

August 26th, 2021
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 Proposed Amendments

Dear Douglas Clark,

The Lung Health Foundation, the leading national organization representing Canadian lung disease patients, appreciates the opportunity to submit feedback to the proposed amendments to the July, 1st 2021 guidelines. While we commend the decision to delay the coming-into-force date of the Regulations to January 1st 2022, we have prevailing concerns with the changes made to the Regulations, as well as the implications of the guidelines and support the need for a redrawing of the regulatory terms within this window.

We would like to reiterate points made in previous submissions to be clear that our opinion on this matter has not changed- we, among many in the patient community, continue to be gravely concerned about the consequences of the regulations and guidelines on access to treatment options for Canadian patients. In particular, our concerns lie in the need for timely access to new and innovative treatments for lung disease patients, ongoing access to the medications that our patients currently rely on, and access to clinical trials in Canada.

Proposed Amendments

First, we would like to comment on the proposed changes to the guidelines before getting into the overlying issues. The amendments made to the 'International Price Tests for Grandfathered Medicines and their Line Extensions' from using the highest international price to the median international price for setting the MLP in the interim will contribute to significant revenue reductions for the pharmaceutical industry.

The patient community remains concerned that this will detract from investments in research and development for new treatment options for our patient populations. In addition, with manufacturers offering patient support programs such as bridging and compassionate drug access options, revenue reductions may put these programs at risk.

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, creates risks for patient access.

The Federal Court of Appeal decision in *Alexion Pharmaceuticals v. Canada* articulates the dangers of the PMPRB going beyond its authority. “Over and over again, authorities have stressed that the excessive pricing provisions in the Patent Act are directed at controlling patent abuse, not reasonable pricing, price-regulation or consumer protection at large”

As expressed by the Court’s decision, the role of the PMPRB is to regulate excessive pricing *not* reasonable pricing. Given the existence of price control bodies like the pan-Canadian Pharmaceutical Alliance, the expanded mandate of the PMPRB is both unnecessary and out-of-scope.

To add to this point, while there is a clear and undeniable link between price control and access, the PMPRB has no responsibility for ensuring access to treatments. This dichotomy is problematic in that your Board is disconnected from the access continuum and pricing decisions do not need to be made with consideration of patient access.

We recognize that many Canadian patients struggle to pay for treatments. We are also acutely aware of the fact that marginalized and at-risk communities are overrepresented in this cohort. That said, making pricing decisions without recognizing the impact this will have on innovation and access to treatments is not beneficial to anyone.

The COVID-19 pandemic underscored the importance of having a thriving life sciences sector. Further discussions on how to achieve this in Canada while ensuring affordability of treatment options is needed. We welcome the opportunity to be engaged in these conversations and propose alternate solutions to the current landscape. Should you have any questions regarding our submission, please do not hesitate to contact me directly at pglazier@lunghealth.ca

Sincerely,



Peter Glazier
Executive Vice President
Lung Health Foundation
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