Medison Pharma Canada Inc.

PMPRB Submission

March 19, 2025

Patented Medicine Prices Review Board
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Submitted via the PMPRB Website Consultation Submission Portal

RE: Medison Pharma Canada Response to the Draft Guidelines for PMPRB Staff

Medison is a global pharmaceutical company focused on providing highly innovative therapies (HITs) to patients in international markets. **At Medison, we believe that every patient, everywhere, has the right to access breakthrough treatments.** Medison is a proud member of RAREi and shares its mission to improve the lives of Canadians with rare disorders. Medison fully endorses the submission by RAREi and echoes the concerns raised with respect to the shift towards a more 'hands-off' approach from PMPRB staff. This creates a lack of predictability in pricing and can cause significant challenges in planning for launches of rare, breakthrough treatments in Canada. We are writing this letter to highlight specific areas in the guidelines which create significant uncertainty for Medison and its partners. We also provide recommendations and questions to be addressed that can help mitigate the uncertainty for innovators. We thank the PMPRB for its continued consultations and integration of stakeholder feedback in the developments of its Draft Guidelines.

Topic 1: Special Provisions on Complaints

The role of the Guidelines as laid out by the Draft Guidelines to PMPRB Staff have been updated to "ensure procedural fairness and consistency in that all similarly placed Rights Holders are subject to the same process and process timelines". Notably, predictability has been removed from the role of the guidelines which is of critical importance to Rights Holders. Although improved predictability and consistency have been achieved through the Initial and Annual Review process within the Draft Guidelines, there exists uncertainty in the Special Provision on Complaints.

The role of complaints adds much uncertainty to the framework as there are no boundaries to the nature of complaints that can be brought forward and thereby induce an In-Depth Review. In practice, a complaint could be filed on perception and without scientific justification for a medication whose price is within the HIP, as is used in the Initial and Annual Review.

Medison proposes two recommendations to improve predictability for Rights Holders and ensure efficient use of resources by the PMPRB:

1. The complainant should be required to provide documentation or evidence to support the complaint about a patented medicine.

2. Complaints received should not automatically lead to an In-Depth Review. Instead, Medison proposes a screening process take place to 1) assess the legitimacy of the complaint based on evidence provided by the complainant, and 2) assess whether a product is above the HIP prior to proceeding to an In-Depth Review.

Medison Canada
400-154 University Ave, Toronto, ON M5H 3Y9
Tel. 1.800.696.1341
medisonpharma.com

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Topic 2: In-Depth Review

The proposed In-Depth Review outlines a number of processes and factors which are considered by PMPRB Staff when determining whether a file should proceed to a Hearing or be closed. Medison cannot comment on the proposed review process as there exist a number of outstanding questions, which create uncertainty in the review process. This includes a lack of clarity in the determination of a comparator's Qualitative Class and the assessment of multiple indications of a medicine.

Medison recommends the following questions be addressed in the next iteration of Guidelines to create additional certainty in the process.

Qualitative Assessment:

- During the Qualitative Assessment, how are meaningful differences in efficacy, safety or patient-assessed outcomes defined?
- How does PMPRB define the "Qualitative Class" of an indirect treatment comparison?
- Please provide concrete examples for how the Qualitative Classes are determined for a medicine's comparators in the Qualitative Assessment.

In-Depth Review:

- Where a medicine has multiple indications, how are those indications and their comparators prioritized during an In-Depth Review?
- When determining comparators during the In-Depth Review, the Draft Guidelines state that "only the approved indications or uses of the patented medicine under review will be considered for the purpose of populating the TCC during In-Depth Reviews." How does PMPRB differentiate between a use and an indication for a medicine?

Topic 3: "Margins" for Prices

The proposed Draft Guidelines for PMPRB Staff do not permit "margins" to account for exchange rate fluctuations and other temporary price fluctuations. Significant economic instability in Canada and globally creates unpredictability of exchange rates and may result in frequent changes to PMPRB11 international prices of a medicine. Due to the increased monitoring required to maintain prices under the proposed Draft Guidelines, the lack of "margin" may result in a significant increase of files triggering an In-Depth Review. This may increase resource use of PMPRB Staff.

Medison proposes "margins" be permitted if a price exceeds the HIP due to exchange rate fluctuations, and Rights Holders be permitted one reporting period to adjust the price before an In-Depth Review is triggered. We believe this can achieve the balance sought by the Board between identifying instances of potential excessiveness and managing the Board and Staff's resources.

We thank PMPRB for consideration of our feedback and its work with industry to create a predictable and transparent pricing system which does not disadvantage Canadian patients from accessing highly innovative treatments. We share a commitment to Canadian patients and their wellbeing, and we remain hopeful that we can forge a path forward that best serves the health of patients both here at home and around the world.

Sincerely,

Maureen Hazel

Medison Canada
400-154 University Ave, Toronto, ON M5H 3Y9
Tel. 1.800.696.1341
medisonpharma.com

MEDISON

Maureen Hazel

Director, Market Access

Cc: Pamela Minden, Country Manager, Medison Pharma Canada

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medisonpharma.com