Medicines Access Coalition - BC

August 31, 2021

Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
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SUBMISSION ON PMPRB UPDATED DRAFT GUIDELINES

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) Notice and Comment: *On the change to the definition of Gap medicines, the references to comparator countries and the international price tests for Grandfathered medicines and their line extensions.*

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. 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 people and Canadians as a first priority and have perspectives on these PMPRB Updated Draft Guidelines which 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 action supporting Canadians and patients.

We would like to express our concern over the recent PMPRB internal information that has been made public with respect to PMPRB's communication plan to manage the dissemination of information by patient organizations. In this document made available through an Access to Information request shows PMPRB making allegations against the BMC and other patient groups. The comments made were disparaging in tone and content towards patient organizations. There has not been a public response or apology for these inaccurate statements made denigrating patient organizations. We hope PMPRB puts efforts in genuinely engaging with patient organizations in a meaningful dialogue rather than developing communications plans to manage these groups working in the best interest of patients. Furthermore, these actions and use of public funds in a communications plan leveraging social media to actively oppose patient organizations rather than making efforts to engage in meaningful consultation and discussion results in PMPRB losing credibility. PMPRB is expected to be an unbiased quasi-judicial agency set up to look out for the best interests of Canadians, in particular the patients, by preventing excessive medicine prices and report on pharmaceutical research and development (R&D) spending in Canada in order to stimulate improved investment in R&D.

We hope our input is considered carefully and acted upon as we must devote precious resources and time to research and prepare useful and insightful feedback to your request in the most difficult time of the year, middle of summer in the midst of 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 most recent updates and changes to the guidelines are complex and have significant potential impact which require deeper research, analysis, and understanding. At this time and with such short notice (changes were released July 15, 2021 and extended deadline for feedback is August 31, 2021), we are unable to provide a thorough, thoughtful and insight response. Details around the justifications, rationale and reasons for these changes as well as the anticipated benefits of these changes have not been provided. We offer comments and feedback as well as highlight some areas which require clarification and further explanation so we can properly respond to this feedback request.

We feel these recent set of changes can have significant detrimental impacts to patients and their access to medicines in the future as a result of these changes, stemming from further stifling new innovations from coming to Canada, as well as diminishing the likelihood of generic drug introductions to the market.

SCHEDULE FOR BASKET OF COMPARATOR COUNTRIES

1. The change to using a Schedule for the basket of comparator countries rather than the wording that stands appears to suggest that the comparator countries may be changing periodically. This would be a very poor approach as this introduces a lack of predictability and consistency for those involved in this sector. If indeed moving to the use of a Schedule for identifying comparator countries is being done to enable frequent comparator country changes or simplifying the process of changing comparator countries without the need for consultation, this will dramatically and negatively impact the number of innovative and new drugs introduced in Canada. The lack of a predictable environment does not stimulate longer term investment and R&D in Canada. This will result in less selection and options of medicines for patients to be treated including drugs which may be for rare conditions or life-saving drugs. The basket of countries for comparison have been set, there does not seem to be a need for a schedule of countries unless this is to enable future changes to be done with less process and consultation required to change the guidelines and regulations. This is unclear and requires clarification or should not be implemented.

   Before moving ahead, and before thoughtful feedback can be provided about the amendment of moving to a schedule of comparator countries rather than leaving the wording as is regarding the comparator countries, a candid explanation as to the reason, purpose and rationale of this change is needed. The perceptions of this change can be significant as we all know that for successful economic health of Canada's pharmaceuticals and healthcare delivery as well as a successful post-pandemic restart, we need predictability, consistency and stability with respect to pricing of medicines and the approach to pricing. Over the past consultations and discussions of the PMPRB reforms, there have been rising concern about the lack of predictability of pricing of medicines and patients cannot accept fewer innovative medicines launches compared to other developed countries in the world. Patients are also concerned about the impact of these changes to other parts of healthcare which may be the unintended consequences where there was a lack of visibility of the effects of lower prices of medicines. This includes the loss of clinical trials carried out in Canada as well as fewer compassionate programs giving Canadians access to important and life-saving medicines.

IMPACT TO GRANDFATHERED MEDICINES

2. The proposed changes to the price test and schedule for Grandfathered medicines is expected to result in list prices of Grandfathered medicines to decline. In fact, he FAQs provided by PMPRB indicate that on average the price decrease is expected to be 10% in the first year following implementation of the Guidelines, with 51% of medicines requiring a price reduction. We welcome lower prices for patients, however, this has implications as to whether these price drops include large decreases which may cause a loss of medicines on the market or fewer generic medicine entries in the future. No data was provided as to the identity of these medicines that are potentially affected and by how much each is anticipated to decrease. From initial estimates, this could mean there are some drugs that could decrease by 80-90% in price and some without any change (ie. 0%) with an average of 10% decrease. The problem here is that if some medicines decrease by 80% in price, the manufacturers will likely

