Health Charities Coalition of Canada
Coalition canadienne des organismes de bienfaisance en santé

Submission to
PMPRB Draft Guidelines Consultation 2022

December 5, 2022

INTRODUCTION

The Health Charities Coalition of Canada (HCCC) is pleased to provide feedback as part of the public consultation process on the revised 2022 PMPRB Guidelines.

HCCC member organizations are trusted and reliable sources of Canadian health information. We invest in vital health research, advance patient partnerships, elevate the patient voice and provide evidence-based information Canadians can access to better manage their health. This includes the latest information on health prevention, diagnosis, and prevention.

The proposed 2022 PMPRB guidelines will have varying degrees of impact to our patient populations dependent on several issues including market size, therapeutic criteria level, availability of accessible data and whether existing therapies are currently available. As such, it is anticipated that individual members of HCCC will provide written submissions to the guideline's consultation highlighting specific impacts for Canadians living with specific diseases and or conditions represented by their health charity.

HCCC supports efforts to lower the costs of prescription drugs for Canadians and believes that care and consideration must be taken to ensure that this is done in a way that balances affordability, availability, and accessibility by Canadians to new medicines and to clinical studies in our country.

Throughout the consultations we have repeatedly recommended that the PMPRB seek opportunities to engage patient representatives meaningfully and continuously in their decision making and regulatory processes. Proposed changes to the guidelines show no improvements to how the PMPRB will meaningfully involve patients. We continue to highlight the relevance and importance of having individuals with lived experience meaningfully integrated into the development of policy and decision-making of the PMPRB.

Accordingly, HCCC makes the following four recommendations, vital to Canadian patients:

1) That an independent third-party be hired to conduct a formal assessment of the potential and real-time impacts of the guideline changes on access to medicines (including access to clinical trials) in Canada and across therapeutic areas.
2) That changes to new investigative criteria will not inadvertently put some patient populations at a disadvantage resulting in further delays in accessing new medicines.
3) That the PMPRB establishes formal mechanisms for meaningfully and continuously engaging patient representatives in its decision-making and processes to ensure patient voice, choice and representation.
4) That the consultation process allows for respectful consideration of stakeholder feedback prior to the implementation date.

BACKGROUND

The Health Charities Coalition of Canada (HCCC) is a member-based organization dedicated to strengthening the voice of Canadians, patients and caregivers by advocating for enhanced health policy and increased investment in health research.

Access to medicines is important to health charities and the Canadians that they serve as our organizations were founded by individuals and their families who had lived experience with a disease and hoped for a different reality for future generations – a future free from the disease that they lived with. For many of our members their vision is eradication of a specific disease. Until that vision is realized, Canadians look to ways that they can better manage their disease. As such, the use of medicines is often a choice that Canadians make, as medicines can help to slow progression of disease, alleviate side effects and ultimately cure disease.

The issue of pricing of drugs in Canada – particularly patented medicines which offer the most scientific progress and hope to those facing serious medical challenges – is of vital importance to the millions of Canadian patients represented by HCCC members. These drugs must be affordable for both the health system and for individual patients. However, affordability is only one element that requires consideration. Timeliness to access and availability of medications through Canada's public and private drug plans are also important considerations.

CONCERNS REGARDING IMPACTS OF PROPOSED CHANGES TO THE GUIDELINES

Canadian patients share governments' concerns about the affordability of medications, and they support policy efforts intended to lower prices. However, such efforts must be balanced in such a way as to encourage continual introduction of new and improved products and the launch and uptake of new medicines into the Canadian market that will meet the needs of patients. Changes in regulatory guidelines that create additional barriers or delays in the length of time that it takes for Canadians to access new therapies must be reconsidered.

There is a concern that the proposed changes may inadvertently impact certain patient populations where there are no reference points because a medicine has not previously been introduced into the Canadian market. The uncertainty around the length of time and impact that this new process will have on the availability of new treatments for these populations requires further examination and understanding prior to implementation.

At this time, it is unclear what the impact of the proposed changes to the Guidelines will be on the availability of medicines under the different categories of drugs and whether changes will have an impact on drug utilization in our country. We therefore respectfully request that an independent third-party be hired to conduct a formal assessment of the potential and real-time impacts of the guideline changes on access and availability of medicines to all Canadians.

Recommendation #1:
That an independent third-party be hired to conduct a formal assessment of the potential and real-time impacts of the guideline changes on access to medicines (including access to clinical trials) in Canada and across therapeutic areas.

Recommendation # 2
That changes to new investigative criteria will not inadvertently put some patient populations at a disadvantage resulting in further delays in accessing new medicines.

IMPACT ON MEANINGFUL INPUT FROM PATIENTS

Throughout the consultation process our members were pleased to provide significant feedback on the impacts that proposed changes might have on individuals living with various diseases and conditions. This included basic information on the disease, treatment options, and variables that impact the pace at which new therapies might be made available to treat their disease. We strongly believe that input and inclusion of people living with diseases is critical to the development of sound public health policy and decision-making as they are the ones who ultimately bear the brunt of any decisions that are made.

A key theme of our ongoing recommendations was to identify and install a formal mechanism for meaningfully and continuously engaging patient representatives in the PMPRB decision-making and processes to ensure patient voice, choice and representation. The current draft of the guidelines has no evidence of mechanisms for continuously engaging patients in the PMPRB.

Additionally, we had previously expressed interest in being involved in the development and implementation of the Guidelines Modernization and Evaluation Process (GMEP) that will, in part, track the impact of the guideline changes on patients, healthcare providers and other stakeholders. As organizations that work directly with patients, we believe that we are well positioned to provide valuable input to PMPRB on both the qualitative indicators that are relevant to patients as well as contribute by providing valuable quantitative data (such as information gathered through our registries). Unfortunately, opportunities to participate in this level of engagement and multi-stakeholder dialogue to determine how best to collectively monitor and evaluate progress going forward have not been extended to the patient community.

The current consultation period closes on December 5, 2022, with the intention of implementing the new guidelines on January 1, 2023. We are concerned that the existing consultation process has not built-in sufficient time to allow for meaningful review, revision and report back to the community of the feedback received from stakeholders through the current consultation process prior to moving to the implementation stage.

We maintain that the inclusion of the patient voice is an important one and we are prepared to work with the PMPRB to identify ways to integrate this voice in meaningful ways.

Recommendation #3:
That the PMPRB establishes formal mechanisms for meaningfully and continuously engaging patient representatives in its decision-making and processes to ensure patient voice, choice and representation.

Recommendation #4:
That the consultation process allows for respectful consideration of stakeholder feedback prior to the implementation date

CONCLUSION

Throughout the consultation process HCCC and its members have brought forward the perspectives and lived experiences of the patient communities that we represent. We are concerned that the views of Canadians living with disease who will be most impacted by these regulatory changes are not being acknowledged, considered and addressed in a collaborative and respectful way.

For further information, please contact:

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