Medison Pharma Canada Inc.

PMPRB Submission

September 11, 2024

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 Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines

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.** We are proud to make this submission, offering feedback that we believe will contribute to a thriving and sustainable healthcare system in Canada and is in the best interests of the patients we serve with our current and future business partners. We have provided feedback on select topics that we believe are the most critical and have also included outstanding questions for PMPRB to consider when drafting New Guidelines.

Topic 1: Price level within the PMPRB11 to be used in the initial and post-initial price review.

Option 2: Highest International Price

Medison proposes that Option 2 can achieve the balance sought by the Board between identifying instances of potential excessiveness and managing the Board's resources. As of July 1, 2022, the new basket of comparator countries (the PMPRB11) has come into force, removing higher priced jurisdictions (US and Switzerland) and adding lower priced jurisdictions as reference countries. As such, the Highest International Price (HIP) now reflects this new reference basket and therefore represents a lower price benchmark than the HIP from earlier guidelines. Medison contends that a price below the HIP is much less likely to be considered excessive due to the inclusion of lower priced jurisdictions.

From our perspective, the other options do not appear to address the resourcing concerns of PMPRB. PMPRB has indicated that Option 3 and Option 1 would require in-depth review for 53% and 78% of all patented medicines respectively. Medison has concerns that limited bandwidth on the part of PMPRB would result in delays in both initial and post-initial price reviews, causing ongoing uncertainty and difficulties in accounting for potential price changes.

At Medison, we work with emerging biotech companies (EBCs), in an affiliate-like partnership, to help these companies expand their reach into markets that are often left behind, including Canada. From our experience, many of these small-to-mid-sized companies weigh pricing uncertainty and concerns as they consider the sequence of their launches or whether to enter a market at all. The difficulty of predicting the median and midpoint may incent companies to hold off on launching in Canada until prices are well established, thus delaying Canadian patient access to new, innovative treatments. Thus, we believe Option 2 provides the greatest level of certainty for smaller companies in the context of post-initial price review by PMPRB and fluctuating prices in international markets.

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Topic 6: Use of clinical evidence to contextualize the degree of similarity of comparators identified for the TCC.

Medison cannot comment on the proposed options as currently defined as we believe there are several questions regarding the methods that would be used to select comparators and assess the degree of similarity.

Medison considers the comparators used for the TCC to be critical to the pricing assessment of innovative drugs. In its five years since inception, Medison has brought six new molecules to market in Canada through our partnerships with emerging biotech companies. Many of these molecules are for the treatment of rare conditions. In many cases, there has been no previously indicated, effective therapy available for these patient populations. Patients and their physicians have often had no choice other than to make do with best supportive care.

Medison believes it is imperative to ensure that proposed guidelines are not punitive to new, innovative market entry products. The lack of reasonable domestic comparators, especially in situations where off-label therapies are currently being used, may mean that innovative therapies face an artificially low-price ceiling. This favours companies who bring "me-too" versions and second and subsequent market entrants to market, but also actively discourages new innovation.

While Medison understands that the PMPRB is not an HTA body, we believe the level of clinical evidence should be considered for all products in the TCC, particularly when assessing treatments for rare conditions where no previously indicated, effective therapy has been available.

Medison's questions to guide further elaboration of guidelines by the PMPRB:

For Option 1, how will the aggregate similarity grade be determined for the group of comparators as a whole?

For Option 2, how does each comparator (even those with a low level of similarity) inform the assessment of TCC?

What considerations will be made for products where currently used treatments are too dissimilar from the product under review? For example, what considerations will be made for rare disease products with very inexpensive / generic best supportive care options?

How will the Staff balance IPC with TCC in their assessment of a product? The current consultation guidance does not clearly define how these two items will be considered in the context of the review process for excessive pricing. Please provide examples of assessments of level of similarity for each option and how it may impact the overall pricing assessment.

How will the manufacturer's feedback be incorporated into the TCC selection and level of similarity assessment?

Topic 4: The individuals/groups permitted to submit a complaint.

Option 1: Limit complaints to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts.

The vision of the Guidelines as laid out by the PMPRB Board are that "transparent, predictable, and procedurally fair Guidelines provide an efficient way for rights-holders to manage risk". This can be accomplished through predictable and transparent identification criteria (IPC) which would give greater certainty to rights-holders as to the likelihood that their medicines will entail in-depth price reviews.

The role of complaints adds much uncertainty to the framework as there are no boundaries to the nature of complaints that could be brought forward and induce an in-depth review. In practice, a

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complaint could be filed on perception and without scientific justification for a medication whose price is within the IPC threshold.

Medison believes that Option 1 provides reasonable boundaries and ensures that complaints funnel through the relevant Ministries. Medison also recommends that PMPRB provide criteria required for a complaint to be considered.

We urge the PMPRB to further clarify the options being considered and to 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. We thank PMPRB for the opportunity to offer feedback and we are committed to continued collaboration.

Sincerely,

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