

December 5, 2022

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

RE: Response to: Consultations on the PMPRB's proposed changes (October 6, 2022)

We thank you for the opportunity to provide feedback on the PMPRB proposed guideline changes released on October 6, 2022.

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. There was hope that the recent decisions from the Courts would bring renewed interest in Health Canada working collaboratively with industry and provinces to develop a policy framework that respected the regulator role of the PMPRB (safeguard against abuse of patent rights and report on pricing trends) and the provinces' role as the provider of health services to citizens and procurer of supplies required to fulfill that role.

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 at a fair price
- 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.

After review of the October 6 guidelines, BioAlberta's position is that the proposed guidelines do not advance any of the above objectives, and in fact, the negative impact to Alberta and Albertans is significant and unacceptable. The new guidelines offer an approach by the PMPRB that attempts to

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maneuver past the boundaries confirmed by recent court decisions to position the PMPRB not as the regulator of unreasonably high prices, but as the regulator of pricing of pharmaceuticals across the health system. This role is not within the mandate of the PMPRB and conflicts with the role of the Pan Canadian Pharmaceutical Alliance (PCPA), a collaborative effort by provinces to achieve the best price possible balanced against the supply needs of each provincial health system.

Increasing Uncertainty at the Wrong Time

We question the sincerity of the PMPRB with respect to this consultation. The proposed guidelines were released on October 6, 2022 with a December 5, 2022 deadline for submissions. While this is an adequate time to solicit quality feedback, the proposed guidelines are to take effect on January 1, 2023. There is less than a month, including Christmas, to review feedback, report back to industry and Canadians on any revisions and industry to prepare for the implementation of the guidelines. Industry is confused as to the intent of the PMPRB, whether it is to implement the guidelines as presented on the January 1 date, or if there will be another extension or delay to be proposed by PMPRB.

We also question the clear conflict in policies by the Government of Canada. The price activism proposed by the PMPRB conflicts with a whole government approach by working against the direction established by the National Strategy on Drugs for Rare Diseases, and more important, the Biomanufacturing and Life Sciences Strategy.

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 ecosystem that can compete globally for clinical trial research as well as drug discovery and commercialization.

Once again, we must request that the PMPRB abandon its proposed guidelines, and that Health Canada engage with provincial policy makers and industry in a meaningful redesign of Canada's supply of innovative medicines. Ill-conceived proposals such as the PMPRB guidelines released on October 6 perpetuate the years of proposal, retrenching and tweaks that negatively impact 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

Copies of this submission provided to the following:

Hon. Jean-Yves Duclos, Minister of Health, Health Canada
Hon. Jason Copping, Minister of Health, Alberta Health



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