HEALTH COALITION
OF ALBERTA

403-605-2859
director@healthcoalitionab.ca
P.O. Box 81187 Lake Bonavista
Calgary, AB T2J 7C9

HEALTH COALITION OF ALBERTA

Submission to the
HOUSE OF COMMONS STANDING COMMITTEE ON HEALTH (HESA)

BRIEF RE: PATENTED MEDICINE PRICES REVIEW BOARD'S GUIDELINES

Beth Kidd, Executive Director
November 6, 2020

Introduction:

Despite providing patient feedback on the Patented Medicine Prices Review Board's (PMPRB) Guidelines for the past several years, there remains too many outstanding questions for Canadians to have confidence in the final Guidelines. The Health Coalition of Alberta appreciates the opportunity to bring patient concerns to the Standing Committee on Health. Our members are worried 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. Our core recommendation is to re-consider the current 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. We also support a step-wise, phased approach to implementation while conducting an immediate and fulsome assessment of impact on patients before moving to the next phase. The Guidelines implementation must be delayed until there is full public disclosure about the impact this will have on access to medications.

There are still far too many unanswered questions for the Health Coalition of Alberta to support these Guidelines. Although we requested evidence to support PMPRB's claims re: impact, we have not received any additional information that may help to alleviate fears this change will jeopardize patient health outcomes.

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.

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. 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[1] , "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[2] 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. Patients want faster new medication launch times in Canada with better access to therapies. In particular, the ability to re-assess prices every time a new indication is launched in Canada could have an impact on many disease states. For example, oncology treatments are approved for a particular tumour or gene mutation. As research continues, new discoveries are oftentimes made that prove the medication is effective for other gene markers or tumours. Focusing on drive down prices over time could easily serve as a disincentive for manufacturers to bring these additional discoveries to Canada and patient care will suffer.

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?

[1] https://lifesciencesontario.ca/canada-may-be-losing-its-status-as-a-top-global-destination-for-new-medicine-launches/

[2] https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/submission-received/june2020/June%202020%20submission_BioAlberta_EN.pdf

Will input from patients be gathered in order to measure the effect of the new Guidelines? How will impact to health outcomes be assessed? Do patient reported outcomes factor into PMPRB's new formula for measuring value?

Is there a guarantee that publicly funded drug plan savings generated by the implementation of these Guidelines will be re-directed into improving patient care? Will the savings be used to eliminate premiums or reduce patient co-pays? Will it help to expand the public drug formularies? How will this be measured? Have private insurance companies committed to directing medication price reduction savings towards providing enhanced coverage or rebates? How will this be measured?

We were told PMPRB conducted research to determine there were no delays in product launches, shortages of medications or reductions in clinical trials in other countries that implemented price reduction strategies similar to this draft. We asked to see this research but it was not made available for review. Many questions remain about this assessment. For example, were the comparator countries ones with both public and private insurance plans? Do the comparator countries have access to a similar number of clinical trials as we do in Canada? Once again, we request that this research is made publicly available.

Canada has a blended model for funding medications with many Canadians participating in private insurance plans. How was affordability and an individuals' willingness to pay threshold determined as both of these aspects can vary greatly for Canadians depending on their coverage. How were these factors set and included in the Guidelines' formulas?

Unfortunately, none of these concerns have been addressed by PMPRB and the 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. Delay the implementation of the Guidelines to allow for the development of a new methodology that is transparent and focused on the PMPRB mandate without over-stepping into areas already addressed by bodies like CADTH and pCPA.
2. Create a simple, staged and flexible model that is an appropriate, consistent tool to regulate prices of medications in Canada.
    a. 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.
    b. 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.

c. 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.

3. Evaluate for effectiveness and unintended consequences.
    a. Develop a monitoring and evaluation system that includes public reporting.
    b. Embed a process of patient engagement to capture any adverse impacts.
    c. Conduct a historical analysis to set benchmarks for Canadian clinical trials, research investments, industry-led patient support programs, etc. to measure impact.
    d. Assess improvements in numbers of new medications and time to launch in Canada.
4. Entrench patient perspectives in PMPRB.
    a. Appoint public members to the Board and Human Drug Advisory Panel to ensure Canadian values are reflected in PMPRB's goals.
    b. Create an Expert Patient Advisory Panel to assess all projects through a societal lens.

Summary:

It is our hope that the Standing Committee on Health's review of the PMPRB Guidelines will bring to light Canadian's fears that once implemented, this will cause disruption to Canadians' ability to access new medications in an equitable and timely manner. In fact, we believe these proposed actions will actually make medications less accessible and have a negative impact on health outcomes for Canadians. The Health Coalition of Alberta hopes the HESA review will trigger the creation of an improved PMPRB model to reduce medication prices while guaranteeing patient access to optimal treatments.

Contact:
Beth Kidd
Executive Director
Health Coalition of Alberta
(403) 605-2859
Email: director@healthcoalitionab.ca
www.healthcoalitionab.ca
@CoalitionAB