

Health Canada Submission to the Patented Medicines Prices Review Board
New draft Guidelines 2022 Notice and Comment/Consultation

In accordance with Section 96(5) of the Patent Act, this letter sets out comments from Health Canada.

The draft Guidelines published on October 6, 2022 with a 60-day Notice and Comment period ending on December 5, 2022, follow the recent consultation and adoption of interim Guidelines. In its consultation documents, the PMPRB states that it would like to issue its final Guidelines by the end of 2022 and have them come into effect on January 1, 2023.

As described by the PMPRB in the consultation backgrounder, this new version of the Guidelines includes a number of differences from existing or previously proposed Guidelines. Importantly, they signal a pivotal change from a long-standing practice of including price tests and price ceilings, to instead including investigation criteria.

Given the new direction set out in the proposed new Guidelines, it is critical that all stakeholders understand fully how the new Guidelines will be implemented. Stakeholders have raised concerns and questions associated with the new Guidelines, and the uncertainty they impart. More information about the potential impacts and the operationalization of some of the key technical aspects of the Guidelines is being requested.

Health Canada needs to understand the potential impact on all stakeholders and health system partners. An understanding of how this new direction could affect various players in the drug development and distribution system in Canada, and any potential effects for patients, care-givers, health care professionals and health care facilities is critical. Given the role of provinces and territories in the pharmaceutical management system, Health Canada would like to consult our counterparts to understand their views on these draft Guidelines.

Based on these considerations, Health Canada asks that the Board consider pausing the consultation process. A pause will allow time to work collaboratively, with all stakeholders and health system partners, to understand fully the short and long-term impacts of the proposed new Guidelines. During this time, we understand that the interim Guidelines currently in place could continue to be in force.

Sincerely,

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