February 15, 2021

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

Delivered via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Response to: Consultations on the PMPRB's proposed changes to definition of Gap medicines and the timeline for compliance

To: PMPRB Board Members,

BioAlberta is the central voice and champion for Alberta's life sciences sector. We are a member-driven, not for profit industry association for a sector of Alberta's economy that has over 300 biotechnology companies and employs over 15,000 people. Our ecosystem includes researchers involved in drug discovery and clinical trials, emerging companies who are commercializing the next modern and innovative therapies to keep Canadians health and safe, and global pharmaceutical companies on the leading edge of our health and innovation sectors.

BioAlberta has been opposed to both the process and consequences of Health Canada's PMPRB regulations since they were first published. Neither Health Canada nor the PMPRB have engaged industry in a meaningful way to reach objectives that all of us should aspire to:

- Provide Canadians with a secure supply of safe innovative therapies
- Fairness in pricing
- A policy framework in Canada that balances pricing with access, recognizing that health system cost and security of supply are mandates of the provinces as the deliverer of health services in Canada
- Policies that recognize the importance of research and commercialization as the foundation of Canada's modern economy, and the importance of remaining competitive in the global competition for investment in research

We thank you for the opportunity to provide feedback on the PMPRB proposed Guideline changes to the definition of Gap medicines and the timeline for compliance. BioAlberta's position is that the regulation changes to PMPRB do not advance any of the above objectives, and in fact the negative impact to Alberta and Albertans is significant and unacceptable. Specific to feedback on definition and timelines related to Gap

medicines, the PMPRB's proposal to halve the transition period for companies to comply with the new Maximum List Price requirements for Grandfathered and Gap medicines is particularly troublesome. The rush for compliance by the end of calendar 2021, when challenges continue on the development and rollout of COVID-19 vaccines amid bolstering our stretched healthcare system, is not acceptable to us and our members. It will divert companies' attention and resources away from the crisis at the worst time possible.

BioAlberta has actively monitored developments related to the PMPRB reforms since they were first introduced and has engaged with government officials, members and other stakeholders out of concern for the potential impacts of the new rules on Canada's diverse life sciences ecosystem and our sector's efforts to support Canadians and the innovation economy at a time when they are need most.

Effects of the proposed changes are being felt on the ground in Alberta. Even though the new pricing rules are set to take effect now in July, we are already seeing **job losses, reduced partnership investments, and a decrease in the number of clinical trials in our province**. We've also been made aware of a number of **drug launches that have been delayed or suspended**. Given that the life sciences sector is an important source of jobs for Albertans and key to the economic diversification of our province, the uncertainty of the proposed changes has begun and will impact the growth of this important sector.

Overall, the proposed draft guidelines are inconsistent with an excessive price standard as reflected in the *Patent Act*. The approach goes way beyond the core objective of the PMPRB which is to prevent abuse of patent. The changes mean that medicine developers are unable to reliably predict allowable price, protect sensitive confidential business information, and provide a fair and appropriate transition for current products on the market in Canada. Each of these components of uncertainty have the unintended consequence on the viability of our life science sector in Alberta.

For these reasons, we strongly urge the PMPRB to:

1) **In the short term, provide a minimum 12 month period (as originally proposed) as opposed to the revised proposed 6 month transition period for Gap medications.**
2) **In the longer term, facilitate and support alternative solutions to meet the government's twin objectives of affordability and access to medicines.**

This has to be done immediately to avoid further impact to our life sciences ecosystem, and our sector's ability to continue to contribute to Canada's rescue, recovery, and resilience efforts, which have never been more important.

Most of all, we feel there is significant risk of impact to **Alberta patients**. With anticipated reductions of product launches, particularly of innovative oncology and rare disease medications, access to therapies that have a significant impact on overall survival and quality of life as Albertans, impacts patients, families and the ability of healthcare professionals to provide the best medications available to their patients. Through this process, there is limited accountability to the patients and the provinces who are responsible for the delivery

of healthcare at the local level. These proposed Guidelines undermine the provincial government's ability to ensure health accessibility or to compete effectively for life science investment on a global scale.

It is important that changes are done right with broad support and involvement. The potential of years of changes, retrenching and tweaks negatively impacts our ability to attract investment and partnerships in life sciences to Alberta.

We welcome the opportunity to be a part of future initiatives that impact our members in Alberta and across Canada.

Submitted on behalf of the members of BioAlberta,

Robb Stoddard
President & CEO