SERVIER

September 5, 2024

Submitted via PMPRB's website for written submissions: https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/discussion-guide-phase2.html

Subject: Response to Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines

This submission is made on behalf of Servier Canada Inc. (Servier) in response to the Patented Medicine Prices Review Board (PMPRB) Discussion Guide released on June 26, 2024, to help shape future guidelines (New Guidelines).

As a member of Canada's Innovative Medicines Canada (IMC), Servier supports the response and position submitted by IMC to the PMPRB, as part of this consultation phase.

Servier is an international pharmaceutical company governed by a non-profit foundation. With a strong international presence in 150 countries, Servier invests over 20% of its brand-name revenue in Research and Development every year. Established in Canada for more than 45 years, Servier provides the Canadian medical community and its patients with innovative therapeutic solutions in treating cancer, diabetes, heart disease, and high blood pressure.

Set out below are Servier's responses to the Discussion Guide topics for PMPRB's consideration.

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

As confirmed by both the Federal Court of Appeal and the Quebec Court of Appeal, the PMPRB's constitutional mandate is limited to the prevention of excessive pricing as a function of patent abuse.

Selecting Option 1: the Median International Price (MIP) or Option 3: the midpoint between the MIP and HIP (Midpoint) would not be appropriate under PMPRB's non-excessive pricing mandate as these price levels do not reflect a focus on excessive pricing, but rather appear to be designed to regulate prices and to drive pharmaceutical prices below non-excessive thresholds.

Furthermore, MIP and Midpoint price levels as well as re-benchmarking through the proposed annual price reviews will be nearly impossible for Rights Holders to predict from product launch to patent expiry especially when they involve 11 comparator countries that regulate medicine prices and have rules against excessive pricing. Such unpredictable price fluctuations will delay or even reduce the likelihood of market entry of innovative medicines in Canada.

In keeping with the court rulings, Servier maintains that the Highest International Price (HIP) is the only price level within the PMPRB11 consistent with an excessive pricing standard (**Option 2**).

SERVIER

Topic 2: The length of time Staff should wait, following the implementation of the Guidelines, to determine whether the IPC identification criteria for an Existing medicine is met.

Existing medicines have entered the Canadian market in good faith and in compliance with the rules and regulations in place at the time of their market entry when the scope and impact of the new PMPRB regime could not have been reasonably foreseen. Furthermore, these medicines have already been subjected to assessment and negotiation by various Canadian agencies, and funding decisions based on value for money and affordability have already been made.

Therefore, regulating existing medicines at the same level as new medicines is unfair to Rights Holders who have already made significant investments based on business analyses done under an existing regulatory framework. Accordingly, existing medicines should be grandfathered under the New Guidelines.

In previous consultations, a transition measure for existing medicines was proposed by the PMPRB whereby existing medicines would be assessed at the HIP level of the PMPRB11. The PMPRB should at least maintain its previous position by instituting the HIP policy for existing medicines.

Nevertheless, existing medicines should be given a 3-year transition period to adapt to the New Guidelines (**Option 3**). This will allow Rights Holders, provincial drug plans and pharmaceutical supply chain stakeholders sufficient time to adapt to the New Guidelines and to properly implement new prices.

Topic 3: In depth review based on CPI increase criteria.

It is difficult for Servier to comment on the Consumer Price Index (CPI) increase criteria and methodology given that there are many unanswered questions regarding the nature of the annual price reviews, as proposed in the Discussion Guide, and how they relate to CPI. Servier encourages PMPRB to provide more clarity on the subject.

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

Servier believes that complaints should be restricted to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts (**Option 1**) which is consistent with s. 86(2) of the Patent Act. Complaints filed by for-profit entities would not be appropriate and will create bias in price assessments.

As stated in the Discussion Guide, this restriction will help ensure that the most pertinent cases of potential price excessiveness will be brought to the PMPRB's attention by key government officials with a vested interest in public health. Moreover, members of the public can alert their elected officials if they believe that the price of a patented medicine may be excessive.

SERVIER

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

It is difficult for Servier to comment on Option 1: one level of similarity is identified for the comparators as a whole and Option 2: each comparator will be assigned a level of similarity due to the numerous unanswered questions regarding the proposed in-depth review process. For instance, it is unclear how the PMPRB will assign levels of similarity to comparators when conducting a Therapeutic Class Comparison (TCC) and how the weighing of Patent Act factors will be performed.

According to the Discussion Guide, the New Guidelines aim to provide transparency and predictability to Rights Holders regarding the process typically engaged in by the PMPRB in identifying patented medicine that may be at a greater risk for excessive pricing. The case-by-case reviews and context-specific weighing of Patent Act factors are not only concerning, but counterintuitive and this will ultimately reduce transparency and predictability for Right Holders.

Topic 7: Future role of HDAP.

Until additional information is provided by the PMPRB regarding in-depth reviews, degrees of comparator similarity identified for the TCC, and weighing of Patent Act factors, it is too early for Servier to comment on the future role of the Human Drug Advisory Panel (HDAP).

Servier believes that, first and foremost, the New Guidelines should provide stable and predictable price thresholds. Moreover, the price of a medicine should be assessed at its introduction to the Canadian market and then only subsequently monitored against the allowable CPI increase. This will provide patentees with greater stability and predictability over the duration of the patent and reduce administrative burden.

Servier is committed to advancing healthcare through timely access to innovative medicines, in order to address unmet medical need for Canadian patients. Servier is hopeful that the comments provided to the PMPRB in this letter and by numerous stakeholders within this consultation process will be seriously considered in the development of the New Guidelines.

As a member of the life sciences community, we appreciate the opportunity to provide feedback on this important consultation and we look forward to working collaboratively with the PMPRB and other stakeholders to address these serious concerns that ultimately affect all Canadians.

Yours sincerely,

DocuSigned by:
Lucie ROUSSEAU
76AF96B75B3A4C2...

Lucie Rousseau
General Manager
Servier Canada Inc.