PULMONARY HYPERTENSION ASSOCIATION OF CANADA

L'ASSOCIATION D'HYPERTENSION PULMONAIRE DU CANADA

August 4, 2020

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

Via Email: ***PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca***

Re: PMPRB Draft Guidelines 2020

Dear Members of the PMPRB,

For more than a year we have anxiously contemplated the implications of changes to the PMPRB regulations/guidelines. We have attempted to educate ourselves on the complexities of the proposed changes and to appreciate the broader policy goals of the Board in modernizing this regime. We have attempted to keep an open mind. We have made our best efforts to meaningfully participate in this consultation process, such that the concerns of people living with pulmonary hypertension (PH) might be considered. Yet, our understanding of the *solutions* proposed by the guidelines remain tenuous at best. Meanwhile, the fear that Canadian patients—especially those with rare diseases—will *suffer* as a result of these changes is as strong as ever. If we have learned anything through this process, it's that the PMPRB has not done enough to gain the confidence of rare disease patients in Canada.

So, in February we joined the chorus of patient groups calling for more accountability and we are pleased to see this call answered in the 2020 draft guidelines in the form of the Guideline Monitoring and Evaluation Plan (GMEP). This commitment to track the impacts of the guidelines, including on access to medicines, is a promising development in the evolution of this framework. It also seems to be the bare minimum of best practices and it's unclear why the GMEP was not included in the first draft of the guidelines. It makes us wonder how we can trust that the GMEP will be implemented in good faith, rather than becoming a communications tool used to placate noisy patient advocates. The GMEP must be a vehicle for patients and advocates to provide real world evidence to the PMPRB and to ensure barriers to treatment are not being erected in the name of "cost containment".

Reasonable people will always be able to disagree on the appropriate balance between the opportunity costs of providing treatments to people with rare diseases (less money for other drugs) and the opportunity cost of *not* providing treatments to people with rare diseases (more costs on other parts of the system). To be fair, these are difficult lines to draw. Yet, people with rare diseases are routinely labeled a burden due to high treatment costs, while countless unnecessary dollars are spent on hospitalizations and other cascading health and social care costs. Ultimately, what is not reasonable is a policy lens that aims solely to reduce costs and not to

enhance patient care or improve patient lives. The PMPRB has an opportunity to shift this lens, join with patients and other stakeholders, and work together towards a framework that aspires to expand care and treatment, improve patient outcomes, and provide transparency to consumers and payers alike.

In regard to the specifics of the 2020 draft guidelines, we join with the Canadian Organization of Rare Diseases (CORD) and other like-minded advocacy organizations to call on the PMPRB to slow down the implementation of the proposed changes. Changes to the basket of comparator countries alone should create a substantial shift in pricing that should be evaluated before further measures are taken. We support an incremental implementation plan, rather than a total adoption of an entirely new and untested model. We also support CORD's call for a public debate on alternative options. Patient groups have been presented with competing visions of the future and conflicting evidence of the past. We deserve the opportunity to explore alternatives, assess real world impact, and propose models that have the potential to provide earlier access to innovations rather than delayed or denied access.

PMPRB still has the opportunity to truly partner with patients to help bring world-class medicines to Canada. PMPRB has the power to create a policy framework founded on fairness, transparency, and equity for all Canadians. We urge you to continue your work with CORD and others, and to delay the full implementation of the 2020 draft guidelines until greater clarity and consensus can be achieved.

Sincerely,

Jamie Myrah
Executive Director