no longer make these medicines available in Canada and patients may lose an important treatment due to a price reduction that is driven by calculations and comparator countries rather than patient-centric decisions. The situation and environment in other comparator countries for their older medicines can be very different than Canada, so introducing this new Grandfathered medicines change to the guidelines can have dramatic implications. In order to properly assess the potential impact of the changes proposed, we need to see data and cases illustrating specific examples which include the low, medium and high cases. The PMPRB FAQs also suggest that the proposed change is expected to have a lesser impact on existing Expensive Drugs for Rare Diseases (EDRDs), with an estimated list price reduction of 3.5%, with 55% of medicines requiring a price reduction. This is the same case with these medicines, no range is provided with respect to the decrease in price and no analysis is offered to test if the medicines will be withdrawn from the market due to the price decrease. Some analysis must have been carried out since PMPRB expects price reductions in over 50% of the medicines which fit this definition. That is a significant number of medicines impacted, but no details are available to better understand the impact it will have to patients and the continued availability of these medicines impacted. There are many medicines which fall into the "Grandfathered" definition, and many of these are single source medications which may have very low prices in other countries due to the time they have been on the market in that country, their use and volume in other jurisdictions. However, applying the same price restriction in Canada may not make any sense due to a very different environment, usage and volume of the same medicines, which can result in the loss of a much needed medicine being withdrawn from the Canadian market.

Research must be carried out prior to the implementation of these changes to Grandfathered and line extensions of Grandfathered medicines to ensure this will not cause the withdraw of single source or orphan drugs from the Canadian market so that patients will no longer have access to drugs which they have been stabilized on. Related to this is also to ensure that these reductions in prices of these medicines do not cause drug shortages, medicine distribution and storage issues as well as a decrease in pharmaceutical care provided by pharmacists and other healthcare providers whose livelihood is directly linked to the price of medicines they work with.

HIP VS MIP IN SETTING PRICE

3. The amendment made to the "Price Tests for Grandfathered Medicines and their Line Extensions" changing the wording as shown below will have a dramatic impact on price:

   a) "The MLP for Grandfathered and Line Extension medicines is set by the lower of the **HIP** for the PMPRB11 countries for which the patentee has provided information; "

   changing to

   b) "The MLP for Grandfathered and Line Extension medicines is set by the lower of the **MIP** for the Schedule Countries for which the patentee has provided information for the reporting period ending June 30, 2021 under the Regulations that are currently in effect (Schedule as per SOR/2008-70, s.6);"

This effectively has the impact of lowering the price further on Grandfathered and Line Extension medicines which have been available on the market for many years at which time other countries for various reasons may have been able to severely lower their price which for unforeseen reasons could not be done in Canada. As a result, this introduces a new unexpected decrease in price which those involved in the sector were not anticipating or predicting which by PMPRB's account will affect over half of the medicines. Since the price decrease identified by PMPRB on these medicines is not a weighted average by volume, the impact on the sector is unpredictable and has a high probability of disrupting those involved in manufacturing medicines, distributing medicines, and dispensing medicines. This all is likely to lead to a detrimental impact on patients who are receiving these medicines. Furthermore, the purpose, reasons, and rationale for using "HIP for the PMPRB11" to the "MIP for the Schedule Countries" has not been provided. It is not possible to provide feedback or assess the anticipated potential impact of this change when it seems to be an arbitrary change focused on controlling prices and reducing prices without consideration of impact to the real-world health system and the ecosystem of medicines in patient care in Canada.

UNINTENDED IMPACT TO OTHER SECTORS IN HEALTH

4. Nowhere in PMPRB's informational items and considerations, now and previously, has the impact of price reduction been analyzed with respect to the impact of price lowering to those who operate in the overarching continuum of pharmaceutical manufacture, distribution, storage, and dispensing of medicines. With the impact now also affecting Grandfathered drugs, the impact will be further broadened to affect those in the pharmaceutical distribution, warehousing, wholesale, and dispensing of medicines, with an indirect impact affecting patient care negatively. As expressed by the Canadian Pharmacists Association, *"Grandfathered patented medicines will be subject to maximum list price (MLP) calculation based on the new comparator (PMPRB11) countries. The proposed reassessment criteria are broad and does not clearly indicate how market dynamics (e.g., change in market size) will be factored in price adjustments on an ongoing basis. This reassessment may lead to price adjustments (reductions) which may not adequately take into consideration the existing decisions that have been made to distribute drugs to pharmacies across Canada. This may lead to misalignment between priorities of manufacturers, distributors, pharmacies and that of the health care system resulting in various unfavorable impacts such as reduced investment on infrastructure, operational plans, and services to rural areas. This can disrupt the supply of drugs to Canada's over 10,000 pharmacies and increases the risk of drug shortages."*

   And now with the lowering of the price of Grandfathered medicines to the MIP instead of the higher HIP in this most recent revision, the prices of these medicines will be further reduced. Patients are fearful that many of those who provide patient care services and those who are integral to the movement, storage and delivery of medicines depend on revenue which is based on a percentage of the medicines' list price, a lower price for medicines results in lower revenue and income for all of those associated. Some of these providers will need to alter their actions and priorities to be fiscally sustainable, deviating from their initial decisions made with new pricing changes, and this is likely to result in less patient care, drug shortages, and/or risks of poor storage conditions, resulting in patient detriment and wastage.

