SERVIER CANADA

August 2nd, 2021

BY EMAIL: pmprb.consultations.cepmb@pmprb-cepmb.gc.ca
ATTENTION: Notice and Comment published on July 15, 2021
Patented Medicine Prices Review Board
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Please find herein Servier Canada Inc.'s (Servier) comments to the Patented Medicine Prices Review Board (PMPRB) Notice and Comment on the change to the international price tests for Grandfathered Medicines and their Line Extensions.

This proposed consequential change to the new Guidelines is the result of the federal government's decision to further delay the coming-into-force date of the Regulations Amending the Patented Medicines Regulations (Regulations) by six months, from July 1, 2021 to January 1, 2022.

Servier's response to this Notice and Comment 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 the Notice and Comment 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 is concerned and objects to PMPRB's proposal to set the maximum list price (MLP) for Grandfathered Medicines and their Line Extensions based on the median price test of the PMPRB7 countries instead of the highest price test as per the current Guidelines. Servier further objects to the proposal of using the median of the PMPRB7 countries for the reporting period ending June 30, 2021 and for subsequent reporting periods up until the implementation of the Regulations.

The Guidelines are intended to provide transparency and predictability to patentees regarding PMPRB's review process in determining whether a patented medicine appears to be priced excessively in Canada. How does proposing a major change to the current international price tests for Grandfathered Medicines and their Line Extensions for not only one reporting period that has already passed but in the event of additional regulatory delays provide transparency and predictability to patentees? Moreover, patentees have already filed sales and pricing information to the PMPRB for the reporting period ending June 30, 2021 and have assessed compliance and financial impact based on the Regulations and Guidelines currently in effect.

Also, PMPRB's proposal to modify the Guidelines by changing price tests should be the subject of a major consultation and not streamlined via a Notice and Comment. This change in methodology will drastically reduce the price of many Grandfathered Medicines and create great uncertainty in forecasting their future pricing despite the fact that these 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 and when the scope and impact of the new PMPRB regime could not have been reasonably foreseen.

Furthermore, the Notice and Comment seems to indicate that the PMPRB intends to use the new Guidelines methodology for assessing the MLP based on Canadian list prices rather than the National Average Transaction Price (N-ATP), as well as the lowest unit prices for medicines with multiple package sizes rather than the average unit prices. If the new Guidelines operationalize amendments to the Regulations scheduled to take effect on January 1st, 2022, how can pricing methodologies specifically developed and evaluated under the new Regulations be proposed under the current Regulations? This will create further uncertainty, unpredictability and complexity in price setting for patented medicines in Canada.

On a related note, although not subject to the current consultation, PMPRB's intent to reduce the compliance timeline from 12 months to 6 months contradicts the federal government's rationale for delaying the Regulations in the first place which was to provide industry with additional time to adapt to the new reporting obligations while maintaining ongoing efforts related to the pandemic response. The proposed 6-month transition period will penalize patentees by significantly reducing the allowable timeframe for patentees to bring list prices into compliance with new price ceilings thus substantially increasing compliance burden. A minimum 12-month transition period from the coming-into-force date of the Regulations and new Guidelines is more realistic and operationally feasible than the current proposal of 6 months.

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.

As an important stakeholder in the healthcare system, we look forward to working collaboratively with the PMPRB and other stakeholders to address these serious concerns that will ultimately affect Canada's access to the newest and most significant innovations to treat and cure diseases.

Yours sincerely,

Arnaud Lallouette
Chief Executive Officer
Servier Canada Inc.