Consultations on Proposed Amendments to the Patented Medicines Regulations

Diabetes Canada

Submission to Health Canada
June 28, 2017

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Diabetes Canada is the registered national charity that is making the invisible epidemic of diabetes visible and urgent. Eleven million Canadians have diabetes or prediabetes. Every three minutes, another Canadian is diagnosed with diabetes. Now is the time to End Diabetes – its health impacts, as well as the blame, shame and misinformation associated with it. Join us to End Diabetes.

Thank you for the opportunity to provide feedback on the proposed amendments to the patent medicines regulations. Diabetes Canada leads the fight against diabetes by helping those affected by diabetes live healthy lives, preventing the onset and consequences of diabetes, and discovering a cure. We advocate on behalf of people with diabetes for equitable and timely access to the drugs and supports needed to optimally manage their disease. People with diabetes have a large stake in how and which medicines are introduced to the Canadian marketplace, and how they are then reviewed, priced and potentially approved for reimbursement by public drug plans in Canada.

We are very concerned about the fact that currently 25% of people living with diabetes report that they cannot adhere to prescribed treatment because of cost. The burden is heavier for lower-income earners: 40% of those earning less than $35,000 per year are unable to adhere to their treatment because of cost.[1] Patients need to choose between rent, food and accessing drugs they need to manage their diabetes. Unfortunately, not all medications for people with diabetes are available in all regions of the country due to differences of provincial drug programs. Therefore, we support efforts to make medications affordable and accessible to patients who need them. Furthermore, we believe that the whole process must incorporate knowledge of best practices, promote equitable, timely and affordable access to evidence-based treatment, and also be transparent, consistent and fair.

The consultation document released by Health Canada describing the proposed amendments to the Patent Medicines Act has prompted several comments and questions for consideration. Diabetes Canada supports the overall principle that drug prices must not be excessive, and medicines must be available, accessible and affordable for Canadians. As a proud member of the Health Charities Coalition of (HCCC), which includes 27 health charities, we reinforce HCCC's recommendation for Patented Medicines Prices Review Board (PMPRB) to meaningfully engage patient representatives in decision making around drug pricing and the importance of equitable and timely access to medicines. The

[1] Canadian Diabetes Association survey, 2015

proposed amendments have not benefitted from meaningful patient engagement, are not supported by evidence made available to us, and further, the consultation documents do not meet the standard of transparency expressed by the Government.

RECOMMENDATION #1: Diabetes Canada recommends that patient groups are engaged in the development of the policy process in a regular, on-going and meaningful way to ensure that policies are meeting their needs.

Engaging with patients and patient groups is important to ensure that the health policy is patient-centred. Engagement is critical for ensuring that patients and their families are able to help make, influence and evaluate the decisions that affect their lives. Diabetes Canada encourages Health Canada to engage patient groups more meaningfully, make available for review additional background information and documents to support the amendments, develop a process to integrate the patient voice in the further development of the amendments to the Act, and ensure the patient perspective is incorporated into the evaluation of this health policy.

Currently, patient organizations and others are asked to comment on proposals without access to all the pertinent data and evidence available to Health Canada. This type of consultation is disingenuous and engenders mistrust between the policy makers and the very people they wish to serve. In order to have meaningful consultation and dialogue, full information must be available in a timely and proactive manner.

RECOMMENDATION #2: Diabetes Canada recommends that the Government of Canada releases its review of international practices to limit excessive pricing of medicines.

There were several practices mentioned in the consultation document to assess if a drug price is excessive including the use of long-term value for money

thresholds, multi-year budget caps, price volume arrangements, systematic therapeutic class and price reviews, and reimbursement and clinical criteria restrictions. Some of these interventions are beyond the mandate of PMPRB, however they may be effective. A whole-of- system approach must be considered in the implementation of policies to maximize benefits and reduce unintended consequences. The proposed amendments included the assessment of willingness to pay through the pharmacoeconomic evaluation of the product, the size of the market and the gross domestic product in Canada. Health Canada should release its review and assessment of the various practices to determine whether a price is excessive and describe why these proposed amendments were chosen. Our organization can more meaningfully provide input if/when we have the same information about the impact of these policies on pricing and access in other jurisdictions as department officials.

RECOMMENDATION #3: Diabetes Canada recommends that Health Canada releases information considered as part of its decision to the use of Quality-Adjusted Life Years (QALYs) for assessment.

The use of Quality Adjusted Life Years (QALYs) to assess the value of a medicine requires careful deliberation. Several questions arise:

1. Not all disease states can measure QALY through a validated instrument. How will this be managed? Will this become a criterion for a medicine to come to Canada?

2. QALY assessments are not static but change over time. Further, not all changes in QALY over time are similar. How will this be managed within the review and how will this influence pricing?

3. A QALY is not the same for all members of the population. Society may value improvements in QALY for children or the severely ill differently than others. How will this be addressed in terms of the impact of a medicine and its value?

