

August 4th, 2020
Mr. Douglas Clark
Executive Director
Patented Medicines Price Review Board
1400- 333 Laurier Avenue West
Ottawa, ON K1P 1C1



Lung Health Foundation Feedback on the Patented Medicine Prices Review Board New 2020 Draft Guidelines

Dear Douglas Clark,

The Lung Health Foundation (previously the Ontario Lung Association) appreciates the opportunity to submit feedback to the PMPRB's 2020 Draft Guidelines. We too applaud your decision to delay the implementation of the regulations until January 2021 given the challenges posed by COVID-19.

COVID-19 has certainly put a spotlight on the value of health research and innovation. The Government of Canada has demonstrated their commitment with its \$1.1 billion investment in a national medical and research strategy. The attention shown to innovation in vaccine and treatments for COVID-19 must be expanded to other disease areas and met with a regulatory environment that encourages health innovation. To this point, while we acknowledge some of the positive changes we see within the new 2020 Draft Guidelines, we have prevailing concerns with the implications of the guidelines.

Knowing that future medications with the potential to save a lung cancer patients' life, or improve the quality of the remaining years of a COPD patients' life, will be delayed or not launched in Canada because of unthoughtful policy warrants disappointment by the patient community.

Positive Changes

We would like to begin by recognizing the positive changes within the new 2020 draft guidelines that will improve patient access to treatment options compared to the 2019 guidelines. We appreciate some of these changes which have signaled to the patient community that the PMPRB is willing to be responsive to stakeholder concerns.

- Improvements to access for grandfathered medicines with the application of the HIP test as opposed to the lower of the MIP. This amendment by the PMPRB eases some of our concerns around lung disease patients losing access to treatments that they currently rely on. We are pleased that the Board was able to acknowledge the devastating impacts that the previous approach could have had on patients.
- Increasing the market size thresholds so that fewer patented medicines fall under Category I.
- Setting the MLP of new patented medicines by the MIP from the PMPRB₁₁ countries, instead of the domestic Therapeutic Class Comparison, when the patentee has filed internationally.

While the Board has made some positive revisions that demonstrate your recognition of stakeholder concerns, this does not sufficiently address some of the overarching issues patient groups have with the guidelines.

Areas of Existing Concern

We continue to have issue with the PMPRB expanding its role outside of its mandate of ensuring the prices of drugs are not excessive. Broadening this mandate to including responsibilities such as negotiating drug prices (a matter of provincial/territorial jurisdiction), and making a determination on the economic value of a patient life, is out of scope and creates risks for patient access. Some of these implications are outlined below.

Innovative Treatments

We are aware of your thoughts on pricing being irrelevant to whether manufacturers choose to launch in Canada. We would like to once again reinforce that the uncertainty created by the proposed policy change could lead to decisions not to launch or to the delay the launch of innovative new medicines. An Innovative Medicines Canada study found that in the 9 months subsequent to the regulations being published, delayed or cancelled drug launches doubled to 42% in comparison to years prior.ⁱ Further, the same report outlines that the therapeutic area that will be most impacted by the changes is oncology. As an organization representing lung cancer patients, we are concerned that the reforms will restrict access to treatments for our most vulnerable patients.

The Lung Health Foundation conducted its own independent study to analyze the effects of the new PMRPB guidelines on lung disease treatments. While the results of the study show that the potential price reductions after the MRP calculations may be manageable to manufacturers, the degree of variation in price reductions and the level of unknowns may still lead to a delay in launches.

Specifically, the creation of different Therapeutic Criteria Levels and the ambiguity around their definitions creates a great deal of uncertainty on how drugs will be classified. The result of this is that the pCPA or payer negotiators who must attempt to make pricing decisions prior to the PMPRB review will likely delay their negotiations or negotiate higher price reductions than they might have otherwise. Both of these scenarios may manifest themselves as private decisions by manufacturers to not launch in Canada. This could be detrimental to patient outcomes and to the health care system, and we strongly urge you to consider the effects of these subtle nuances.

Clinical Trials

We also continue to be alarmed that if, due to the aforementioned reasons, a manufacturer does not plan on launching a drug in Canada, they will likely opt to launch clinical trials in another jurisdiction. For patients with lung cancer, where trials are often the only treatment option, this is not a risk the patient community is willing to concede.

