PULMONARY HYPERTENSION ASSOCIATION OF CANADA

L'ASSOCIATION D'HYPERTENSION PULMONAIRE DU CANADA

December 5, 2022

Patented Medicines Pricing Review Board (PMPRB)
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Via Online Submission Form

Re: 2022 Proposed updates to the PMPRB Guidelines

Dear Members of the PMPRB,

The Pulmonary Hypertension Association of Canada (PHA Canada) represents a complex patient population. On the one hand, pulmonary hypertension (PH)—a serious, life-threatening condition characterized by high blood pressure in the pulmonary arteries, is relatively common—affecting an estimated 1% of the global population and up to 10% of the cohort over 65 years[1]. For most of these patients, there are currently no targeted therapies available to treat their PH. On the other hand, Group 1 PH—known as pulmonary arterial hypertension—is a rare disease affecting less than 10,000 Canadians. Like millions of other rare disease patients, people with PAH experience significant delays in receiving an accurate diagnosis and a profound lack of access to appropriate therapies to manage their condition optimally. Also, like other rare disease patients, their prognosis remains poor, with median survival after diagnosis of approximately 5 years[2] despite there being 11 PAH-specific medicines approved in Canada. It is on behalf of all these patients that PHA Canada writes to you today to urge you not to implement the proposed updates to the PMPRB Guidelines.

As we were in 2020, PHA Canada remains concerned that the PMPRB Guidelines will have a negative impact on PH patients by delaying or potentially even denying access to new medicines and clinical trials. The current iteration of the Guidelines creates uncertainty and complication while continuing to send the message that the PMPRB's policy objective is to drive down the cost of new medicines, rather than prevent patent abuse. Under the guise of "flexibility", the PMPRB has introduced a process of investigation that lacks transparency and risks a biased approach driven by the policy agenda of the PMPRB's staff. Meanwhile, by stripping the Guidelines of any consideration of therapeutic value in favour of a threshold related entirely to domestic therapeutic class comparison, incentives for bringing products that offer improvements over the existing standard of care are significantly diminished. With Canada already lagging behind the global average for the number of new medicines launched each year[3], it is reasonable for patients to fear that these Guidelines will cause further delay to the launch of innovative medicines in Canada. This lack of consideration of therapeutic value also risks reducing investments in research in Canada at a time when Canadians expect the federal government to be investing in solutions to the rising cost of medicines (such as domestic research, development, and manufacturing) rather than creating barriers. Finally, the Guidelines are also not consistent with the goals of the proposed Rare Disease Drug Strategy, which aims to increase access to effective medicines.

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[1] Hoeper et al. *A global view of pulmonary hypertension.* Lancet Respir Med. 2016; Apr;4(4):306-22.
[2] Weatherald et al. *The evolving landscape of pulmonary arterial hypertension clinical trials.* Lancet 2022; 400; 1884-98
[3] *Yearly trend number of New Active Substances launched in Canada and Globally: 2007-2021.* IQVIA MIDAS Database (as reported by CORD on November 18, 2022)

PHA Canada joins with other patient organizations to call on the PMPRB to undertake an incremental approach and first test the outcomes of the implementation of the new basket of comparator countries (PMPRB11) to lower list prices. The reductions in cost for both existing and new medicines are anticipated to be substantial and well within the thresholds previously established by the PMPRB. It is not the responsibility of the PMPRB to seek to drive prices down further in the name of "reasonability" or "affordability". Canada already has numerous other processes in place for achieving such policy objectives. The PMPRB must remain focused on its mandate to protect consumers from patent abuse and, in doing so, demonstrate to patients that it is not causing a reduction in access to medicines, especially for those with high unmet needs, such as PH patients. Regardless of whether these Guidelines are implemented with or without further changes, the impacts on patients must be fully studied through a multistakeholder process that centres the expertise of patient communities. As such, PHA Canada endorses the position of the Best Medicines Coalition that "the federal government ensures a truly independent evaluation of the impact of its Patent Act regulations by engaging a third-party entity to undertake fulsome consultations with all stakeholders to develop and ultimately implement a monitoring and evaluation regime for the PMPRB-related regulations"[4].

However, even if an independent evaluation were to conclude that patients were being harmed by the PMPRB's Guidelines, once implemented, these changes would be very difficult to reverse. It would likely take decades before another "modernization" took place. That is why the only reasonable alternative is the one that patients have been asking for all along – for the PMPRB to slow down and take an incremental approach to change that is driven by *all* stakeholders and based on *trusted* evidence. The government cannot expect patients to disregard the concerns of industry and place all their faith in the government's plans, especially when those plans in no way reveal a commitment to improving the health of patients. The Guidelines offered by the PMPRB do nothing to quell the fears of patients that Canada will become a second-tier country for clinical trials and the launch of new medicines. Instead, it has deepened the concern that the government is using the PMPRB to achieve policy objectives outside its jurisdiction.

PHA Canada exists to create a better life for all Canadians affected by PH. Ensuring PH patients have equitable access to timely and optimal treatment is critical to achieving this vision. Any policy that stands to decrease investments in Canada's life sciences sector or reduce Canada's standing as a top-tier market for new medicines fails to meet the needs of PH patients and cannot be supported by PHA Canada. We urge the PMPRB to exercise restraint and not push forward simply because the work of updating these regulations has gone on for so long. We welcome any opportunity to continue to support the work of the PMPRB by participating in a true multistakeholder process that aims to develop a policy that balances the need to protect consumers with the need to alleviate the suffering of patients. It is possible, but these Guidelines make it clear that we have not gotten there yet.

Sincerely,

Jamie Myrah
Executive Director

[4] Best Medicines Coalition. *Input Regarding PMPRB Proposed Guideline Monitoring and Evaluation Plan.* Submission to the PMPRB, July 21, 2021

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Background

Pulmonary hypertension (PH) is a rare and very complex lung disease which is progressive and potentially fatal. PH is defined by high blood pressure in the lungs, which leads to enlargement and weakness of the right side of the heart—a serious type of heart failure. PH can strike anyone regardless of age, sex, or social/ethnic background. While there is currently no cure for PH, many patients are living longer, healthier lives thanks to available treatments.

PHA Canada is a federally registered charity whose mission is to empower the Canadian pulmonary hypertension community through support, education, advocacy, awareness, and research. Since 2008, PHA Canada has brought together pulmonary hypertension patients, caregivers, and healthcare professionals to better the lives of Canadians affected by PH and represent a united national PH community.