February 13th, 2020

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

The Ontario Lung Association's Stakeholder Feedback to PMPRB's Proposed Guidelines

Dear Douglas Clark,

The Ontario Lung Association is deeply concerned about the guidelines put forth by the Patented Medicine Prices Review Board on the proposed approach to the price review process. As a patient organization representing Canadians with lung disease, the guidelines fail to fully take into account the interests and values of Canadian patients. We believe the presented guidelines will further stifle innovation, discourage clinical trials, and delay the launch of new treatments in Canada -all things that patients desperately require. With this being said, we appreciate the opportunity to submit feedback to your government, and hope it is given the necessary attention.

Our concerns lie in the need for timely access to new and innovative treatments for our patient populations, as well as ongoing access to the medications that our patients currently rely on. This includes ensuring lung cancer patients can access innovative treatments such as precision medicines made possible due to recent scientific advancements. It also means that patients with chronic diseases such as chronic obstructive pulmonary disease (COPD) and asthma are entitled to be provided access to treatments that are incrementally better than the current options available. These treatments, although not considered breakthrough, can have a significant impact on a patient's abilities to perform day-to-day activities, and live life without unmanageable symptoms and side effects. The lack of consideration of the interests and values of patients, and threat to patient's access to treatments are the basis of our feedback below.

Clinical Trials

Many patients with lung cancer rely on access to clinical trials as a treatment option, particularly at advanced stages of the disease when trials are the best, and often final, treatment option for these patients. This is not limited to lung cancer patients, but applies to numerous oncology and rare disease patient groups. Clinical trials with molecular targeted therapies, as well as trials that offer combinations of targeted therapy and standard chemotherapy have demonstrated effectiveness in improving survival and quality of life (QOL) for lung cancer patients.[i] Moreover, general consensus among the lung cancer community determines that options to participate in clinical trials should be a part of standards of care for lung cancer patients.[ii] The guidelines proposed by the PMPRB threaten this access significantly.

The inclusion of a therapeutic class comparison may deter drug companies from launching novel clinical trials in Canada if the prospect of generating a return on investment is jeopardized. The International Therapeutic Class Comparison will result not only in a delay in launching drugs in Canada until prices can be negotiated in other jurisdictions, but also dissuade manufacturers from

bringing clinical trials to Canada. A study conducted by the Canadian Health Policy Institute, comparing 31 OECD countries, found that the price ceilings being suggested by the PMPRB will result in a "substantial decline in the number of industry-funded clinical trials in Canada."[iii] The improvement that clinical trials offer to individual patient survival and QOL, to future treatment options, as well as the overall benefit to the medical community should warrant a reassessment of the guidelines.

Delays and Threats to Accessing Medications

Preliminary research has revealed that the proposed guidelines generate a significant amount of uncertainty for drug companies seeking to launch new medicines in Canada. This uncertainty extends to existing medications given the decision to subject "grandfathered patented medicines" to the guidelines.[iv] This is of great concern from both an access and capacity perspective. First, the inherent risk of applying the new scheme to existing medications is that patients lose access to medications that they are presently relying on. If manufacturers are obligated to reduce the price of a treatment by a significant amount, or risk being shut out of the market, they may likely choose the latter dependent on revenue considerations. Second, we question how the PMPRB will have the internal capacity to review novel drugs entering the market as well as treatments that have already been reviewed and approved. As our patient's lives are dependent on timely access to treatments, further setting back the already delayed process is not only unacceptable, but unethical.

Basing pricing schemes on "comparable courses of treatment" is also problematic given the disregard for the clinical effectiveness and improvement in QOL that certain treatment options may offer patients. It is unclear how the PMPRB will weigh different factors in assessing appropriate price ceilings for medications. Additionally, the reasonable relationship test and comparable dosage forms indicated in the guidelines do not take into consideration the medical needs of asthma and COPD patients who have preferences on the inhaler device they use. There exist differences in quality of devices which can impact a patient's response to the treatment. The guidelines indifference to these nuances will impact patient's options in accessing orally inhaled products that best fit their individual treatment needs.

Moreover, the guidelines detail how pharmacoeconomic analysis in the price assessment process will influence decision-making. These stipulations alarm us given our existing concerns with HTA processes in Canada. The patient community has worked for many years, and continue to advocate for increased patient engagement at the HTA level. In recent years, CADTH has begun to take the concerns of patients more seriously by creating avenues for patient representation and input. Expanding the role of the PMPRB to utilize HTA in setting excessive price ceilings is not only stepping outside of PMPRB jurisdiction, but also creating risks for patients in being further locked out of pricing decisions that will ultimately affect them the most.

Inadequate Community Engagement

The direction taken to develop the guidelines was pursued with a lack of meaningful patient engagement, and without an understanding of the values and priorities important to patients across Canada. The PMPRB Steering Committee of Guidelines Modernization (SC) was not representative of all Canadian patients, with only three patient members being consulted. The SC

concerns have not at all been rectified in the guidelines, which validates that the PMPRB did not appropriately reflect or consider the insights provided by the patient members. In addition to this, the guidelines are complex and convoluted to the point that the proposed scheme is incomprehensible to most individual patient members and lay persons (for example, setting the MLP or MIP).

In consideration of the above feedback, we urge the federal government to reexamine the implications the guidelines will have for Canadian patients prior to the proposed July implementation date. We are certain that developing a framework for reasonably lowering costs, while maintaining a competitive market for global investment is indeed possible, if done in partnership with the patient community. Alternatives to the current framework that comply with the regulations such as considerations around transition periods and introducing other avenues for determining excessiveness should be discussed in greater detail with stakeholders. Patients need to be placed at the forefront of these discussions, and should be given the opportunity to actively participate in setting the context and direction of these consultations. To this end, we call on the Government of Canada to assess alternative options to the proposed guidelines through meaningful and comprehensive engagement with patient groups and patient representatives.

We welcome the opportunity to engage with the PMPRB through consultations, working groups, written submissions, or any other arrangement. Should you have any questions regarding our submission, please do not hesitate to contact me directly at pglazier@lungontario.ca.

Sincerely,

Peter Glazier
Vice President, Marketing, Development, and Public Affairs

Please note: effective February 26th, 2020 the Ontario Lung Association's name will change to the Lung Health Foundation.

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[i] Zaric, B., Perin, B., Ilic, A., Kopitovic, I., Matijasevic, J., Andrijevic, L., ... & Antonic, M. (2011). Clinical trials in advanced stage lung cancer: a survey of patients' opinion about their treatment. *Multidisciplinary respiratory medicine*, *6*(1), 20.

[ii] Lung Cancer Canada (2015*). 2015 Faces of Lung Cancer Report*. Retrieved from https://www.macleans.ca/wp-content/uploads/2015/11/Faces-of-Lung-Cancer-2015.pdf

[iii] Skinner, B (2018). Patented drug prices and clinical trials in 31 OECD countries 2017: implications for Canada's PMPRB. Canadian Health Policy Journal. Toronto: Canadian Health Policy Institute.

[iv] Rawson, N. S. B. (2019). New patented medicine regulations in Canada: a case study of a manufacturer's decision-making about regulatory submission for a rare disorder treatment. Can Health Policy. Toronto: Canadian Health Policy Institute; 2018.