February 11, 2021

BY EMAIL: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca
ATTENTION: Notice and Comment published on January 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 proposed consequential amendments to the January 1, 2021 PMPRB Guidelines (Guidelines) which target to change the definition of Gap medicines and the timeline for compliance.

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 reduce the compliance timeline for Grandfathered and Gap Medicines from 12 months (2 reporting periods) to 6 months (1 reporting period).

The proposed consequential amendments to the Guidelines are the result of the federal government's decision to delay the coming-into-force date of the Regulations Amending the Patented Medicines Regulations (Regulations) by six months, from January 1, 2021 to July 1, 2021.

PMPRB's proposal to reduce the compliance timeline from 12 months to 6 months for Grandfathered and Gap Medicines contradicts the federal government's rationale for delaying the Regulations which was **to provide industry with additional time to prepare for the new reporting obligations and to familiarize themselves with the Guidelines**. 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.

Under the Guidelines, patentees are required to submit their semi-annual PMPRB Form 2 reports for the January to June 2021 reporting period to the PMPRB by July 30th, 2021. The compliance status reports which contain the new price ceilings are communicated by the PMPRB to patentees by mid-September 2021. Thus, under a Guidelines transition period of 6 months, patentees would have approximately 3 ½ months (from September 15th to December 31st, 2021) to review compliance information for all of their patented medicines, determine if an Maximum List Price (MLP) calculation has been impacted by the reporting of benefits and submit an exception request if applicable, and reduce list prices where necessary in all provincial/territorial jurisdictions as per their respective policies and timelines. Such important policy changes should provide patentees with an adequate compliance timeframe. Unfortunately, a 6-month transition period does not allow patentees to fully understand, evaluate and apply compliance obligations.

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.

In summary, given the ongoing pandemic and for the reasons stated above, a minimum 12-month transition period from the coming-into-force date of the Regulations is more realistic and operationally feasible than the current proposal of 6 months.

As a member of the life sciences community, we appreciate the opportunity to provide feedback on this Notice and Comment 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,

Philip Van Muylders
Servier Canada Inc.
Zone Director
Northern Europe and Canada