Dr. Jan Hux
President, Diabetes Canada

February 14, 2018

Patented Medicines Consultations
Karen Reynolds, Executive Director, Office of Pharmaceuticals Management Strategies
Strategic Policy Branch, Health Canada
10th Floor, Brooke Claxton Building
70 Colombine Driveway, Tunney's Pasture, Ottawa, ON K1A 0K9

Re: Response to the proposed amendments to the Patented Medicines Regulations

Dear Ms. Reynolds:

Please find attached Diabetes Canada's response to the proposed amendments to the *Patented Medicines Regulations* in Canada Gazette Part 1, Vol. 151, No. 48.

Improving medication access for Canadians is extremely important to our organization. People living with diabetes have a large stake in everything from drug research and innovation, to the process and timing of new products coming to our markets, to the way treatments are assessed, priced, reimbursed and prescribed. In order to be able to optimally manage their disease and realize their health potential, people with diabetes must have appropriate, accessible and affordable treatments.

We believe the federal government has a duty to develop an effective regulatory system for medications that is based on sound science, mindful of facilitating the best outcomes for Canadians and does not create additional barriers to access. In the policy and advocacy work we undertake to promote optimal therapy, Diabetes Canada is steadfast in our commitment to the following principles:

1. any one intervention must be considered in a broader context, as it may have far-reaching and serious effects in the health and research ecosystems
2. all suggested approaches must be in full partnership with patients, who will experience the benefits and harms of regulation

The development of the proposed amendments to the *Patented Medicines Regulations* violates both of these principles.

Health Canada needs to assess the issue of medication pricing in a much more comprehensive and systematic manner. It has neither made a convincing case that it has identified the challenges correctly, nor has it provided adequate evidence for its recommendations. On this file to date, Health Canada has failed to operate in a manner that is transparent, honest and collaborative, which is inconsistent with the values of good public policy making. Thus, we request a pause in this process by the Government of Canada, until such a time as stakeholder feedback can be meaningfully considered.

Diabetes Canada represents close to 11 million people living with diabetes or prediabetes – that is one in three Canadians. Our mandate is to stem the tide of diabetes and work to improve the lives of those afflicted, all the while searching for a cure. We speak on behalf of those with, or at risk of, diabetes, as well as their caregivers, their families and friends, and their communities.

People with diabetes have the right to timely access to medications that can help improve their health outcomes and may decrease the likelihood of future interventions, which are often more costly and less effective. Diabetes Canada will continue to work to end diabetes and would be pleased to be more fully engaged with Health Canada to improve access to optimal therapy. We hope our input to this consultation will help bring to life a process that is more open, inclusive, thorough and evidence-based henceforth. We look forward to being informed on next steps.

Thank you.

Sincerely,

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DIABETES CANADA

Regulations Amending the *Patented Medicines Regulations*

Diabetes Canada Response to Canada Gazette Part 1, Vol. 151, No. 48

February 14, 2018

Submitted to:
Patented Medicines Consultations
Karen Reynolds, Executive Director, Office of Pharmaceuticals Management Strategies
Strategic Policy Branch, Health Canada
10th Floor, Brooke Claxton Building
70 Colombine Driveway, Tunney's Pasture, Ottawa, ON K1A 0K9

Diabetes Canada is a national health charity representing 11 million Canadians living with diabetes or prediabetes. The organization leads the fight to end diabetes by helping those affected live healthy lives, preventing the onset and consequences of the disease, and working to discover a cure. It is supported in its efforts by a community-based network of volunteers, employees, health care professionals, researchers and partners. By providing education and services, advocating on behalf of people with diabetes, supporting research and translating it into practical applications, the organization is delivering on its mission.

The accessibility of diabetes medications, devices and supplies varies significantly within and across provinces and territories, presenting real barriers to Canadians trying to manage their diabetes. The costs of medications, devices and supplies may be covered by government programs and/or private insurance, including insurance through employers. If the costs are not covered, however, the financial burden may limit access to the treatments and supports required for diabetes management. For all payers – governments, private insurers and individual Canadians – the cost of medications is a real concern. The Canada Health Act, adopted in 1984, states that all Canadians should receive reasonable access to publicly funded, medically necessary hospital and physician services. The prevalence of chronic disease, its treatments and delivery of health care has changed over time and the health system must as well. It is high time for reform of the systems that offer access to medications in Canada.

