



August 21st, 2023

Submitted via PMPRB's online Feedback Form

Attention: Notice and Comment - Amendment to the Interim Guidance re: New Medicines
Patented Medicine Prices Review Board
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

As part of the current consultation process, Servier Canada Inc. (Servier) would like to provide comments on the Patented Medicine Prices Review Board (PMPRB) 2023 Proposed Amendment to the Interim Guidance re: New Medicines (the Draft Guidance).

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 period.

Servier is an international pharmaceutical company governed by a non-profit foundation. With a strong international presence in over 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Servier would like to make the following comments regarding the Draft Guidance.

Adhere to PMPRB's statutory "Excessive Pricing" mandate

As confirmed by both the Federal Court of Appeal and the Quebec Court of Appeal, the PMPRB's mandate is limited to ensuring drug prices are non-excessive as a function of patent abuse. The proposed price test in the Draft Guidance for New Medicines – below the median international price for the 11 comparator countries – would not be justifiable under this mandate as it does not reflect a focus on excessive pricing, but rather appears to be designed to regulate prices and to drive pharmaceutical pricing downward. Pricing below the median international level would imply that half of all countries in the basket will always have excessively priced medicines. Yet no one truly believes that the new basket of 11 comparator countries is composed of countries which systematically tolerate excessively priced medicines, since the PMPRB11 countries already regulate the price of their medicines.

Servier believes that any price test within the Draft Guidance and Final PMPRB Guidelines must adhere to PMPRB's excessive pricing mandate and submitted Canadian list prices should be considered compliant as long as they do not exceed the highest available price within the new basket of 11 comparator countries.



Incorporate the Consumer Price Index (CPI) Change

The Draft Guidance proposes to extend the prohibition of taking CPI-based price increases during the interim period which will continue to put patentees at a significant economic disadvantage especially in the current inflationary environment.

“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 Draft Guidance and Final PMPRB Guidelines. No rationale has been provided by the PMPRB for diverting from the current practice and the criteria set out in the Patent Act.

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

A minimum twelve-month transition period (i.e., two full reporting periods) would be needed following the implementation of the Final PMPRB Guidelines to allow patentees and pharmaceutical supply chain stakeholders to properly adjust their business plans to the new pricing guidelines. Since patentees do not have visibility into the Final PMPRB Guidelines, the interim period should not be considered as part of the transition period. 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 will be seriously considered and incorporated in the Draft Guidelines and Final PMPRB 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,

A handwritten signature in blue ink that reads "Lucie Rousseau".

Lucie Rousseau
Director of Operations
Servier Canada Inc.