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Dr. Mitchell Levine
Chairperson of the Board
Patented Medicine Prices Review Board

RE: Feedback on the Draft Patented Medicine Prices Review Board (PMPRB) Guidelines 2020

Thank you for the opportunity to provide feedback on the Draft PMPRB Guidelines 2020. In our previous letters and submissions, we strongly advised against implementing regulations and guidelines that do not address the concerns of patients and patient groups regarding access to medicines. However, these concerns, while occasionally acknowledged by your officials, have largely resulted in inaction. This steadfast and unrelenting approach, without adequately addressing the potential harms to patients, nor the legitimate concerns of patient groups, especially during these unprecedented times, is indeed, very discouraging. As such, due to the timing and uncertainty surrounding the implementation of the guidelines, as well as the rapidly changing economic and political landscape in Canada, we recommend that the PMPRB delay the implementation of the Draft PMPRB Guidelines 2020.

People living with diabetes have a large stake in the drug policy environment, because it impacts their ability to access the therapies, including medications, that allow them to optimize their health outcomes. The reality is that many people living with diabetes cannot afford the medications prescribed to them by their health-care provider. One quarter of people living with diabetes report that their treatment adherence is affected by cost. Some must choose between paying for food, rent, and/or utilities and accessing the right medication for their clinical situation. Others take their medications less frequently and/or at a lower dose than indicated to extend their prescription and save money. Some studies suggest that cost prohibits as many as 18% of people from filling their prescriptions. This may be due to the out-of-pocket expense or the fact that the medication is only partially reimbursed by their insurance plan. Canadians deserve better. The federal and provincial

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governments have an obligation to be good stewards of public funds, while ensuring that people receive access to world-class pharmacare.

It is an important and desirable goal to provide Canadians with lower cost medications; however, we do not want a system that decreases people's ability to procure medications due to unintended consequences¹. Patients' needs and outcomes must be a central component in the implementation of the proposed guidelines. Improved health outcomes should be the cornerstone of healthy public policy. Canadians are entitled to a forward-thinking, comprehensive assessment of all the factors that influence access to medications and the implementation of an integrated plan that will bring about improvements in the short and long terms.

We ask that you consider the following feedback while finalizing the Draft PMPRB Guidelines 2020:

- 1. *Scope of Practice:*** PMPRB should act less like a punitive body and more like a “public good” agency. PMPRB should seek to transparently collaborate with patients, clinicians, payers, and other stakeholders, to implement pricing guidelines that benefit and protect all parties involved.
- 2. *Medication Affordability and Patient Access:*** Changes to guidelines must not only address medication affordability but must also ensure ongoing patient access to needed treatments. Diabetes Canada is concerned that that the price reductions that will result from the new PMPRB guidelines will discourage innovators from introducing new therapies and technologies in Canada. Patients may be caught in the middle of this battle between regulators and industry and will bear the burden, in terms of sub-optimal health outcomes, additional treatment costs incurred by the public health-care system, and out-of-pocket costs incurred by patients to manage their condition.
- 3. *Public-Payer Perspective:*** Based on the potential for cost-savings to the public system, the perspective of the s.85 factors is that of a public payer. A public-payer perspective accounts for government-borne health and social care expenditures; but fails to consider other expenditures borne to patients including personal health and social care

¹ Unintended consequences are the unanticipated or unintended effects that arise from the actions of government or decision-makers.



expenditures, health and social expenditures covered by private insurers, and personal wages and circumstances. These additional parameters and expenditures would be considered if a societal perspective were to be adopted. For patients, this perspective is very important.

- 4. *Pharmacoeconomic Value:*** The PMPRB Guidelines 2020 have increased the pharmacoeconomic value threshold from \$60/QALY to \$150K/QALY, which is an improvement. However, whether the PMPRB is the right organization to set the maximum \$/QALY is still a point of contention, and PMPRB should still use the economic factor assessed by CADTH/INESSS as a starting point for negotiation.

The quest for a monetary value of a QALY has raised a number of debates within the literature, especially in relation to the existence of a single value of a QALY that is unique and can be applied to all situations.² To obtain a monetary value of a QALY one needs to attain an individual's willingness to pay per QALY. Individual preferences are then aggregated into a value that is applied to society, which is a complex notion. While this process is commonly done for academic purposes, there still exists concerns as to whether it is possible to use individual subjective valuations in a societal decision-making arena. Further, there is also a question of whether QALY gains that arise from specific diseases would also have an impact on the monetary value of a QALY. Moreover, an extension of this concern, is whether the value of a QALY varies depending on the specific disease or therapy being considered, since the morbidity associated with each disease varies between diseases and over time.