A typical diabetes management regimen includes intensive lifestyle interventions and often prescription medication. Most people must concurrently take several antihyperglycemic, lipid-lowering, renal protective and antihypertensive agents to properly regulate blood sugar, minimize disease symptoms and decrease their risk of long-term complications. We know that the cost of drugs directly impacts adherence to treatment, with the burden being particularly heavy on those earning a low income. In a 2015 Diabetes Canada-led study, 45% of respondents with diabetes reported that they had to choose between food/rent/utilities and buying their medication; 18% said they did not fill their prescriptions or take medications because of the cost.[i]

People with diabetes must have the right medications that will allow them to achieve their health potential. Interventions to reduce medication pricing must not promote shortages, reduce availability, or deter innovative research and discovery. But the problems in Canada related to medication go beyond pricing. The affordability, accessibility and

availability of medication must all be in balance to optimize benefits to patients. Diabetes Canada endeavours to promote solutions that achieve this equilibrium.

When draft amendments to the *Patented Medicines Regulations* were made available for consultation in summer 2017, Diabetes Canada voiced major concerns, which other like-minded health charities and organizations shared, and provided feedback to the Patented Medicines Prices Review Board (PMPRB). We were dismayed to note in Canada Gazette 1 (Vol. 151, No. 48) that little to no consideration had been given either to the points we raised or the series of recommendations we proposed. Diabetes Canada supports policies that are transparent, evidence-based, fair, and inclusive of the patient perspective. The regulatory framework outlined in Canada Gazette 1 (Vol. 151, No. 48) has not benefitted from an honest discussion of the potential negative implications of the proposed amendments.

Moreover, the process with which the amendments were developed is not consistent with the values of good governance and policy making. Diabetes Canada has been shut out of the policy development process. Numerous attempts to seek additional information about the evidence to support the amendments and Health Canada's rationale for proceeding with a new regulatory framework were fruitless and left us exceedingly frustrated. In response to multiple requests and ultimately an Access to Information inquiry, we finally received a heavily redacted, and essentially useless, set of documents recently that did not provide us with any additional information about the rationale for these regulations. This is unacceptable. Instead of being a partner in creating regulations to reduce medication costs that could help to improve access to diabetes treatments in Canada, we have been forced to stand against the proposed policy, which, in its current state, we fear will adversely affect people living with diabetes, and the process with which it was developed, which greatly lacked integrity.

Our specific concerns are as follows:

1. **In this most recent consultation period, Health Canada did not sufficiently solicit and engage patients.**

The patient voice was notably absent from these consultations conducted on medication regulations. Health Canada made little effort to reach out to the Canadian public for reactions and input to the proposed medication pricing amendments. There was no real

forum for patients to share their feedback. Background information with rationale from PMPRB on the proposed amendments was unavailable. Open and free access to this information would have made it easier for people to provide informed commentary to Health Canada. The patient perspective enhances reform processes. Health Canada ought to have consulted the public much more thoroughly for the benefit of all stakeholders and the resulting proposed policy.

People living with diabetes must have an opportunity to have their say when it comes to a set of regulatory changes that will impact their ability to manage their disease. At Diabetes Canada, we are deeply aware that our constituents, and other Canadians who live with illness, have the most to win, or lose, through drug policy reform. The establishment of a multi-stakeholder group, including patient organizations and patient representatives, tasked with working on enhancing medication access, is essential. Where legislative amendments are needed, this group, working in an advisory capacity, could be ready to provide feedback and public policy recommendations to government on improving the affordability, availability and appropriate use of medications in Canada.

Recommendation #1: Health Canada should engage patient groups and patients more meaningfully through the establishment of an advisory group for medication policy reform.

2. The problems related to patented medicine pricing in Canada, and need for amendment, have not been fully described to stakeholders.

