December 19th, 2023

Submitted via PMPRB's online Feedback Form

Patented Medicine Prices Review Board
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Attention: PMPRB's Scoping Paper for the Consultations on the Board's Guidelines

This submission is made on behalf of Servier Canada Inc. (Servier) in response to the Patented Medicine Prices Review Board (PMPRB) Scoping Paper for the consultations on the Board's Guidelines (Scoping Paper) released on November 10, 2023 to inform this first phase of consultations on the PMPRB's final guidelines (Final 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.

Servier requests consideration of the following four recommendations in relation to the Scoping Paper which are fundamentally consistent with its input provided in past submissions.

1. GUIDELINES MUST ADHERE TO PMPRB'S NON-EXCESSIVE MANDATE

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. The Scoping Paper contains questions that examine the appropriateness of using the median of the PMPRB11 countries as a reference point for determining price excessiveness.

Selecting a reference point at the median price threshold would not be justifiable under PMPRB's non-excessive pricing mandate as it does not reflect a focus on excessive pricing,

but rather appears to be designed to regulate prices and to drive pharmaceutical prices below non-excessive thresholds.

Furthermore, a median price will be nearly impossible for patentees to predict from product launch to patent expiry especially when it involves 11 comparator countries that regulate medicine prices and have rules against excessive pricing. Unpredictable price fluctuations throughout the product lifecycle will delay or even reduce the likelihood of market entry of innovative medicines in Canada.

Servier believes that any price test included in the Final Guidelines must adhere to PMPRB's constitutional mandate, and the only price test that would be constitutionally acceptable would be the Highest International Price (HIP) pricing threshold. The latter would provide for a high level of predictability for patentees.

2. ALLOW PRICE ADJUSTMENTS ALIGNED WITH INFLATION

"Changes in the Consumer Price Index" is an explicit factor for assessing if a medicine is being sold at an excessive price in the Patent Act and should be reflected in the Final Guidelines. Consequently, a list price that has been increased in the range of CPI should not, in and of itself, be deemed excessive or trigger an investigation. The Final Guidelines should offer clear and predictable rules governing price adjustments aligned with the Consumer Price Index.

Servier urges the PMPRB to reinstate the patentee's legislative right of taking price increases based on the Consumer Price Index (CPI) in the Final Guidelines, and to continue to update its CPI-Based Price-Adjustment Factors for Patented Drug Products.

3. ALLOW GRANDFATHERING OF EXISTING MEDICINES

It is important to note that existing medicines 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, existing 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 patentees 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 regime.

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4. NO REASSESSMENT OVER A MEDICINE'S LIFECYCLE

In the Scoping Paper, the PMPRB poses questions on the appropriate timing and reasons for price reassessment over the lifecycle of a medicine. With respect to this inquiry, we ask the PMPRB to reflect on the following question: How can patentees make viable business decisions nationally and globally when the viability of their patented medicines can be negatively impacted by a reassessment at any time during their lifecycle and for various reasons, many of which are beyond the foreseeability or control of the patentee?

Servier believes that, first and foremost, the Final Guidelines should provide stable and predictable price ceilings that do not fluctuate over time. Moreover, the price of a medicine should be assessed only once 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.

A minimum twelve-month (two full reporting periods) transition period would be required following the implementation of the Final Guidelines to allow patentees, provincial drug plans and pharmaceutical supply chain stakeholders to properly implement the new prices. The interim period must not be counted toward the transition period as there is no clarity on the Final Guidelines that would allow patentees to prepare for them. This twelve-month transition period is aligned with what PMPRB has previously proposed.

Servier is hopeful that the comments provided to the PMPRB in this letter and by numerous stakeholders within this consultation process and during the Policy Roundtable discussions held on December 5th and 6th, 2023, will be seriously considered in the development of the Final 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,

Lucie Rousseau

Lucie Rousseau
Director of Operations
Servier Canada Inc.