According to Rawson (2020), the number of clinical trials registered in Canada between November 1, 2019 and March 15 2020 fell by 52 percent compared with the previous year.ⁱⁱ

Based on Health Canada data, the amount of approved clinical trials not related to COVID-19 in the first two quarters were 64 percent and 71 percent lower than the 2019 averages, respectively.ⁱⁱⁱ These findings echo the sentiment expressed by manufacturers in Life Sciences Ontario *Impact of PMPRB Pricing Changes* survey.^{iv} Manufacturers conveyed through the survey that they would not launch clinical trials in Canada due to the risk that they would need to continue to keep patients on a therapy without the prospect of reimbursement.

Vaccines

The Lung Health Foundation recently hosted a policy forum entitled *Immunization in the Age of COVID-19: Vaccine Development, Immune Responses, and Implications for Federal Policy* where Dr. Nigel Rawson presented on the changes to the PMPRB and how uncertainty may be a major disincentive to bringing new vaccines to Canada.

While the global research and pharmaceutical community is racing to discover a vaccine that will protect against the COVID-19 virus, and effective treatment options to treat those who have contracted the virus, the world awaits in anticipation. If and when these innovations are developed, imagine the outrage and disappointment Canadians would exhibit if they were not afforded timely access to these discoveries. Given our work in encouraging vaccine uptake and innovation to protect the lung health of Canadians, we remain concerned that subjecting vaccines to the PMPRB guidelines will result in novel vaccines not being introduced into Canada.

For example, innovations in the influenza vaccines have offered more robust protection against infection and against the potentially deadly effects of the flu. Due to the changing nature of the virus, immune responses of certain individuals, and the manufacturing methods used, there are extensive challenges with ensuring the effectiveness of influenza vaccines. A regulatory environment that cultivates innovation is necessary to drive vaccine uptake up, thereby pushing the incidence of influenza down. Including vaccines as a patented medicine under PMPRB jurisdiction puts access to vaccine discoveries at risk, not only for novel infectious diseases like COVID-19 but also for existing infectious diseases like influenza and pneumonia.

In light of the above feedback, we hope your Board recognizes that the complexity and ambiguous nature of the 2020 guidelines continues to put patient lives at risk. If the PMPRB had engaged patients and patient groups meaningfully from the onset, these concerns could have been mitigated. With the new implementation date approaching, we once again call on the PMPRB to offer more meaningful consultation opportunities where you can hear directly from patient representatives.

Recommendations

- (1) Introduce a phased approach to implementing the regulations. Begin by implementing the PMPRB₁₁ and after evaluating the effects of this change, introduce the pharmacoeconomic factors. This should be done once more clarity is given to the TCLs.
- (2) Exclude vaccines as a patented medicine subject to the guidelines.

Please do not hesitate to contact me if you have any existing questions, or would like to discuss this submission further.

Sincerely,



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ⁱ Innovative Medicines Canada (2020). Early Signs of Negative Impacts for Patients of Health Canada Pharmaceutical Pricing Reforms. Retrieved from <http://innovativemedicines.ca/wp-content/uploads/2020/06/20200630-CADTH-EarlySigns-FINAL.pdf>

ⁱⁱ Rawson, Nigel S. b. 2020 "Clinical Trials in Canada Decrease: A Sign of Uncertainty Regarding Changes to the PMPRB?" *Canadian Health Policy*, April 2020. Available at <https://www.canadianhealthpolicy.com/products/clinical-trials-in-canada-decrease--a-sign-of-uncertainty-regarding-changes-to-the-pmprb-.html>.

ⁱⁱⁱ Rawson (2020). The Patented Medicine Prices Review Board is Selling Canadians A Lemon: Nigel Rawson for Inside Policy. Retrieved from <https://www.macdonaldlaurier.ca/is-the-patented-medicine-prices-review-board-selling-canadians-a-lemon-nigel-rawson-for-inside-policy/>

^{iv} Life Sciences Ontario (2020). Impact of PMPRB Pricing Changes, Final Research Report. Retrieved from <https://lifesciencesontario.ca/wp-content/uploads/2020/02/Research-Etc.-PMPRB-Survey-02-03-20.pdf>