# Medicines Access Coalition - BC

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Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
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Submitted via the PMPRB Website Portal: https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/2022-proposed-updates-guidelines.html

**SUBMISSION ON 2022 PROPOSED UPDATES TO THE PMPRB GUIDELINES**

**BACKGROUND**

The 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 access to medicines in BC by providing a unified voice of patient advocacy 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 National 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 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 and provide feedback on the 2022 Proposed Updates to the Patented Medicine Prices Review Board (PMPRB) Guidelines.

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, innovative and breakthrough medicines as well as participate and gain benefit from clinical trials involving new medicines. Not only is early access to innovative and life-saving medicines in parity with the rest of the world important, but continued access to existing medicines is also a necessity. As a leading country among developed nations, Canada should have excellent access to medicines to ensure Canadians are able to achieve a

high level of quality of life and life expectancy, enabling contributions to the success of Canada as a whole. Patients and patient organizations focus on the health and well-being of Canadians as a first priority and have perspectives on the 2022 Proposed Updates to the PMPRB Guidelines. Perspectives of patient advocates and patient organizations are unique and may be different from those who are regulators, policy makers, budget planners, or owners and employees of for-profit corporations. We draw your attention to a number of areas which we highlight so you may consider, engage and take appropriate actions in supporting Canadians and patients.

With respect to moving towards lower and fair price for medicines in Canada, we welcome the announcement of April 14, 2022 by Minister Duclos proceeding with the implementation of the new basket of comparator countries which is expected to help lower prices of medicines for Canadians. However, on December 23, 2021, Minister Duclos announced another delay of PMPRB regulations coming into force and stated, that "To bring these amendments into force, in the context of a global pandemic, requires preparedness and consultation. A delay also allows the Government to further engage stakeholders on the application of these amendments within the changing pharmaceutical landscape." We feel that to date, patient organizations and patient advocates have not had the opportunity to have a fulsome consultation with Government around PMPRB changes. The anticipated impact to patients with respect to the new 2022 proposed updates have not been provided in detail and raise some concerns.

We recommend following through with the statements made by Minister Duclos in December 2021 where we need "Government to further engage stakeholders on the application of these amendments within the changing pharmaceutical landscape". With this respect, we ask for a proper review and evaluation of the potential impact of these proposed updates and determine if these changes will in fact result in a reduction of new and innovative medicines being introduced in Canada due to these changes. We ask for analysis of the potential impact, risk and benefits of guideline changes so there is a basis for engagement and meaningly consultation around these amendments and their application.

Below we provide some feedback, views and considerations. We hope our input is considered carefully and acted upon. As an organization, we must devote precious resources and time to research and prepare useful and insightful feedback to your feedback requests and often they occur at inopportune times, sometimes at the most difficult time of the year and during a pandemic.

**FEEDBACK, VIEWS AND CONSIDERATIONS**

As a starting point, we support and endorse the submission and input provided by the Best Medicines Coalition (BMC), who have provided their submission under separate cover directly to PMPRB.

The expected impact and potential consequences resulting from the implementation of the most recent updates and changes to the guidelines have not been well reported and we hope more detailed analyses can be done which will help to illustrate the risks and benefits of implementing such changes. We are aware that recently, the uncertainty of PMPRB Guidelines changes may have caused

Canada to only have a fraction of the newly introduced innovative medicines compared to the other G7 countries. This raises concerns, if this is a result of the uncertainty the PMPRB changes has caused with multiple delays and changes.

Canadians do require affordable prices for medicines and should have good access to therapies they require. With the renewed discussion around a National Pharmaceutical strategy to provide universal access to medicines for all Canadians, the impact together with PMPRB changes are further complicated. With such complexity and uncertainty of the overall impact on patients in Canada, deeper research, analysis, and understanding is necessary before approving or implementing PMPRB Guideline changes.

PRAGMATIC APPROACH RESULTS IN INCONSISTENCY AND LACK OF PREDICTABILITY

There appears to be a number of areas which are unclear and would result in inconsistency and lack of predictability. This may lead to a further decrease in clinical trials in Canada for patients to participate and fewer new medicine entries compared to other developed countries. In the proposed changes, an investigation is trigged if a complaint is received in respect of the pricing of the medicine; or the list price increased by more than the changes in the Consumer Price Index (CPI); or No international prices were filed by the rights holder. It is unclear whether frivolous complaints will be acted upon and how this may impact introductions of new medicines to Canada. In addition, it would seem that if a Rights Holder did not have a product available in the new basket of countries (PMPRB11), that an investigation would also be triggered since there is no international price filed. It needs to be determined whether the likelihood of introductions of a new medicines will be discouraged from coming to Canada due to its lack of availability in the new PMPRB11 basket of countries. Canadians need to be assured that the pragmatic approaches in the guideline updates are not viewed as potential for inconsistency or unpredictability that results in fewer new entries of medicines in Canada compared to other countries in the world.