- 5. *Post-Implementation Monitoring and Evaluation Strategy:*** Currently the draft PMPRB 2020 guidelines do not outline how the impacts of the guidelines will be monitored and evaluated. The guidelines should be accompanied by an outcomes framework, which lays out the indicators that will be used to monitor and evaluate the outputs of the guidelines, including the s.85 factors, category I and II medicines, and new patentees' reporting requirements. Further, the CADTH allows patients to submit feedback as part of the Common Drug Review (CDR) and Therapeutic Review (TR). As part of the PMPRB Guidelines' monitoring and evaluation strategy, patients and patient groups should have the opportunity to provide input that conveys their experiences and perspectives

² Mason H, Baker R, Donaldson C. Willingness to pay for a QALY: past, present and future. *Expert Rev Pharmacoecon Outcomes Res.* 2008 Dec;8(6):575-82.



of how the guidelines have impacted their ability to manage their disease at an optimal level.

A monitoring and evaluation mechanism will allow PMPRB to capture, analyze, and continually report on outcomes related to the PMPRB Guidelines including cost of medications, availability of medications, equitable access to medications, launch delays or not, stagnation of R&D or not, etc. This would provide policymakers with the evidence needed to make any real-time changes to the Guidelines as they evolve in the Canadian context; and generate trust with patients, patient groups, and industry. Patients must be part of the process to review and report on changes to the drug policy environment.

- 6. *Transparency and Consultations:*** Throughout this reform initiative, patients have not been meaningfully engaged. While there were meetings, and calls for input, meaningful engagement requires respect and understanding. Further, when Diabetes Canada requested for evidence developed by the government to support these proposed changes, the documents shared were sparse and heavily redacted. We were disappointed that the detailed and thorough input we provided on the draft PMPRB Guidelines 2019 were not reflected in the draft PMPRB Guidelines 2020; many of our same concerns remain unaddressed. These practices have left Diabetes Canada and other patient groups feeling excluded and disrespected.

Moving forward, during the development of the monitoring and evaluation mechanism, Diabetes Canada believes that patients and patient groups should be meaningfully engaged to contribute to the design and ongoing operation of such a mechanism, to ensure that it is capable of effectively tracking all indicators, especially those that require patients, patient groups, and other stakeholders to provide input.

- 7. *Unintended Consequences:*** The PMPRB guidelines are predicted to give rise to short-term cost-benefits, primarily cost-reductions. The PMPRB has failed to describe the unintended consequences that may arise from the implementation of the PMPRB Guidelines 2020 and the approaches they will employ to mitigate these consequences. Potential unintended consequences include:
- Decreased availability of medications, which could cause increased costs throughout the Canadian health system and could negate all or some of the perceived savings.



- Significantly lower prices, and pricing uncertainties could cause medication launch delays in Canada. Further, some manufacturers may forgo launching in a low-price country. Medication launch delays means delayed treatment options for patients, which could negatively impact their health outcomes.
- Clinical trials of new therapies may be impacted as some manufacturers may not conduct clinical trials in countries they do not expect to launch in. Manufacturers are less likely to conduct clinical trials in countries where: [1] price controls force prices below the global pricing corridor, [2] reimbursement is unlikely, and [3] there is sufficient uncertainty as to whether an acceptable price and/or reimbursement can be achieved.³ This could potentially affect patients' treatment outcomes, as patients will have decreased access to new medications, technologies, and services if manufacturers choose to conduct their clinical trials elsewhere.
- Patient support program for new therapies could be at risk since they are largely funded by the pharmaceutical industry.

While PMPRB staff continue to reiterate that there is no evidence to suggest that these concerns are likely to become a reality, we need more than verbal reassurances. A respectful, and truthful, unbiased review of current data, and international context would have been helpful. We hope, in the future, that we, and other patient groups can engage in consultations without being slandered, for even raising the concerns.

- 8. Cost-Savings:** The guidelines explicitly indicate that the draft guidelines will give rise to cost-savings; however, there is no mention of how the cost-savings will be used. Cost savings could be reinvested into:
- Innovations in R&D;
 - Patient support programs that may be reduced by manufacturers to offset any negative impact on patients;
 - Offsetting the costs of patents that merit an exceptional circumstance authorization;
 - The national pharmacare plan that is under development; and/or
 - Disease prevention and health promotion strategies.

Our concerns are grounded in the perspectives and experiences of patients living with diabetes; our understanding of the importance of access to medications, devices, and

³ Innovative Medicines Canada. PMPRB Briefing Webinar for Patient Groups/Health Charities. December 2019.



services for Canadians; and our appreciation of the importance of life science research in Canada. We hope that our concerns will be considered and addressed in the next iteration of the guidelines. Diabetes Canada will continue its important work to end diabetes and urges the PMPRB to contribute to this effort through the creation of sound and supportive public policy. We would be pleased to engage with the PMPRB again to address the concerns mentioned above and to work together to improve access to optimal therapy for people living with diabetes.

Sincerely,

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