



Feb. 13, 2020

**RE: Patented Medicines Draft Guidelines**

To Whom it May Concern:

On behalf of the Health Coalition of Alberta, I am writing to express our views regarding the draft Guidelines to support the Patented Medicines Regulations. We are not confident that the proposed pathway to modernize PMPRB will improve access or affordability of new medications and are concerned this will actually trigger delays in launching new medications in Canada.

As members of the Best Medicines Coalition, we fully support their submission. However, after having met with a team from the PMPRB for a briefing on the Guidelines, we were asked to provide feedback on some areas. We have also provided a summary of our concerns as part of the consultation process for the Patented Medicines Regulations and refer you to that document as many of the questions we posed have not been fully answered.

Unfortunately, the draft Guidelines only reinforce 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.

**Who We Are:**

The Health Coalition of Alberta is a group of more than 90 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 (*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 and Questions:**

The release of the PMPRB Draft Guidelines has only resulted in further confusion regarding the potential impact caused by such sweeping reforms.

1. Patient groups have heard widely varying estimates from PMPRB, Industry and by conducting their own reviews. They indicate price reductions could be anywhere from 20- 30% upwards to 80-90% and that no specialized therapies will be able to meet the new QALY threshold. With such wildly differing assessments, there is no confidence these Guidelines present appropriate, consistent tools to regulate price.
2. Patients want to see faster new medication launch times in Canada with better access. Will these Guidelines lead to improving time to listings in Canada and expanding access to new medications? How will they improve the healthcare system in Canada as well as health outcomes for all? PMPRB has not provided evidence that the Guidelines will achieve these goals.
3. 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.
4. Canada has a blended model for funding medications with the many Canadians participating in private insurance plans. What assessment has been done to ensure leveling all payer markets to one lower price will not have a negative impact on patients? 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?
5. How did PMPRB determine that the \$60,000 QALY (quality-adjusted life year) is the correct threshold? How was the incremental increase allotted for drugs for rare diseases determined? Is there evidence that shows both these thresholds are sufficient in order to maintain or improve Canadians' ability to access new medications?
6. What measures are in place to prevent unintended consequences triggered by these Guidelines? Are benchmarks set to measure the number of new medications launched in Canada, timing of launch compared to other countries, number of clinical trials conducted in Canada, etc. over the past few years and will these factors be monitored beginning immediately after the Guidelines are adopted? What process is in place to evaluate the consequences of these changes?
7. How will input from patients be gathered in order to measure the effect of the new Guidelines? How will impact to health outcomes be assessed?

8. 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?
9. Have private insurance companies committed to directing medication price reduction savings towards providing enhanced coverage or rebates? How will this be measured?
10. Has the potential closure of industry-led patient support programs been assessed and, if so, what steps will be taken to ensure patients continue to have access to this service?
11. Do patient reported outcomes factor into PMPRB's new formula for measuring value? Is the use of value measurement tools even appropriate for a pricing regulation body?
12. Does PMPRB's introduction of pharmacoeconomics, and the use of QALY, not simply duplicate assessment that is already completed by CADTH? Why does this need to be done twice by two separate agencies funded by tax-payers?
13. If PMPRB moves to set a Maximum Rebated Price ceiling will this not cause another duplication of government agency function as this negotiation is currently conducted by the Pan-Canadian Pharmaceutical Alliance?

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 and evaluation, we have not received any additional information that may help to alleviate fears this change will jeopardize patient health outcomes. We do not see a clear link between the goal of achieving affordability with a guarantee of patient access to optimal treatments.

**Our Recommendation:**

Our recommendation is to delay implementation of the Guidelines until there is full public disclosure about the impact this will have on access to medications. 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.

If you have any questions about this submission, please contact me at [director@healthcoalitionab.ca](mailto:director@healthcoalitionab.ca).

Sincerely,



Beth Kidd  
Executive Director