NEED FOR IMPACT ASSESSMENT OF UPDATED GUIDELINES

There is a need to forecast the impact of any new updates to guidelines, which include measures which are related to the direct impact to patients and their treatments, in particular, new medicines coming to Canada as well as potential for existing medicines to be removed from the Canadian market. Impacts and unintended consequences have not been explored in detail and this should be carried out before the approval and implementation of guideline updates. In addition, a comprehensive, robust, and accurate monitoring plan in combination with a monitoring process and details describing the sources of data and definitions is largely absent in the PMPRB Guidelines. We ask that the PMPRB provide 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. Details of the previously mentioned Guideline Monitoring and Evaluation Plan (GMEP) have not been made available nor has there been

meaningful consultation with patient organizations around the plan. As part of the evaluation and surveillance 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.

Both a qualitative and quantitative measures are also needed around the quality and 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, and compared to 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. We encourage the government be proactive versus reactive when it comes to the healthcare of Canadians and carry out the appropriated analyses to help anticipate the impact of changes.

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. In the past, 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 introduced in Canada which patients have access. The numbers and trends should be the same if we have clearly defined measures and methods, 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 years after the 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:

- 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.

## INTEGRATED APPROACH NEEDED WITH ACCESS TO MEDICINES REFORMS

In the past 12 months there have been a significant number of announcements at the National level which requires an integrated approach. An aligned and integrated approach is not apparent at this time and may lead to duplication, wastage, inefficiency, and even contradictions in policy it these reforms move forward in silos. More specifically, current priorities impacting the access to medicines involves updates to PMPRB Guidelines, National Pharmacare Strategy and National Strategy for Drugs for Rare Diseases (NSDRD), all being looked at simultaneously without integration. How the 2022 Proposed Updates to the PMPRB Guidelines integrate with NSDRD to ensure accessibility and fair and affordable pricing are not addressed. The lack of integration may also result in unintended negative

consequences to patients and at this point no review or evaluation has been described. A review of how these integrate and align is needed prior to the approval and implementation of the new updates to the Guidelines.

UNINTENDED IMPACT TO OTHER SECTORS IN HEALTH

There is a lack of recognition in PMPRB's background items and information, available currently or previously, has evaluated the impact of new PMPRB updates and changes on the operations and supports of healthcare. More specifically, there are a number of stakeholders whose operations are part of the overarching continuum of pharmaceutical manufacture, distribution, storage, and dispensing of medicines, all of which are dependent on the prices of medicines. A reduction in the price of medicines has direct impact on those resources and supports. Since proposed guidelines affect new and existing medicines, there is impact to the existing pharmaceutical distribution, warehousing, wholesale, and dispensing of medicines, with an indirect impact affecting patient care, which is expected to be negative as prices are reduced. Some of these impacts may translate into shortages of medicines patients are stabilized on as well as delays in getting necessary medicines. With supply chain issues an ongoing concern, there needs to be some assessment on how these Guideline updates will impact the prices of existing medicines and the associated unintended consequences to the supply chain, access to medicines and their use.

**SUMMARY**

As patients and patient organizations, we appreciate the opportunity to provide input, feedback and consultation. However, despite the existence of the consultation process, many stakeholders including MedAccessBC members have asked – without success – for improvements to the PMPRB's transparency and that PMPRB demonstrate greater accountability through rigorous monitoring and evaluation. We ask for more in-depth and fulsome consultation with respect to proposed updates before approval and implementation. It makes practical sense to include patients and patient organizations in a genuine consultation process, but many of those who have been directly involved in any form of consultation have felt and expressed frustration that the dialogue has not been comprehensive. In some cases, PMPRB has moved forward with updates to regulations and changes without truly considering the input, recommendations, and knowledge that these individuals and groups have provided. We suggest a delay in the approval and implementation of the 2022 Proposed Updates to the PMPRB Guidelines until more details are provided around anticipated impact, evaluation plans, and meaningful discussion with patients and patient organizations can be carried out. We hope to have meaningful engagement that respects the efforts the tireless individuals and groups who have put in effort and time to review background and prepare submissions and feedback. Regulations, guidelines and policies are made, or indeed should be made, in the best interest of Canadians who need medicines.

We encourage PMPRB to take a more comprehensive look at the potential impact of these changes and publish the analyses in a transparent manner looking at risks and benefits of such changes. Potential impacts, both positive and negative, should be shared and can help form the basis of

meaningful exchanges between patients and patient organizations who can shed light on the otherwise unforeseen and unintended consequences.

We would like to express that the preference of patients and patient organizations is that dollars are not spent on legal court cases and litigation, but rather towards research and development and improvements in patient care. The continued conflict that is foreseen and even predictable as a result of these changes between Government and the Rights Holder is likely to result in more and more court cases, consuming public taxpayer dollars and private sector expenses to resolve these conflicts. An approach which satisfies fair and non-excessive pricing which incorporates a patient centric thought process and leverages the expertise of the life sciences sector and brain trust in Canada is intensely needed. We hope to be involved in future engagements and consultations to improve access to medicines and ensure fair prices.

We are grateful for the opportunity to provide this submission and are open to further dialogue with PMPRB leaders and staff.

Sincerely,

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Encl.

Members of the Medicines Access Coalition – BC are listed below.
Our complete membership list is available at https://medaccessbc.org/

aHUS Canada
BC Coalition of Osteoporosis Physicians
BC Lung Association
BC Schizophrenia Society
Canadian Cancer 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
Women's Health Initiative Network