August 31, 2021

Dr. Mitch Levine

Chair, Patented Medicine Prices Review Board

333 Laurier Street, Suite 1400

Ottawa, ON K1P 1C1

Via Email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

RE: Patented Medicines Prices Review Board (PMPRB) - *On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions*

Dear Dr. Levine:

On behalf of Ipsen Biopharmaceuticals Canada Inc., we agree with the comments brought forth by Innovative Medicines Canada (IMC) and by RAREi with regards to the proposed amendments to the July 1, 2021 guidelines and strongly believe that the changes as currently proposed will have a significant and negative impact on patient access to new medicines in Canada. IMC's comments underscore industry's concerns with the proposed changes and how the changes will impact patentees and patients. Ipsen has particular concern with the proposed changes to the reference country pricing which "*reflect an arbitrary and significant change in the Board's policy regarding what constitutes an excessive price for existing products and line extensions. Because no clear rationale has been provided, patentees and other stakeholders are left with the impression that this reversal is essentially punitive to further lower prices of patented medicines in light of the government's regulatory implementation delays caused by the ongoing COVID-19 pandemic*."

Furthermore, the proposed guidelines have greatly added a layer of ambiguity in the Canadian pharmaceutical industry and for patients in the rare disease community. RAREi's submission highlights this "*Overall, the proposed guidelines changes add to the climate of uncertainty and instability that has affected the whole life sciences sector – and the rare diseases medicines community as a whole – since pricing reforms were first proposed in 2016. These changes and the unwillingness of the PMPRB to consult constructively or respond to the valid concerns of stakeholders have led to a serious destabilization of the Canadian market for pharmaceuticals, which are a crucial part of the Canadian health care system*."

We fully support and endorse the comments made by both IMC and RAREi and ask that you consult with these groups for a more detailed examination of industry's comments and concerns with the

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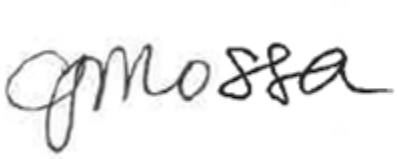
changes as currently proposed. We appreciate the opportunity to provide input in the PMPRB consultation process and trust that you will take our comments into consideration.

Sincerely,



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