4. How will the interpretation of a medicine's impact on QALY by the Canadian Agency for Drugs and Technologies in Health's (CADTH) expert committee integrate with PMPRBs interpretation of impact on QALY. For example, if a recommendation from CADTH's expert committee states that a medicine should not be listed due to cost, does this imply that the price is excessive for PRPRB's review as well? Will CADTH and PMPRB create a process to integrate their review and interpretation of the manufactures pharmcoeconomic evaluation? How will the patient voice be heard in this process? CADTH currently has a process for patient input which allows patient groups to describe the patient's experience with the drug and disease. That process is insufficient for the proposed amendments to the Patent Medicines Act which, under the proposed amendments, should consider the patient's willingness to pay.

It is our understanding that Health Canada conducted a review of international practices that may have considered the above questions and concerns. Thus it is unclear to us if there are ways to mitigate these issues or if they have been considered at all. In the spirit of openness, transparency, inclusion and patient-centred policy, we recommend a release of this review to patient groups.

RECOMMENDATION #4: Diabetes Canada recommends that the Government of Canada releases any assessments of the potential unintended consequences of the proposed regulatory amendments in Canada, including but not limited to, potential delays in access, reduction of access to new innovative medicines or duplication of services across drug review processes.

Department officials invited selected patient groups to a meeting on June 9, 2017. All groups raised concerns about potential duplication in process and potential increased delays in patients getting the medicines they need for their health. There were assurances that there would be no duplication between the PMPRB process, CADTH process, and Pan-Canadian Pharmaceutical Alliance (PCPA) process and there would be no bureaucratic delays as a result of the amendments. Delayed access as a result of this policy could be life changing for

some patients.

The decision to launch a medicine in Canada is at the discretion of the manufacturer, but is certainly influenced by the regulatory environment. Regulatory changes that may systematically change the number of medicines launched in Canada must be duly considered. This is very important point – Canadians want and need timely access **and** affordable drugs--not less access and cheaper drugs, and not less access to drugs at the same cost (as prior to the amendments).Thus any changes to the regulatory process must analyze potential unintended consequences that could inadvertently harm patients through creating delays and/or decreasing availability of new and innovative medicines in Canada.

The size of the market in Canada may be an important factor in the evaluation of the prices of medicines. However, it is not clear from the consultation document how this information will be used to guide pricing and the impact it will have on patients' access to affordable medicines. While the details are to be described in the guidelines to the regulations, it is not possible to provide meaningful input on this proposed amendment, as its application is unclear.

The potential impact of the proposed amendments on the research environment should also be considered. Diabetes Canada partners with organizations like Diabetes Action Canada to fund essential generation of new knowledge about the prevention, treatment and control of diabetes. Have unintended consequences on research been explored?

There is serious concern that the proposed changes could have a negative impact on access to important medications and other parts of the health system continuum.

RECOMMENDATION#5: Diabetes Canada recommends that the Government of Canada considers the availability of new drugs and the time to launching new drugs in the proposed countries to be added to the Schedule, in addition to the countries' similarities in terms of economics and consumer protection.

RECOMMENDATION #6: The Government of Canada releases its assessment of the potential countries that were assessed to be included in the Schedule along with the criteria for inclusion.

The proposed amendments will change the Schedule to include countries that are more aligned with Canada economically and from a consumer protection standpoint. The assessment of alignment should also include the comparison countries availability of new drugs and the time to launching new drugs. Specifically, in order for a country to be comparable, it needs to give its residents access to new and innovative treatments in a similar or faster way than residents of Canada currently, not only inexpensive drugs. Has this factor been considered in the selection of proposed countries to be included in the schedule? What is the availability of new and innovative drugs and how long does it take for new drugs to become available in the countries proposed to be added to the Schedule?

RECOMMENDATION #7: The underlying principle of the amendments is to provide more affordable drugs to more Canadians; Diabetes Canada recommends that any funds saved as a result of these amendments should be redirected toward improving greater access to appropriate drugs by all Canadians.

Health policy interventions must be evaluated over time. If indeed, the policy amendments are implemented and if there are savings realized it is essential that patients benefit from these savings. The funds should remain within the health system, and specifically should be used to improve appropriate, affordable, evidence-based treatments for all Canadians.

RECOMMENDATION #8:

Diabetes Canada strongly recommends that the Government of Canada provides patient groups with the information required to determine the impact of the proposed amendments on patient's affordability, accessibility and availability of medicines prior to proceeding with regulatory changes.

This respects the principles of transparency, openness, and meaningful patient engagement,

Conclusion

This submission represents Diabetes Canada's questions, concerns and input on the proposed amendments to the patent medicines act. Diabetes Canada works with the goal of enabling people with diabetes to optimally manage their condition and to achieve their health potential. Ultimately this is what matters to patients. This includes availability, accessibility and affordability, with each factor being intricately related to the other. One cannot consider altering one factor without examining the impact on the other. If Health Canada has considered the implications of the proposed amendments on cost (affordability) as well as availability and accessibility, it has not been well described in the consultation document.

Thank you for the opportunity to provide our perspective.