June 21, 2021

Dr. Mitchell Levine
Chair, Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Dear Dr. Levine,

BIOTECanada welcomes the opportunity to provide written feedback on the PMPRB's proposed Guideline Monitoring and Evaluation Plan (GMEP). Given the significance and scope of the changes to the PMPRB, planning for an appropriate evaluation of PMPRB reform is important, especially in view of the lack of consensus on the new regulations and guidelines and the serious concerns raised by the industry and many other stakeholders – concerns that the inherent market uncertainty and potential for unprecedented price limits will discourage the availability of new treatments to the detriment of patients and Canadian health care.

As the national industry association, BIOTECanada represents more than 240 member companies including innovators at all stages of the product lifecycle from basic research and development to commercialization. Some member companies are patentees who report to the PMPRB, but most are focused on early research and development in the hopes of bringing new therapies to patients and the health care system in the future, not just in Canada but globally. This membership group includes developers and manufacturers of vaccines and the latest technological advances to address unmet medical needs.

The COVID-19 pandemic has heightened awareness of the importance of the sector in delivering healthcare solutions and economic growth. Accordingly, as governments prepare for future health challenges and begin the process of rebuilding the post-pandemic economy, significant investments are being directed to the growth of Canada's biotech sector. Indeed, the recent federal Budget 2021 recognized its value noting that: "These growing fields are not only critical to our safety, but are fast-growing sectors that support well-paying jobs and attract investment." The budget allocated $2.2 billion over seven years "towards growing a domestic vibrant life sciences sector."

It remains a concern of BIOTECanada that PMPRB reform process began before the pandemic and has continued in isolation and works at counter purposes to these broader "whole of government" policies. BIOTECanada has strongly advocated for delaying the implementation of the new PMPRB regulations and guidelines and instead build on the industry-government relationship built during the pandemic to develop a more sustainable path forward. Contrary to the assertion in the consultation document, it is not just the pharmaceutical industry that is "steadfast in its opposition to the reforms". BIOTECanada on behalf of its members and the entire Canadian biotechnology ecosystem has consistently expressed concerns regarding the lack of a holistic policy approach and the negative impact this will have on investment and ultimately the development of Canadian biotech companies.

PMPRB reform has attracted an unprecedented level of controversy with divergent and strongly-held views among stakeholders. In such circumstances, BIOTECanada recommends that an evaluation of PMPRB reform should be conducted by an independent third party with expertise in program evaluation and with input from an advisory panel composed of experts and key stakeholders. Other public programs in this sector, such as CADTH and the pCPA, use external bodies to increase the objectivity and credibility of their evaluations. Another option is the Auditor-General of Canada who conducted an independent review of the PMPRB in 1998; provincial Auditors-General regularly conduct reviews of the public drug programs.

The need for an independent evaluation is reinforced in this case by the imperative for the PMPRB to maintain its integrity as a quasi-judicial body. The PMPRB has already taken public positions on its expectations of the likely impact of PMPRB reform and its defence of those views in response to criticism has attracted further publicity and criticism.

The PMPRB has historically reported on the price trends for patented medicines, sales of patented medicines in Canada, compliance with its guidelines, and its enforcement activities. These reports are authorized or required by the *Patent Act*. These reports have shown that Canadian prices continue to be stable, not increasing by more than inflation, and fall in the mid-range of seven highly-industrialized countries. The PMPRB will continue to apply its current guidelines and report these price trends even if the new regulations and guidelines are delayed.

BIOTECanada is also concerned the PMPRB's proposed GMEP is too broad in scope. Many of the additional matters the PMPRB proposes to report on under the GMEP are not in its statutory mandate but are the responsibility of other agencies and programs. The PMPRB should not initiate and conduct evaluations of policies and programs not related to the PMPRB's specific jurisdiction over prices of patented drugs.

Furthermore, the proposed GMEP raises significant methodological problems which will challenge its potential value. Factors such as total drug spending in Canada, patient access to optimal treatments, price and coverage decisions by public and private plans, clinical trials, and the pharmaceutical ecosystem are only partially and indirectly impacted by prices of patented drugs. The COVID-19 pandemic is also significantly disrupting the trends in the sector. Federal and provincial policies that impact this sector are continually evolving, for example, the support to the life sciences sector in federal Budget 2021 and previously-announced funding for a rare disease strategy to improve patient access. Moreover, the PMPRB's reporting metrics for industry research and development expenditures have not been updated to reflect the new way in which drug discovery and development is conducted. Correspondingly, the data collected is not meaningful in the context of evaluating the impact of the PMPRB reforms.

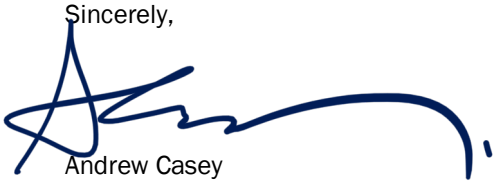
These methodological challenges must be addressed to ensure the results of an evaluation are not undermined by confounding factors and lead only to more debate and disagreements.

A further challenge to address is the effect of the long period of uncertainty and delays resulting from the PMPRB reform process. The industry response has had to adjust from the period prior to the publication of proposed regulations in 2017, to the period of uncertainty from then until today and will adjust again with the ultimate coming-into-force day. How will a GMEP define and account for these time periods?

Finally, the industry considers the development of the GMEP as premature given the significant environmental and marketplace uncertainty. The validity of the new regulations and guidelines is in dispute in the courts and not likely to be resolved for several years. Furthermore, the courts have invalidated a key element of the new regulations, the reporting of prices net of third-party rebates, which is fundamental to the "Maximum Rebated Price" concept in the new guidelines. The full impact of the pandemic has yet to be realized. In this context, moving forward now with the GMEP ignores these important market influences.

In this context, the industry strongly recommends the government develop a collaborative, multi-stakeholder approach to an evaluation of PMPRB reforms, with support from the PMPRB as appropriate taking into account the limits of its jurisdiction. We look forward to working with the government in this regard.

Sincerely,



Andrew Casey
President & CEO

c.c. The Honourable Patty Hajdu, Minister of Health