December 1st, 2022

Submitted via PMPRB's online Feedback Form
Attention: Consultation on the 2022 Proposed updates to the PMPRB Guidelines
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) 2022 Proposed updates to the Guidelines (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 period.

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 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 comments regarding the 2022 Proposed updates to the PMPRB Guidelines.

Need for Clear & Predictable Price Tests and Impact Assessment

The mandate of the PMPRB, as established by the Patent Act (Act), is to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive. The Guidelines, which are issued pursuant to subsection 96(4) of the Act, are intended to provide transparency and predictability to patentees in determining whether a patented medicine appears to be priced excessively in Canada.

The Guidelines, as currently proposed, do not foster a clear and predictable pricing environment. Instead, the proposed application of investigation criteria in lieu of clear bright line pricing tests creates great uncertainty and unpredictability in price setting for patented medicines from product launch to patent expiry.

The Guidelines also provide the PMPRB with inappropriately broad discretion such that it can use any methods or tests regardless of whether they are in scope of the Guidelines.

Combine this with the application of arbitrary investigation criteria, the PMPRB is free to develop non-transparent product specific pricing policies that apply downward pricing measures especially for the most innovative future products.

When considering the enormous scope and potential implications of the Guidelines, it is of great concern that the PMPRB is unable to conduct an impact assessment on its proposals prior to the implementation of the Guidelines based on their proposed investigation criteria (i.e., in the absence of clear price rules/tests). Subsequently, the Guidelines could lead to far lower price levels than previously expected by the PMPRB and its stakeholders.

Guidelines Inconsistent with an Excessive Price Standard

If PMPRB's mandate under the Act is to ensure non-excessiveness, why is the current methodology being changed from highest (a plausible measure of excessiveness) to median (a mid-point value)? The Guidelines propose pricing above the median as an investigation trigger. This 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. 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 who have their own distinct pricing regulations/policies. Unpredictable price fluctuations throughout the product lifecycle will delay or even reduce the likelihood of market entry of innovative medicines in Canada.

On top of establishing the median international price as an overall ceiling for new patented medicines, the Guidelines also incorporate additional investigation criteria that assess price excessiveness based on “lower of”, and “lowest” values (e.g., 50% lower than the lowest international price). The PMPRB is ignoring the recent court decisions that limit its mandate to ensuring patented medicines are not excessively priced at a level that constitutes an abuse of patent in accordance with section 85 of the Patent Act. Consequently, the proposed “lower of” and “lowest” approach would not be justifiable under this mandate.

Recognize Innovation and Consider Levels of Therapeutic Improvement

Innovation is key to ensuring that Canadian patients benefit from new and effective medicines, and live healthier and longer lives. Since the creation of the PMPRB in 1987, the Guidelines have always included a level of innovation in the price review process as a way to recognize and reward pharmaceutical innovation. Under the current Guidelines, new patented medicines are assigned a ceiling price based on their degree of therapeutic benefit relative to existing drugs. When a medicine offers therapeutic improvement (breakthrough,

substantial or moderate), premium pricing is allowed above therapeutic compactors. This concept can be found in the pricing systems of countries such as France, Germany, Italy and Japan which are part of Canada's new basket of comparator countries for reference-based pricing.

The Guidelines do not differentiate between innovative first in class medicines that treat effectively a particular illness or addresses effectively a particular indication (breakthrough) and some "me-too" medicines that offer slight or no therapeutic improvement over existing therapies. This complete disregard of level of innovation between new patented medicines will significantly penalize price ceilings associated with new highly innovative drugs (e.g., for rare diseases, oncology drugs and drugs with multiple indications) and will negatively impact investment in clinical trials in Canada.

Given the high level of uncertainty and unpredictability of the Guidelines, 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 Final Guidelines.

In conclusion, Canada's health care system is already complex and implementing investigation criteria instead of predictable bright line pricing tests for determining allowable price ceilings does not make for a favorable commercial environment and increases the cost/risk of doing business 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,

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Chief Executive Officer
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