















October 14, 2021

Dr. Mitchell Levine Chair, Patented Medicine Prices Review Board (PMPRB) 333 Laurier Avenue West, Suite 1400 Ottawa ON, K1P 1C1

Subject: Request to postpone decision on July 15, 2021 PMPRB Guidelines changes

Dear Dr. Levine,

As leaders of eight of Canada's provincial health and life sciences organizations, we are writing to express concerns about the PMPRB's impending decision on the above-noted proposed Guidelines changes. We strongly believe you should postpone any decisions related to this initiative for several important reasons.

First, it would be untimely to take a final decision on these changes before the opening of the 44<sup>th</sup> parliament, following the recent federal election. This initiative is part of a major change to Canada's pharmaceutical pricing environment, and it merits careful assessment by political leaders, many of whom ran on a mandate to help bolster our health system, life sciences research and manufacturing capacity to finish the fight against COVID and build back better. It is worth noting that this initiative also runs contrary to the 5<sup>th</sup> pillar of the Federal Biomanufacturing and Life Sciences Strategy, which strives to enable innovation by ensuring "world class regulation." We strongly recommend waiting until new ministers and other political appointments have been made, mandate letters have been issued, and decision-makers have been briefed on this issue before moving forward.

Secondly, and on a related note, the proposed changes are creating significant uncertainty for the Canadian market. The changes to price tests for Grandfathered medicines were initially proposed, universally criticized, later abandoned, and now unilaterally proposed once again by the PMPRB without any explanation. Companies need predictability and stability to operate and guide long-term planning. This unexpected change further reduces Canada's attractiveness as a place to do business.

Lastly, when added to the PMPRB regulatory changes, which are still undergoing significant legal challenges (one that includes the province of Quebec), this latest initiative serves as a cumulative, additional, and unnecessary deterrent to the Canadian market for life sciences companies. This is particularly troubling at a time when our country is confronted by the fourth wave of the pandemic and federal and provincial governments are actively trying to create a more attractive business and policy environment for these same companies.

This proposal demonstrates that a broad range of the PMPRB's regulatory activities are subjective, unpredictable, and unreasonable, and these issues need to be reviewed by political leaders.

In sum, it would be inappropriate and irresponsible to move forward on taking a final decision on the proposed changes at this time. It would be prudent to reconsider the present initiative and take the time to assess the extent of its impacts on companies and federal and provincial life sciences growth imperatives before moving forward.

We trust that this letter will resonate with you so that we, as a sector, can all constructively move forward. We remain available for any questions you or your officials may have about this request.

Sincerely,

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cc. The Honourable Patty Hajdu, Minister of Health
The Honourable François-Philippe Champagne
Michelle Boudreau, Executive Director, Office of Pharmaceuticals Management Strategies