



June 17, 2021

**Submitted via PMPRB's online Feedback Form**

Attention: Consultation on the Guideline Monitoring and Evaluation Plan  
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) proposed Guideline Monitoring and Evaluation Plan (GMEP).

Servier's response to this consultation is not intended and should not be interpreted as supporting the amendments to the Regulations. Servier continues to have grave concerns about the practicality and legality of the amended Regulations, which are the subject of ongoing legal challenge. Servier reserves the right to oppose any aspect of the Guidelines that exceeds the jurisdiction of the federal government under the relevant legislation.

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 150 countries, Servier reinvests 25% of its global turn-over in Research & Development (R&D). Established in Canada for more than 40 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 recommendations regarding the new regulatory framework and in response to PMPRB's consultation on its proposed GMEP.

**Suspend the July 2021 Implementation of the Amended Regulations/Guidelines**

The COVID-19 pandemic has had a drastic effect on the health and economic sectors in Canada and worldwide. It highlights the importance of working with governments, public health authorities, industry partners and researchers towards innovation, investment in clinical research/trials and timely access to life-saving medicines and vaccines. Servier urges the federal government to suspend the July 1<sup>st</sup>, 2021 scheduled implementation of the amended Regulations and Guidelines until after the pandemic has subsided. This delay will allow stakeholders to continue to focus on the real priority, which is fighting COVID-19 and will provide adequate time for industry, patients and governments at all levels to work together to find a more balanced approach for the benefit of all Canadians.



## **Abandon the Maximum Rebated Price (MRP) Concept**

The MRP ceiling, as calculated in the Guidelines, is determined based on the knowledge that the Amended Regulations required patentees to include the quantum of confidential third-party rebates provided by patentees. In light of two court rulings invalidating PMPRB access to confidential third-party rebates, Servier believes that the MRP concept should be abandoned altogether and price ceilings of new patented medicines should be based on the median level of relevant and appropriate international prices. Consequently, the PMPRB will need to revise the Guidelines and engage in meaningful discussions with stakeholders in order to develop a more predictable and less complex regulatory framework. Furthermore, it is difficult to provide constructive feedback on the GMEP when key concepts such as the MRP are inoperable under the Guidelines and will need to be revisited.

## **Allow for an Independent Third-Party Assessment of the GMEP**

The Guidelines already provide the PMPRB with inappropriately broad discretion such that it can use any methods or tests deemed appropriate and consistent with the Act and Regulations, regardless of whether they are in scope of the Guidelines. Given PMPRB's broad discretionary powers and in order to ensure a fair, legitimate and credible monitoring and evaluation process, the impact of the Guidelines before and after implementation of the new framework should be assessed at arm's length by an objective third-party. The latter will introduce a degree of impartiality and transparency into the PMPRB consultation process which has been called into question on numerous occasions throughout this reform.

## **Modernize PMPRB's 1987 Definition of R&D**

Since the PMPRB's creation in 1987, the R&D model for innovative pharmaceutical companies has evolved considerably (including the way organizations are now investing in Canada as a result of new business models) while the methodology for determining pharmaceutical R&D spending has essentially remained unchanged. Consequently, many of the indirect investments and contributions made by the pharmaceutical industry are not captured in the current calculation of R&D ratios made public in PMPRB's Annual Reports, thus not recognizing the significant improvement to Canadian investments for patented medicines. For instance, financial flows coming from a foreign entity outside Canada (such as a global pharmaceutical company head office) are not considered while still representing significant contribution to the Canadian economy. Servier urges the PMPRB to modernize its definition of pharmaceutical R&D in order to capture the full extent of industry investments in Canada.

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In conclusion, Servier believes that all Canadians should have timely and optimal access to innovative medicines and vaccines especially during this time of pandemic and is of the view that the Amended Regulations and Guidelines will have the unintended consequence of decreasing access to innovative medicines for Canadian patients and deterring companies from launching new drugs in Canada.

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 black ink, appearing to read "A. Lallouette", written over a horizontal line.

Arnaud Lallouette  
Chief Executive Officer  
Servier Canada Inc.

## **SERVIER CANADA INC.**

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