August 4, 2020

Patented Medicine Prices Review Board
333 Laurier Ave. West, Suite 1400
Ottawa, Ont. K1P 1C1
Email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

RE: PMPRB Revised Draft Guidelines

To Whom it May Concern:

Thank you for the opportunity to provide feedback on the Patented Medicine Prices Review Board’s (PMPRB) Revised Draft Guidelines. Although we appreciate the changes made to the last iteration of the Guidelines, too many of the questions brought forward by the Health Coalition of Alberta remain unanswered. We are concerned about the uncertainty, complexity, lack of clarity and unintended consequences caused by the looming implementation of these Guidelines.

It is a laudable goal to lower medication prices, and one that our members support. However, this must be balanced with the need to secure robust access to new therapies and clinical trials in Canada. We urge the PMPRB to re-consider this approach and instead work with stakeholders to find a new methodology that is transparent, simple, and focused on the PMPRB mandate without over-stepping into areas already addressed by bodies like CADTH and pCPA.

As a member of the Best Medicines Coalition (BMC), we support their submission and encourage the PMPRB to implement BMC’s recommendations aimed at achieving effective, fair and balanced pharmaceutical pricing regulations. Many of our 100 members have also provided input to PMPRB that represents the views of patients from across the country. Although the PMPRB staff conducted briefing sessions during the past few months, these submissions are our only opportunity to highlight patient issues and bring awareness to health outcomes that may be impacted by the implementation of the Guidelines.

Who We Are:
The Health Coalition of Alberta is a group of 100 voluntary health sector organizations, consumer groups and individuals committed to working together and advocating with a united voice for better access to optimal healthcare for all Albertans. Primary initiatives of the Health Coalition include advocacy on key healthcare access issues, education of members and the public, and awareness regarding healthcare reform decisions and service changes which could impact Albertans, and particularly patients in their care pathways and health outcomes.

www.healthcoalitionab.ca
We envision a healthcare system which is available with equal and equitable access by all Albertans regardless of condition or disability, age, income status and geographic location. We also want a system that is universal, people-centered, evaluated as being effective and efficient, timely and transparent.

Access to medications is one of the key advocacy priorities identified by Health Coalition members (Health Coalition of Alberta Strategic Plan 2016-2020). All Albertans should have equal, timely access to medications. Patient health outcomes can be improved by appropriate access to medication, particularly access to new, more effective drugs.

**Our Concerns:**
Health Coalition of Alberta members have expressed concerns about the impact the proposed Guidelines may have on patients who require high cost medications or have health conditions requiring targeted therapeutics. Recent advances in medications have brought about an innovative era of personalized drug and treatment development that has transformed care in areas like oncology and rare diseases. We are worried that unique patient population health needs in these areas will be jeopardized by the Guidelines.

Our members are apprehensive about unintended consequences triggered by these Guidelines. According to a recent study conducted by Life Sciences Ontario (link), “In 2019, the year the drug price controls were adopted, there was a dramatic 40% drop in the number of new drugs launched in Canada – this despite the overall number of global launches rising during the year.”

Bio Alberta also reports to PMPRB that its members have experienced “job losses, reduced partnership investments, and a decrease in the number of clinical trials in our province at our primary research centres at the University of Calgary and the University of Alberta”.

Clearly, these reports highlight fears patients have that such sweeping reforms will result in fewer or delayed launches of new medications in Canada. Patients want faster new medication launch times in Canada with better access to therapies.

Will hospitalization rates increase with the potential reduced access to medications? Will Canada’s record high number of medication shortages increase due to dramatic price reform? Will we see reduced industry investment in patient support programs, the loss of which could trigger increased burden on our healthcare system by creating gaps in patient education and assistance? Will industry funded companion diagnostics and treatment clinics be eliminated, impacting access to established healthcare teams and drive up wait times and public system costs? Will this across-the-board restructuring create gaps in access for Canada’s vulnerable populations and reduce health outcomes for patients?

Unfortunately, none of these concerns have been addressed by PMPRB and the recent Guidelines have reinforced fears that once implemented, this will cause disruption to Canadians’ ability to access new medications in an equitable and timely manner.
Our Recommendations:

1. Create a simple, staged and flexible model that is an appropriate, consistent tool to regulate prices of medications in Canada.
   - Launch only the proposed basket of comparator countries to focus on achieving a 20% reduction in public list prices of medications, as the goal stated by the federal government in 2017.
   - Do not wade into regulating confidential rebates as this duplicates the mandate already established by pCPA on behalf of Canada’s public drug plans. These rebates do not impact patients who pay out of pocket due to lack of insurance or plan co-pays. A reduced medication list price will benefit both patients and payers equally.
   - Create flexible assessment options that incorporate other factors such as patient preferences to ensure access to high cost medications, promising medications with limited data, life-saving therapies, and treatments for rare diseases or those with limited therapeutic choices.

2. Evaluate for effectiveness and unintended consequences.
   - Develop a monitoring and evaluation system that includes public reporting.
   - Embed a process of patient engagement to capture any adverse impacts.
   - Conduct a historical analysis to set benchmarks for Canadian clinical trials, research investments, industry-led patient support programs, etc. to measure impact.
   - Assess improvements in numbers of new medications and time to launch in Canada.

3. Entrench patient perspectives in PMPRB.
   - Appoint public members to the Board and Human Drug Advisory Panel to ensure Canadian values are reflected in PMPRB’s goals.
   - Create an Expert Patient Advisory Panel to assess all projects through a societal lens.

It is our hope that PMPRB reviews submissions from Canadians like the Health Coalition of Alberta’s members and uses this feedback to develop an improved model to reduce medication prices while guaranteeing patient access to optimal treatments. If you have any questions about this submission, please contact the Health Coalition at director@healthcoalitionab.ca

Sincerely,

Beth Kidd
Executive Director