July 18th, 2022

Douglas Clark, Executive Director
Patented Medicine Prices Review Board (PMPRB)
Box L40|Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario, K1P 1C1

Dear Mr. Clark,

BIOTECanada is providing written feedback on the PMPRB's proposed *Price Review Approach During the Interim Period following publication of Amendments to the Patented Medicines Regulations*. The more than 230 members of BIOTECanada include innovators at all stages of the product lifecycle from basic research and development to commercialization. BIOTECanada members are at the forefront of producing the next generation of health care solutions and biologic based medicines, including vaccines, therapies for rare diseases, cell therapies and many new dynamic technologies holding great promise for the future of healthcare.

The pandemic has demonstrated the value of a constructive industry-government relationship and it will be important to maintain this momentum over the period ahead. The government considered the patented medicines regulatory framework modernization within the context of more holistic strategies to improve sustainability and access to the best available medicines in Canada while investing in Canada's biomanufacturing and life sciences strategy[i] and national strategy for drugs for rare diseases[ii]. These new initiatives recognize the nature of a healthy biotechnology ecosystem that includes active investments and partnerships with multinational biopharmaceutical companies. Operating on a global scale, these companies rely on a competitive regulatory, reimbursement, and pricing environment granted by our governmental entities, including the PMPRB.

Recent court rulings have invalidated elements of the 2019 proposed amendments to the Patented Medicines Regulations while significant savings will be achieved with the implementation of the new basket of comparator countries set out in the Amendments to the Patented Medicines Regulations.[iii]. According to guidelines in effect prior to July 1st 2022[iv], guidelines are intended to uphold transparency and predictability to patentees regarding the process followed by the PMPRB in establishing if a patented medicine is priced excessively. Patent holders wish to remain compliant and avoid unnecessary penalties upon transitioning to the new guidelines. In this context, patent holders understand that all reasonable interpretations of the interim guidance will be recognized as compliant with the proposals.

With respect to the PMPRB's proposed price review approach during the interim period, BIOTECanada supports an approach that limits disruption of ongoing practices and does not create administrative burden based on temporary rules. BIOTECanada acknowledges the need to balance the timeline of this consultation with the need to quickly determine interim measures. To allow a process with a robust and meaningful engagement, proper time to reassess proposals and relay information back to global teams, a longer timeline of at least 3 months for the upcoming consultation on the proposed final guidelines is required.

Below, BIOTECanada members are making a number of assumptions about the interim measures and status quo approach suggested by the PMPRB, for clarification:

1. **Vaccines are managed through a complaint-based approach:** Given the low risk of excessive pricing for vaccines due to the procurement ("tendering") process, vaccines will be managed by Health Canada/PMPRB through a "complaint" based approach similar to veterinary, over-the-counter and generic products.

2. **Two reporting periods to comply with the result of an investigation:** The interim measures indicate the criteria that would trigger an investigation but do not provide information regarding how an investigation will be conducted. In the event of an investigation, the industry requests the PMPRB provide no less than 2 reporting periods to comply with any result of an investigation. For vaccines, no investigation will be conducted unless a complaint is received, and the vaccine's list price is deemed not to be compliant.

3. **CPI adjustments will begin in January 2023:** According to the *Patent Act*, price increases may reflect a change in inflation as measured by the consumer price index (CPI) and would in fact normally be observed under a "status quo". Industry will appropriately adjust prices to reflect inflation starting in 2023, if the interim period remains in effect longer than the period initially anticipated by the Notice and Comment document. It is assumed that these price increases will not trigger an investigation and that CPI will be included in the future guidelines.

4. **Ensure new guidelines are consistent with the PMPRB's mandate:** BIOTECanada acknowledges that there is no guidance for new products launched during the interim period. Industry anticipates that the new guidelines will reflect the legal framework underpinning the PMPRB's mandate and that upon introduction of these new guidelines, fair measures will be taken to ensure continuity and limit disruption.

Thank you for this opportunity to provide feedback on this consultation. BIOTECanada and its member companies are committed to working cooperatively with the PMPRB to continue to establish drug pricing policy that ensures the health of Canadians and provides for a sustainable health care system. BIOTECanada will collaboratively work with government to ensure Canada's competitiveness as a destination for innovation continues.

Sincerely,

Andrew Casey
President & CEO

[i] Canada's Biomanufacturing and Life Sciences Strategy
[ii] Building a National Strategy for Drugs for Rare Diseases: What We Heard from Canadians - Canada.ca
[iii] Canadian patented drug prices: Gauging the change in reference countries (pbo-dpb.ca)
[iv] Preamble, Compendium of Policies, Guidelines and Procedures - Updated February 2017 (pmprb-cepmb.gc.ca)

600-1 rue Nicholas Street, Ottawa, Ontario, Canada K1N 7B7
☎ 613.230.5585 🖷 613.563.8850 • www.biotech.ca