stakeholders, including patient communities, should be consulted on design, and be involved in implementation and application. Specifically, patients should be part of the team that oversees this process. In addition, an independent audit or independent evaluation would be appropriate to provide Canadians with confidence in our federal pricing regulator.

Summary

MedAccessBC request that the PMPRB consider the implementation of the new PMPRB11 without delay and measure its impact and savings, gathering more knowledge on impacts before proceeding to other more complex Guideline implementations. The feedback provided on the GMEP with respect to monitoring the impact of any tool to reduce drug prices can be used to measure and monitor the impact of the change in the basket of comparator countries. With the full implementation of the PMPRB Guidelines changes, 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 with you or your staff.

Sincerely,

Alan Low, BSc.(Pharm.), Pharm. D., RPh, ACPR, FCSHP, CCD
Executive Director, Medicines Access Coalition – BC (MedAccessBC)
c/o 845 West Broadway, Vancouver, BC, V5Z 1J9
Email: alow@medaccessbc.org

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