INNOVATIVE MEDICINES CANADA | MÉDICAMENTS NOVATEURS CANADA

President's Office | Bureau de la présidente

November 28, 2022

Dr. Mélanie Bourassa Forcier
Acting Chairperson
Patented Medicines Prices Review Board
Box L40, Standard Life Centre
1400–333 Laurier Avenue West
Ottawa, Ontario, K1P 1C1

Via email: melanie.forcier@pmprb-cepmb.gc.ca

Dear Dr. Bourassa Forcier:

Thank you for your letter dated November 21, 2022, I appreciate your openness to have a constructive dialogue on the Patented Medicines Prices Review Board's (PMPRB) revised draft Guidelines. This is something we have respectfully sought previously, in 2018 and again in 2019, and I sincerely believe that such an engagement would be productive for all.

In your response to our request for a meeting, you invited Innovative Medicines Canada (IMC) to list the elements of the proposed Guidelines that are problematic to our members and provide a detailed proposal concerning changes to the Guidelines.

IMC will be pleased to provide a submission to the PMPRB on its revised draft Guidelines proposal by the current consultation deadline. However, as a first step towards the establishment of a constructive dialogue, we would propose a meeting between the Chair of IMC and yourself, accompanied by a few members of leadership of our respective organizations. This meeting would be an opportunity for us to better understand the intent of the proposed draft guidelines changes, and for you to have a better understanding of our interpretation of these changes.

In the hope that the following will set the table for a productive meeting and pave the way to a better appreciation of the issues from both of our perspectives, IMC would like to discuss several issues within the proposed Guidelines, including:

- The proposed use of the lower of the Median International Price (MIP) and the domestic Therapeutic Class Comparison (dTCC) as an investigation trigger;
- The anticipated use of a multifactorial series of other potential investigation triggers at the discretion of Board staff;
- The need for an impact assessment prior to Guidelines implementation; and
- The need for more time to consult on all these issues. IMC remains concerned with the PMPRB's proposal to finalize the 2022 Guidelines by the end of the year.

In IMC's view, to abide by its legal and constitutional obligations, the PMPRB must focus on excessive prices – prices that exceed the PMPRB11 and other section 85 benchmarks, as expressed in recent cases, rather than the proposed measures that seem more designed to regulate pharmaceutical prices downward. Additionally, while the proposed Guidelines suggest there are no longer any price ceilings, the only criteria provided appear unrelated to the Board's mandate to regulate for patent abuse in the form of excessive prices.

To further nurture a spirit of collaboration and dialogue, IMC would propose that the PMPRB consider holding quarterly meetings with IMC to discuss policy matters, as happens with other departments and agencies of government. Such meetings have proven to help promote a better understanding of issues and foster the development of mutually acceptable solutions. The modernization of the definition of R&D expenses is a good example of the type of policy issue that could be examined during such meetings.

A postponement of the new Guidelines implementation would be a strong signal of the PMPRB's intent to establish a more constructive dialogue, not only with IMC, but with all stakeholders concerned.

Thank you for your consideration of this request and I look forward to your reply. Should you have any questions or if I can be of any further assistance, please do not hesitate to contact me.

Sincerely,

Pamela C. Fralick
President

cc: The Honourable Jean-Yves Duclos, Minister of Health, hcminister.ministresc@canada.ca
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