1400–522 University Avenue, Toronto, ON, Canada,
Call us: 1-800-BANTING (226-8464)
Visit us: www.diabetes.ca
Charitable number: 11883 0744 RR0001

Dr. Jan Hux
President and CEO
Diabetes Canada

February 20, 2019

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

Re: PMPRB guideline modernization case studies

Dear Dr. Levine:

Diabetes Canada is writing to express concern about the case studies recently released by the PMPRB. We understand that these hypothetical scenarios represent the impact of the proposed regulations. We have several questions about their development and how they will be used going forward.

The prevalence of diabetes has increased significantly over the past two decades. This is due to a greater number of people being diagnosed, as well as a bigger proportion living longer with the disease than ever before. The change in longevity is the result of enhanced access to health services, multidisciplinary care, educational resources and self-management supports, and is unequivocally related to more effective medications and better glucose control. Improved treatments have literally helped millions of people to live well with this disease. People 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 cannot afford the medicines prescribed to them by their health-care provider. One quarter of people with diabetes report that their treatment adherence is affected by cost. Some must choose between paying for food/rent/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 per cent 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 governments have an obligation to be good stewards of public funds, while ensuring that people receive access to world-class pharmacare.

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Diabetes Canada is in favour of the review of the pricing regulations affecting medications, drug review processes, price negotiations and drug reimbursement systems when they are intended to enhance access for patients at a lower cost. However, we also do not want a system that decreases people's ability to procure medications. In making amendments to pricing regulations, patients' needs and interests must always come first. Improved health outcomes should be the cornerstone of good 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 order to better assess the proposed amendments, Diabetes Canada would like more information about the case studies that were made available by the PMPRB. In Case Scenario 1, a hypothetical medication for people with diabetes is presented. We also note that medicines included in other scenarios may ostensibly be for diabetes treatment (as medicines become personalized, target sub-populations and possibly new mechanisms). Specifically, we are looking for responses to the following:

1. Is the perspective of the QALY analysis that of the public payer or a societal perspective?
2. What methods were employed to arrive at the estimates?
3. What assumptions were made to arrive at the estimates?
4. How was the threshold of $60,000/QALY identified? Were patients engaged to determine if this is an appropriate cut-off for medicines from their perspective?
5. How does the value from the quality of life assessment fit into the HTA review that may be completed by CADTH? Will it be more likely to have a positive recommendation from CDEC for these lower priced medicines?
6. Do the pricing framework and price cap impact the work undertaken by pCPA?
7. Will this pricing framework result in more formulary listings by the provincial drug plans?
8. Will the time from the point at which the product receives approval by Health Canada to product accessibility by public drug plans increase or decrease as a result of this new framework? Will the time to access for patients change?
9. Has the advisory committee or the PMPRB considered similar regulations in other countries? What has the impact been on patients and has their access to new medicines changed?
10. Have there been delays in the introduction of new medicines compared to the period prior to the QALY assessments and price reductions? If yes, has the PMPRB done a scan of all possible ways to reduce or control pricing around the world to determine the most reasonable way to proceed, while ensuring availability is not compromised? Were patients engaged in evaluating these data? If so, how?

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The nature and volume of questions we pose point to a lack of clarity in the case studies and the implications of the proposed regulations. Methodological details for the scenarios are notably absent. Acknowledgement and proposed mitigation of potential adverse consequences are not addressed. We find this to be completely unsatisfactory.

Furthermore, we were dismayed to hear the disparaging views of the PMPRB leadership toward patient groups, which have been widely publicized in the news as of late. The bias that has been shown against advocacy organizations, who work tirelessly to reduce the burden of illness in our country day in day out, is shocking. The general disregard for patient groups and their interests was also evident in the lack of additional information provided on the proposed new guidelines when it was solicited in past correspondence. Diabetes Canada previously submitted an Access to Information and Privacy request to the PMPRB, hoping to elucidate the rationale and evidence for these regulatory changes. The response we received was of little to no use at all.

The transparency around the proposed changes to date has been poor and we have been highly disappointed with the PMPRB's lack of meaningful collaboration with patient groups. We should be standing alongside one another to improve access for Canadians, not being sidelined in this process. Diabetes Canada, who is normally a strong supporter of evidence-based reform, is not in a position at this point to endorse policies like the ones proposed by the PMPRB where the outcomes are not known and may not improve patient outcomes.

We hope that our questions and concerns will be respectfully considered and addressed this time around. Diabetes Canada will continue our 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 and Health Canada around the questions above and to work together to improve access to optimal therapy for people living with diabetes. We request a follow up meeting in the near future to begin these discussions.

Sincerely,

Jan Hux, MD
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Cc: The Honourable Ginette Petitpas Taylor, P.C., M.P., Minister of Health
Douglas Clark, Executive Director, Patented Medicine Prices Review Board