Diabetes Canada seeks to understand the problems Health Canada is attempting to correct with these legislative amendments. Medication pricing is a serious concern, but are prices truly too high? Health Canada has not convincingly shown that excessive pricing is a linchpin in the access debate. Issues pertaining to medication access extend far beyond price and these factors are not present in the discussion.

Patients require individualized treatments, including getting the right medications at the right time. Many things impact this and cost is only one factor. Furthermore, consensus is lacking on the metrics and data Health Canada has used to define the problem – namely that Canada's pricing of patented medications is among the highest worldwide. Greater consideration of the body of research and evidence is warranted to more fully describe the

problem and influencing factors, and to show that the proposed approach of modifying patented medication prices will improve access.

Recommendation #2: Health Canada should provide more information to explain the need for pricing amendments and draw from expert opinion, as well as extensively from the literature, to ensure it has accurately defined the problem.

3. Health Canada's proposed price regulatory mechanisms are nebulous.

Information is lacking with respect to the decision to consider certain practices in the excessive pricing determination, specifically:

- Is it necessary and appropriate to incorporate additional variables like GDP and market size into pricing assessments?
- How does the update to the schedule of reference countries used for international price comparison reflect Canada's economy and its aspirations regarding access to medications, including availability of new medications and time to launch of new medications?
- What impact will 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 make?
- How will processes and future opportunities in Canada for research and development be impacted as a result of these changes?

Health Canada may or may not have considered these issues, but a clear and transparent rationale has been withheld from the people who will ultimately experience the consequences of this public policy. It is impossible for Diabetes Canada to offer meaningful, appropriate feedback on price regulation without sufficient background information.

Recommendation #3: Health Canada should release its review and assessment of the various practices to determine whether a price is excessive and describe the rationale for why these proposed amendments were chosen.

4. There are major limitations associated with use of Quality-Adjusted Life Years (QALYs) that have not been adequately addressed.

The inclusion of QALYs in the assessment of a medication's inherent worth has the potential to lead to a flawed conclusion if it is not interpreted carefully. This is because the measure has restrictions in its use. QALYs change over time. The changes are not consistent over time. QALYs cannot be validated for every disease state. It is unclear how any of these issues would be accounted for in a medication's assessment. QALYs are also not the same across population groups and vary based on age, severity of disease, presence of comorbidities and other factors. It is important to know how these limitations will impact pricing considerations.

Furthermore, the proposed amendments fail to address possible inconsistencies that may arise in the interpretation of the QALY measure between assessing parties (e.g. Canadian Agency for Drugs and Technologies in Health [CADTH], PMPRB, pan-Canadian Pharmaceutical Alliance [pCPA]). There are no present plans we are aware of that acknowledge the need to integrate the various reviews that will come from different groups. This may prove problematic when the time comes to implement regulatory decisions. Incorporating QALY data into medication value assessments requires careful consideration and not enough clear evidence has been provided to how the use of this measure will be applied to the medication worth determination.

Recommendation #4: Health Canada should make the information related to its proposed use and application for QALY data available to stakeholder groups, in the spirit of openness and transparency.

Recommendation #5: The intention for Health Canada, CADTH, PMPRB and pCPA to cooperate, integrate and provide Canadians with better access to medications should be examined and widely shared with all stakeholders.

5. **As they stand, the implementation of several of the recommended changes to price regulation are beyond the current scope and mandate of PMPRB.**

Several proposals outlined in Canada Gazette 1 (Vol. 151, No. 48) suggest a departure for PMPRB from its traditional role, the need for which has neither been demonstrated nor approved. Historically, it has been Heath Technology Assessment (HTA) agencies, like CADTH, l'Institut national d'excellence en santé et en services sociaux and pCPA, that have been tasked with providing rigorous value-for-money analyses on various medications for the public payer. What is perceived as a change in PMPRB's role represents a duplication of

services between PMPRB and HTA groups. This is inefficient and a waste of Canadians' money, much of which comes from people who are jointly taxpayers and patients, hoping to benefit from these policy changes.

Recommendation #6: PMPRB must ensure that any and all responsibilities it assumes fall well within the boundaries of its mandate and that it does not act outside of its jurisdiction without specific discussion on the need to do so.

