Biogen's Written Submission Regarding the Patented Medicines Price Review Board's 2021 Guidelines Monitoring and Evaluation Plan

On behalf of Biogen Canada, we are pleased to submit our response and recommendations on the Patented Medicines Review Board's (PMPRB) 2021 Guidelines Monitoring and Evaluation Plan (GMEP).

We recognize that the PMPRB sought to establish its most comprehensive GMEP that incorporates stakeholder feedback received during consultations. However, we maintain our applicable recommendations submitted to the PMPRB in August 2020 on the 2020 Draft Guidelines and provide this submission in supplement to those as well as the GMEP submissions of our industry associations, BIOTECanada and RAREi.

As an overarching recommendation, Biogen believes that the PMPRB should anchor its GMEP in international best practices for policy monitoring and evaluation. The recommendations that follow are based on the monitoring and evaluation principles of the Organization for Economic Cooperation and Development (OECD).[1]

The OECD vision for effective monitoring and evaluation starts with participative and collaborative efforts where the intended purposes of policy evaluation are negotiated upfront.[2] We strongly recommend that the PMPRB foster a culture of monitoring, evaluation, and learning through collaboration with a broad range of interested stakeholders including manufacturers, public and private payers, patient groups, Health Canada, CADTH and INESSS.

On the GMEP, we recommend that the PMPRB:

1. Delay implementation of the 2020 Guidelines and the GMEP
2. Limit the scope of evaluation and data sources to the PMPRB's legislative mandate and regulatory filing data sources
3. Modernize the definition of R&D collected by the PMPRB to capture direct and indirect consequences of the PMPRB regulations
4. Authorize an independent third party of evaluation experts to develop evaluation metrics and conduct the evaluation annually
5. Establish a transparent and accountable process for timely identification and implementation of corrective measures

Recommendation #1: Delay implementation of the 2020 Guidelines and the GMEP

Currently, the PMPRB's Guidelines will come into effect in July 2021 and the GMEP will come into effect in January 2022. In our previous submission regarding the PMPRB's June 2020 Draft Guidelines, we recommended not only accelerating the development of the GMEP framework but also launching it

[1] OECD (2019), *Open Government in Biscay* , OECD Public Governance Reviews, OECD Publishing, Paris. *https://doi.org/10.1787/e4e1a40c-en*
[2] OECD, 2019, p. 119

simultaneously with the Draft Guidelines to reduce data lag and improve accountability and the timely actioning of necessary adjustments.

We strongly recommend that the PMPRB delay both the 2020 Guidelines and the GMEP until they can be launched simultaneously with revisions from stakeholders' input.

Recommendation #2: Limit the scope of evaluation and data sources to the PMPRB's legislative mandate and regulatory filing data sources

Biogen recommends that the GMEP's scope and data sources be limited and directly tied to the PMPRB's mandate of protecting consumers by ensuring that the prices of patented medicines are not excessive and providing information on pricing trends in the pharmaceutical industry via its annual reports.

The current draft GMEP includes the monitoring and evaluation of many endpoints extraneous to the PMPRB's mandate requiring data from third parties such as CADTH and the pCPA. We do not support the expansion of the PMPRB's mandate beyond its mandate.

We do, however, agree that pricing regulation changes of this magnitude could have broader economic impacts on Canadians that are within the scope of the PMPRB. To appropriately capture this, recommend that the PMPRB modernize its definition of R&D as noted in our submission on the 2020 Guidelines and explained in more detail in recommendation #3.

Recommendation #3: Modernize the definition of R&D collected by the PMPRB to capture direct and indirect consequences of the PMPRB regulations

Investments of the pharmaceutical and biotechnology industry to the Canadian economy extend far beyond the PMPRB's current definition of R&D. In contrast to the PMPRB's reports of Canadian R&D investments, Statistics Canada reports R&D-to-sales ratio more than twice as high as that reported by the PMPRB. As recommended in our previous submission on the 2020 Guidelines, Biogen believes the PMPRB should expand the nature and type of investments allowable in the regulatory filings to include a more holistic accounting of Canadian investments such as productivity and socioeconomic cost, medical and research investments, patient support programs and compassionate access programs.

Recommendation #4: Authorize an independent third party of evaluation experts to develop evaluation metrics and conduct the evaluation annually

To ensure impartiality, we recommend that the final GMEP be developed and conducted by an independent third party of evaluation experts reporting directly to the House of Commons Standing Committee on Health (HESA). Numerous methodological issues are outstanding in the draft GMEP including the development of appropriate international comparator indicators and the establishment of an accurate baseline that controls for several confounding variables including the COVID-19 pandemic and the extended period of uncertainty dating back to 2017.

Recommendation #5: Establish a transparent and accountable process for timely identification and implementation of corrective measures

From 2011 to 2014, the PMPRB implemented the existing GMEP on an annual basis for their revised guidelines which were implemented in 2010. However, there has not been an update since 2014. Similarly, the PMPRB has not addressed if they will have a similar procedure within its GMEP, at what frequency reports will be published and for which reporting periods. The GMEP does not address how the PMPRB will identify and implement corrective measures and at what frequency improvement cycles will occur. Biogen urges the PMPRB to take a collaborative approach with stakeholders in the identification of negative impacts and the development and implementation of corrective measures.

Thank you for the opportunity to participate in this consultation. Biogen looks forward to continued dialogue with the PMPRB.