PULMONARY HYPERTENSION
ASSOCIATION OF CANADA

L'ASSOCIATION D'HYPERTENSION
PULMONAIRE DU CANADA

12 March 2025

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

Via Online Submission Form

Re: Draft Guidelines for PMPRB Staff: Administrative Process for Excessive Price Hearing Recommendation

Dear Members of the PMPRB,

In September 2024, the Pulmonary Hypertension Association of Canada (PHA Canada) offered our feedback to the PMPRB on the new Guidelines during the consultation phase. On behalf of Canadians affected by pulmonary hypertension (PH), a serious, progressive, and life-threatening condition characterized by high blood pressure in the lungs, we are pleased to comment on the Draft Guidelines. In this submission, we offer further input the seven topics on which the PMPRB sought comment during the earlier consultation phase.

Topic 1: Price level within the PMPRB11 to be used in the initial and post-initial price review

We agree that the highest international price (HIP) is an appropriate and efficient threshold (section 51), assuming the countries in the PMBRB11 are suitable comparators for Canada.

Topic 2: The length of time Staff should wait, following the implementation of the Guidelines, to determine whether the IPC identification criterion for an Existing medicine is met

We agree that one year after the guidelines take effect is a reasonable adjustment period for Rights Holders (s.55).

Topic 3: In-depth review based on CPI increase criteria

We agree that using the one-year increase in CPI unless the Rights Holder did not take a list price increase in the previous year and the increase in the second year is lower than or equal to

the total change in CPI over those two years offers adequate predictability and transparency for Rights Holders (s.62).

Topic 4: The individuals/groups permitted to submit a complaint

We agree that allowing private and public payors as well as Federal, Provincial, or Territorial Ministers of Health offers a good balance between openness and efficiency (s.67).

Topic 5: Expanding the list of products that would only be subject to an in-depth review following a complaint to include biosimilars and/or vaccines.

We agree with s.65: there is no need to expand the list of products subject to an in-depth review only when a complaint is received beyond patented generic medicines, over the counter medicines and veterinary medicines. In future, the inclusion of biosimilars and vaccines could be added to this list to increase efficiency.

Topic 6: Use of clinical evidence to contextualize the degree of similarity of comparators identified for the TCC

We were pleased to see that each comparator will be assigned an individual level of similarity (s.77). In complex conditions with a small patient population such as pulmonary arterial hypertension, newer medications, which are often more expensive, can add significant value and should not be grouped with older (often generic) medications.

Topic 7: Future role of Human Drug Advisory Panel (HDAP)

We were pleased to see that the HDAP will continue to be available to PMPRB staff (s.87). For rare diseases such as pulmonary arterial hypertension, the ability for staff to seek additional clinical or scientific expertise is important.

Conclusion

While we recognize that assessments are conducted from a population therapeutics perspective and not from the perspective of needs of individual patients and are not intended to address all circumstances (s.76), we encourage the PMPRB to consider the needs of patients with rare diseases, who, by definition, are unusual in both their disease and their circumstances.

Thank you for the opportunity to provide further feedback on the Draft Guidelines. As a patient organization, we welcome all opportunities for input and collaboration; it is critical that we work together to achieve an efficient, fair, transparent, and effective drug pricing system in Canada.

We hope PMPRB staff will find the Guidelines add clarity and help expedite product reviews for the benefit of all Canadians. We look forward to hearing about the impact of these changes and hope that PMPRB will report on ongoing monitoring and evaluation efforts as we all pursue better outcomes for patients.

Sincerely,

Joan Paulin
Chair, Board of Directors

Jamie Myrah
Executive Director

Background

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 pulmonary hypertension and represent a united national PH community.

Fewer than 4,000 Canadians have pulmonary arterial hypertension (PAH), a rare, clinically distinct, complex subtype of pulmonary hypertension. Like all types of pulmonary hypertension, PAH 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. PAH can strike anyone regardless of age, sex, or social/ethnic background.

Patients with pulmonary arterial hypertension experience barriers at every stage of their journey: an accurate diagnosis often takes months or years; pulmonary hypertension expert centres are located in urban centres and require regular visits for optimal care, often necessitating significant travel; and, despite 11 approved PAH-specific medicines so far, median survival after a pulmonary arterial hypertension diagnosis has plateaued at only approximately five years[1]. For PAH patients and many other patients with rare diseases, access to new, innovative medicines and enhanced access to existing medicines is essential for improving their health outcomes and quality of life.

[1] Weatherald et al. The evolving landscape of pulmonary arterial hypertension clinical trials. Lancet 2022; 400; 1884-98