6. **Details about the intended use of the monies saved from the proposed amendments to regulations on patented medications have not been forthcoming.**

Living with diabetes represents a huge cost to individuals. Reimbursement for medication to treat diabetes is quite variable within and across jurisdictions. An individual's level of coverage significantly impacts out-of-pocket costs. Diabetes Canada estimates that adults with type 1 diabetes who rely solely on public coverage for therapy consisting of multiple daily insulin injections spend, on average, $1,100 to $2,600 a year to manage their condition, depending on their income.[ii] People with type 1 diabetes who meet medical criteria for insulin pump therapy and use an insulin pump must pay anywhere between $1,400 and $4,900 annually.[ii] Those with type 2 diabetes also face prohibitive treatment costs and can spend $1,200 to $1,900 every year on average.[ii] Third party payers may offset some medication costs, but many people report challenges in obtaining or affording private insurance. As a result, too many Canadians do not have insurance at all and end up falling through the cracks.

The cost-savings that the proposed amendments are projected to accrue need to be used to help improve the health of Canadians and must remain within the health portfolio. Health Canada has not detailed its plans with respect to this. Stakeholder groups and Canadians alike have the right to know what the government plans to do with these funds.

Recommendation #7: Any funds retained through new pricing mechanisms should be redirected toward improving medication use and access for Canadians, including those with diabetes. The government should disclose what its intentions are for monies saved.

7. **Very little information has been provided on the possible unintended consequences of the proposed regulatory amendments related to potential**

delays in access and reduction of access to new innovative medicines, among others.

Diabetes Canada and other patient groups continue to be very concerned about the relentless pursuit to implement regulations that may cause significant unintended consequences. There has been much discourse about the potential for these regulatory changes to have a negative impact on the number of medications that will be launched and the time to launch in Canada. These unintended consequences will have a lasting impact on the health outcomes of Canadians and disastrous implications to future generations.

Consequences, both anticipated and unintended, need to be fully considered and addressed publicly in order for stakeholders to understand, debate and accept the rationale for proceeding despite the risks, for mitigating policies to be instituted and/or for the likelihood of these potential harms to simply be dispelled. The action of Health Canada and PMPRB during this policy development process, however, has been to refuse to address these concerns head-on. The rationale for the secrecy is unclear.

Recommendation #8: Health Canada should release information on the assessment of unintended consequences that may adversely impact the timeliness of medication access, the viability of Canada's research and development industry, and the market for innovative medicines in this country.

In conclusion, we feel the policy process undertaken to amend the *Patented Medicines Regulations* violates the principles of honesty, integrity, transparency and meaningful partnership. The Government of Canada should therefore proceed with the regulations only when the points raised herein, and by other stakeholder groups, including those representing patients, have been appropriately addressed. Given the significant concerns that Diabetes Canada has with the content of Canada Gazette 1 (Vol. 151, No. 48) and the process with which it was developed, we ask that the Government delay implementing any changes until such time as the feedback can be considered in a sincere and fulsome manner. We would welcome the chance to meet with Health Canada officials to discuss our recommendations further.

Thank you for your consideration.

[i] Diabetes Canada. *2015 Report on Diabetes: Driving Change*. Toronto, ON: Diabetes Canada, 2015. Retrieved from https://www.diabetes.ca/getmedia/5a7070f0-77ad-41ad-9e95-ec1bc56ebf85/2015-report-on-diabetes-driving-change-english.pdf.aspx.

[ii] Estimated out-of-pocket costs for type 1 and type 2 diabetes are calculated based on composite case studies. As such, the estimates may reflect the out-of-pocket costs for many people with diabetes in Canada, but not all. The costs are 2015 estimates and may vary depending on income and age. For details on the methodology and estimates, please see the appendix in the Diabetes Canada's *2015 Report on Diabetes: Driving Change,* available at https://www.diabetes.ca/getmedia/5a7070f0-77ad-41ad-9e95-ec1bc56ebf85/2015-report-on-diabetes-driving-change-english.pdf.aspx.