FUNDAMENTAL CHANGES TO GUIDELINES WITH BROAD IMPACT

5. The changes in Table F in the paragraph on Price Tests for Grandfathered Medicines and their Line Extensions, the new wording which now excludes the original wording, "Lower of list and RR or level pricing subject to HIP", would seem to further restrict the price of Grandfathered and line extensions of Grandfathered medicines to an even lower price than the previous guideline changes. In effect, this latest set of guideline updates are making some fundamental changes to the guidelines and regulations without true consultation. This exercise of "Notice and Comment", which this feedback represents, is not a replacement for appropriate and fulsome consultation on guideline changes. It must be noted that lowering of patented medicines will directly lower the price of generic medicine entries, since the pricing of generic medicines is a percentage of patented or brand name medicines. If prices are too low, there is no case or incentive for generic manufacturers to launch a generic version and as a result, a lower price generic alternative will not come to market. These price reductions may also result in the loss of the availability of generic medicines in Canada if their price falls below a threshold where the manufacture and distribution of the medicines is no longer feasibly due to price controls, and as a result the medicine is no longer viable for sale in Canada. The Tiered Pricing Strategy of pCPA ensures that generic prices are a percentage of brand name prices of medicines and all those which are interdependent will decrease accordingly with those drugs being limited source drugs or single source drugs having a high risk of no longer being manufacturer and marketed for Canadians due to these price controls being implemented. It is also unclear which medicines will fall into the definition of Grandfathered Medicines as we start to consider older medicines which still have patent or drugs owned by generic manufacturers which have patents, etc.

We cannot emphasize strongly enough the problems and frustrations introduced with these changes that were proposed and published only on July 15, 2021 and were made available after a third delay of the implementation of the PMPRB updated guidelines and that these changes are significant, complex, and have great potential to negatively impact patients. As such, they need to be properly investigated for their potential impacts on the health and wellbeing of Canadians and their access to medicines before implementation. Furthermore, it would seem these changes are far reaching and include fundamental changes which require appropriate meaningful consultation with stakeholders who may be significantly impacted, including patients and their representative patient organizations.

As patients and patient organizations, we appreciate the opportunity to provide input, feedback and consultation. However, despite the existence of the reform consultation process, many stakeholders including the MedAccessBC members have asked – without success – for improvements to the PMPRB's transparency and that they demonstrate greater accountability through rigorous monitoring and evaluation. 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 been mainly one-way. PMPRB has moved forward with its plan without truly considering the input, recommendations, and knowledge that these individuals and groups have provided. Involvement in consultation and preparing submissions are a significant undertaking for patient groups, many of which are registered charities and non-profit organizations operating with small budgets and volunteers. Meaningful engagement is the very least

these tireless individuals and groups should receive for all the efforts and time they put in. Afterall, these regulations, guidelines and policies are made, or indeed should be made, in the best interest of Canadians who need medicines.

SUMMARY

The most recent set of guideline changes are significant and have fundamental changes which require proper research and consultation prior to implementation. Some of the changes identified have a real and high probability of causing some Grandfathered and line extensions of Grandfathered medicines to be withdrawn from the market because they are reduced below a price which it would be kept available in Canada resulting in the loss of a needed medicine. The purpose, rationale, and reasons for these guideline changes including the creation of a schedule of comparator countries is not provided and can be viewed as another area that lacks predictability, consistency and stability in a market that requires these. The full impact of further lowering prices in the area of Grandfathered and line extensions of Grandfathered medicines has not been researched and shared by PMPRB, there have not been any illustrative cases and scenarios and the impact on the areas related to medicines can be negatively impacted resulting in the potential of drug shortages and a decrease in pharmaceutical care provided to patients. A decrease in the introduction of generic medicine entries as a result of lowering prices of Grandfathered and line extensions of Grandfathered medicines will mean fewer lower cost generic alternatives in the market, leaving only the high priced originator. Similar highlights are submitted by BMC and MedAccessBC supports the August 31, 2021 BMC submission.

We encourage PMPRB to take a more comprehensive look at these proposed changes and fully assess the potential impact, both positive and negative, which can result from these changes and incorporate meaningful engagement of patients and patient organizations who can shed light on the otherwise unforeseen unintended consequences these changes may have. Once this is done, then the information should be shared with patients and patient organizations so more thoughtful consultation and feedback can be provided. We would like to express that the preference of patients and patient organizations is that dollars are not spent on court cases and litigation, but rather towards research and development and patient care. The continued conflict that is foreseen and even predictable from these changes is likely to result in more and more court cases, using 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 would be pleased to be involved in any engagement and consultation 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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Members of the Medicines Access Coalition – BC who have endorsed this submission 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 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