Health Canada | Santé Canada

Deputy Minister | Sous-ministre

Ottawa, Canada
K1A 0K9

Your file *Votre référence*

Our file *Notre référence*

May 9, 2023

Patrick Williams, Clerk
Standing Committee on Health
Sixth Floor, 131, Queen Street
Ottawa, Ontario
K1A 0A6

Dear Mr. Williams,

I am writing to respond to the motion of the Committee on May 4, regarding the Patented Medicines Price Review Board.

Specifically, on May 4, 2023, the Standing Committee on Health (HESA) adopted the following motion:

> *That witnesses produce correspondence they consider relevant to support their testimony to the committee, in relation to the study of the Patented Medicine Prices Review Board, which shall be submitted to the clerk of the committee by Tuesday, May 9, 2023, at 4:00 p.m.*

In response to the order of the Committee, the Department is providing the attached correspondence in both official languages.

Enclosed you will find two items; a letter from Minister Duclos to Ms. Mélanie Bourassa Forcier, and the submission of the Department to the Patented Medicine Prices Review Board.

We are available, as always, to address the Committee's questions and concerns.

Sincerely,

Dr. Stephen Lucas
Deputy Minister of Health

Canada

Minister of Health

Ministre de la Santé

Ottawa, Canada K1A 0K9

Ms. Mélanie Bourassa Forcier
Acting Chairperson and Chief Executive Officer
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
1400-333 Laurier Avenue West
Ottawa, Ontario K1P 1C1

Dear Ms. Bourassa Forcier:

I would like to provide you with perspectives regarding the current consultation on the new draft Guidelines, in accordance with the Patent Act.

Thank you for your continued leadership as the Acting Chairperson and Chief Executive Officer of the Patented Medicine Prices Review Board (PMPRB).

The amendments to the *Patented Medicines Regulations* (PMR) came into force on July 1, 2022. In anticipation of this coming into force, the PMPRB issued interim Guidelines for establishing non-excessive prices for medicines launched during the period of time between the coming into force of the Regulations and the publication of its final Guidelines. The consultation process for the interim Guidelines, launched in June 2022, proposed that once the draft Guidelines were published there would be a targeted consultation process with key stakeholders to develop final Guidelines. Subsequently, the draft Guidelines were published on October 6, 2022 with a 60-day Notice and Comment Period ending on December 5, 2022. In its consultation documents, the PMPRB states that it would like to issue its final Guidelines by the end of the year. Following which, they would come into effect on January 1, 2023, and compliance monitoring and implementation by Board staff would begin in January 2024.

The proposed new Guidelines incorporate the new Schedule of 11 comparator countries (“PMPRB11”), as per the amendments to the PMR, as well as contain a number of substantive changes that form part of the modernization efforts that the Board has been undertaking for several years. Importantly, this new version of the Guidelines 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. Many stakeholders have raised concerns and questions associated with the new Guidelines, and are looking for more information about the potential impacts and on the operationalization of some of the key technical aspects of the Guidelines. It is only with this more detailed understanding that stakeholders can engage meaningfully in the

consultation process. In parallel, the Board will benefit in receiving the considered views and feedback of stakeholders as part of its decision-making.

Furthermore as Minister of Health, I am especially interested in understanding any potential impacts respecting drug shortages, which affect the availability of medicines for Canadians. In addition, given the role of provinces and territories in the pharmaceutical management system, I would like to consult with my colleagues to understand their views on these draft Guidelines.

Based on these considerations, I respectfully ask that the Board consider pausing the consultation process, so as to allow time to work collaboratively, with all stakeholders, to understand fully the short and long-term impacts of the proposed new Guidelines. During this time, I understand that the interim Guidelines currently in place could continue to be in force.

Please accept my best wishes.

Yours sincerely,

The Honourable Jean-Yves Duclos, P.C., M.P.

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,

Eric Bélair
Associate Assistant Deputy Minister
Strategic Policy Branch, Health Canada