August 21st, 2023

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

RE: BIOTECanada's submission to the Patented Medicine Prices Review Board's consultation on amending the Interim Guidance regarding new medicines

Dear Mr. Couillard,

BIOTECanada welcomes the important and timely opportunity to provide written feedback on the Patented Medicine Prices Review Board's (PMPRB) proposed *Amendment to the Interim Guidance regarding New Medicines* (the Interim Guidance).

BIOTECanada is the national industry association with over 240 members located across the country and reflecting Canada's health, industrial and agricultural biotechnology sectors. The Association's membership is representative of the Canadian biotechnology ecosystem which includes emerging research-focused small and medium sized enterprises, universities, investors, incubator and accelerator organizations, and multi-national pharma and biotech companies. The Canadian biotech sector is experiencing a period of significant growth and investment as the pandemic has served to highlight the sector's economic, social, and health value.

Indeed, 2023 has seen more than $4 billion dollars of investment through licensing, acquisitions, product development, and clinical trials secured from multinational partners into Canadian biotech companies including Bellus, Repare Therapeutics, Aspect Biosystems, Chinook, and most recently, Inversago Pharma. Importantly, the PMPRB plays a critical role in shaping the policy environment for the multinational pharma and biotech companies who are vital investors and partners within the broader ecosystem.

With this submission, BIOTECanada is providing technical input with respect to the Interim Guidance amendments. At a less technical level, the industry strongly encourages the PMPRB to align the Interim Guidance and future Guidelines with the government's broader objectives to grow the Canadian biotech sector for purposes of economic and healthcare benefits to Canadians. This includes the federal government's National Strategy for Drugs for Rare Diseases[1], the federal Biomanufacturing and Life Sciences Strategy[2], and recommendations of the Health and Biosciences Economic Strategy Table Report[3] all of which look to enhance Canada's competitiveness and making Canada's health and biosciences sector a globally competitive hub of innovation through more agile and streamlined regulatory approaches that support access to life saving medicines and vaccines needed by Canadians.

BIOTECanada's 2022 interim guidance consultation response elements still stand.

In its 2022 response to the PMPRB's initial consultation on the Interim Guidance, BIOTECanada acknowledged that there was no specific guidance on new products and suggested that reasonable interpretation of the interim guidance should be recognized as compliant. We continue to support an approach that limits disruption of ongoing practices and reduces administrative burden based on temporary rules.

[1] Health Canada, Government of Canada improves access to affordable and effective drugs for rare diseases, Government of Canada improves access to affordable and effective drugs for rare diseases - Canada.ca, March 22nd 2023
[2] Health Canada and ISED, Canada's Biomanufacturing and Life Sciences Strategy, July 28th 2021
[3] Innovation, Science, and Economic Development Canada, Report from Canada's Economic Strategy Tables: Health and Biosciences, September 27th 2018

The Interim Guidance and new PMPRB Guidelines should be aligned with the PMPRB's legislative mandate as confirmed in recent court rulings.

The Interim Guidance and new PMPRB Guidelines must reflect the PMPRB's mandate under the Patent Act to remedy instances of excessive pricing of patented medicines. The PMPRB's role is separate from Canada's robust regulatory, reimbursement, and pricing framework for medicines, which ensure that Canadians have access to the most appropriate and optimal therapies at prices that support drug plan sustainability. Within a global context, the value of medicines for Canadians is assessed through the influence of many factors, including existing clinical practice, health technology assessment (i.e., CADTH, INESSS), the pan-Canadian Pharmaceutical Alliance, and Product Listing Agreements with payers.

The proposed 2023 amendment to the Interim Guidance intends to prioritize new medicines to receive "early guidance and greater predictability" if *below* the median of the PMPRB11. BIOTECanada recognizes the PMPRB is facing a growing backlog and the Board wishes to reduce uncertainty for some files, however, it is unclear how this proposal will reduce uncertainty for a portion of files (see "further clarification" below). Moreover, this proposal uses "median-based rules" to implement the new PMPRB11 basket of countries and under an excessive pricing mandate any price within the range of the new PMPRB11 (i.e., countries that have been selected for comparison purposes because they do not have excessive prices) should be considered compliant.

The Interim Guidance and New Guidelines should permit clear and predictable rules governing price adjustments aligned with the Consumer Price Index.

According to section 85 (1) of the Patent Act, in determining whether a medicine is being or has been sold at an excessive price, the Board shall take into consideration changes in the Consumer Price Index (CPI). Corresponding price increases should not be a *de facto* investigation trigger for existing medicines; rather, consistent with the Patent Act, prices adjustments aligned with CPI should be permitted. The PMPRB should issue 2024 CPI-based price adjustment factors for patented drugs and revisit its decision to use the 2022 NEAP throughout the interim period as communicated in its August 2022 decision following the initial interim period guidance consultation.[4]

The PMPRB Guidelines should provide stable price ceilings.

The Interim Guidance is silent regarding whether and how new drugs the PMPRB deemed "reviewed" would be subject to reassessment under future guidelines. The industry supports moving away from multiple price re-assessments following the establishment of a ceiling price at introduction. This will support the PMPRB's objective of providing greater predictability to patentees and reducing administrative burden.

Requesting further clarification on the proposed amendment to the 2022 Interim Guidance.

The Industry is supportive of the principle of providing greater predictability; however, there remains a lack of clarity on what "considered as reviewed" means and how this status brings about more predictability to patentees; how these files will be treated during the interim period; and how these and other new medicines will be assessed once the new guidelines come into force. As well, more clarity on "when" the maximum price is calculated is required. To provide meaningful feedback on the proposed interim regime, more clarity on the implications of "reviewed" status is necessary.

[4] Note: FAQ section of the PMPRB's Decision resulting from the consultation on the PMPRB Price Review Approach During the Interim Period following publication of Amendments to the Patented Medicines Regulations, Decision resulting from the consultation on the PMPRB Price Review Approach During the Interim Period following publication of Amendments to the Patented Medicines Regulations - Canada.ca, 2022,08.18

A constructive industry-government relationship to achieve meaningful consultation and finalization of new PMPRB Guidelines.

The pandemic has demonstrated the value of a constructive industry-government relationship. Industry wishes to maintain this momentum by working cooperatively with the PMPRB on consultations to achieve future PMPRB Guidelines that offer stability and predictability to patentees.

Thank you for this opportunity to provide feedback. BIOTECanada is eager to engage in meaningful dialogue and analysis of this and future proposals to develop workable Guidelines that ensure the health of Canadians, provides a sustainable healthcare system, and maintains Canada's competitiveness as a destination for innovation.

Sincerely,

Andrew Casey
President & CEO