August 31, 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 (July 15, 2021) to definition of gap medicines, references to comparator countries and the international price tests for grandfathered medicines and their line extensions

To: PMPRB Board Members,

We thank you for the opportunity to provide feedback on the PMPRB proposed Guideline changes to the definition of gap medicines, references to comparator countries and the international price tests for grandfathered medicines and their line extensions.

BioAlberta is a member-driven, not for profit industry association for Alberta's life sciences sector, a contributor to Alberta's economy of over 300 biotechnology companies and employment for 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 healthy and safe, and global pharmaceutical companies on the leading edge of our health and innovation sectors.

BioAlberta remains opposed to both the process and content of Health Canada's PMPRB draft regulation proposals since they were first published. Health Canada has not 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

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- 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.

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. Upon review of the July 15 proposal, we find the same arbitrary approach by the PMPRB, one which is inconsistent with the PMPRB's legislative mandate to ensure that the prices charged for patented drug products are not excessive. In fact, the proposed changes shorten the transition faced by industry to adjust to new regulations, introduce significant new negative and burdensome impacts for patentees' existing products, and result in further market uncertainty. This comes at a time when the Canadian economy is struggling to recover from the negative impact of COVID-19 and the emergence of the Delta variant and corresponding "fourth wave." Further, Government of Canada's decision to call an election has increased the level of uncertainty facing Canadian business. For the industry most impacted by COVID, the proposed PMPRB regulations and the uncertain role of the new Canada Drug Agency and its impact on provincial health providers and their drug plans, the clock ticks away towards another arbitrary date.

With anticipated reductions of product launches, 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 impacts are directly opposite of the intention of the current government, each political party and Canadians as a whole. Canadians want and should expect to have access to health innovations that improve their life and their health. 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 regulatory changes that directly impact Canada's innovation economy as well as province's ability to predict and manage drug supply and costs are done right, with broad support and involvement. The proposed guidelines will add to the uncertainty and unpredictability within the entire life sciences sector. These changes, and the unwillingness of the PMPRB to engage in meaningful consultation with all stakeholders, do not allow for an innovative health eco-system, and conflicts with the Government of Canada's desire to implement its recently released Biomanufacturing and Life Sciences Strategy.

It's time for the Government of Canada to abandon all proposed changes to PMPRB and its archaic, arbitrary and irrelevant methods, and focus on how to improve the pan Canadian approach that has evolved in the past 10 years that reinforces the role and accountability of the provinces as the planners and operators of our health system. The PMPRB and the framework for investment and pricing that was a great policy innovation of the 1980s no longer has relevance within the health system and will impact our ability to move to a modern and agile economy.

The potential of further years of changes, retrenching and tweaks negatively impacts our ability to attract investment and partnerships in life sciences to Alberta. It impacts the health system in Alberta and potentially the health of Albertans. This flawed process needs to stop, and a process that involves government and industry in a meaningful engagement is the best path forward to a high-quality health system and an innovative economy.

Submitted on behalf of the members of BioAlberta,

Robb Stoddard
President & CEO