August 31, 2021

Dr. Mitchell Levine
Chair, Patented Medicine Prices Review Board (PMPRB)
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Submitted via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Dear Dr. Levine,

Subject: Notice and Comment - On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions

On behalf of Astellas Pharma Canada, Inc. (Astellas), thank you for the opportunity to provide feedback on the above noted consultation.

Astellas has contributed to and supports the submission of our industry association, Innovative Medicines Canada, and we hope that the following additional comments help highlight some of the issues and recommendations that are important to Astellas. More specifically, we have several substantive concerns regarding the PMPRB's intention to apply new price tests within a compressed timeline for Grandfathered medicines.

In sum, the latest proposed changes are unreasonable and lack a rationale, the reduced transition period runs contrary to the government's decision to delay the regulations and the proposed changes threaten the commercial environment for pharmaceuticals and life sciences strategies, which are critical for the Canadian effort to address the COVID-19 pandemic.

1. Lack of rationale for the latest proposed changes

The latest PMPRB proposal to change international price tests for on-market medicines and their line extensions from the Highest International Price (HIP) to the Median International Price (MIP) is arbitrary and unreasonable. While the PMPRB noted in its consultation document that the proposed changes are "an appropriate response" to the recent six-month implementation delay of the amended *Patented Medicines Regulations* (the regulations), no rationale was provided to explain why the PMPRB deems this an appropriate response.

Following the 2020 guidelines consultation, the PMPRB committed to implement the HIP for Grandfathered medicines "as a concession to patentees whose expectations may have been raised by the Health Canada's Cost Benefit Analysis (CBA) and in recognition of the impact of

changing the schedule of comparator countries."[1] Without any reasons provided, the PMPRB's reversal on this matter appears to be a punitive move taken in response to the government's recent decision to delay the implementation of the PMPRB regulations due to the ongoing COVID-19 pandemic.

Unfortunately, this latest initiative is part of a pattern of concerning behaviour from the PMPRB that includes revoking previously agreed to concessions, insufficient consultations and inappropriate advocacy campaigns.

2. Reduced transition period undermines government rationale for regulatory delay

The PMPRB previously committed to provide patentees with a 12-month compliance period following the implementation of the regulations. This was confirmed in the October 2020 publication of the final guidelines and reaffirmed by the Board earlier this year. However, the latest changes have effectively halved the compliance period for Grandfathered medicines from twelve months to six months post-implementation of the regulations, without any explanation.

This proposal is incongruent with the federal government's rationale for delaying the entry into force date of the regulations by six months – namely, to facilitate our sector's response to the COVID-19 crisis. If the compliance period is reduced in such a manner, patentees will face continued challenges that detract attention and resources away from responding to the pandemic and supporting Canadians who need access to treatments during this critical period, especially as we enter the fourth pandemic wave.

3. Impacts on commercial environment for pharmaceuticals and life sciences strategies

The proposal to change prices tests for Grandfathered medicines from the HIP to MIP will introduce significant new negative impacts across the pharmaceutical supply chain, impacting not only patentees but also distributors, pharmacies, generics, etc. Moreover, this is an unexpected burden. Over the past year, patentees and other supply chain stakeholders have been adjusting their business strategies and planning based on the previously announced price tests and transitional timeframes, only to be confronted with an entirely new set of rules and considerations. All stakeholders in the pharmaceutical supply chain need a stable and predictable regulatory environment to guide their business decisions. Unfortunately, the PMPRB's approach to policymaking is a growing disincentive for developing, deploying and adopting medicines and vaccines in Canada.

These developments will unfortunately cause a further erosion of Canada's pharmaceutical environment and stifle ongoing federal efforts to grow the life sciences sector, most notably

[1] PMPRB Backgrounder on June 2020 Draft Guidelines: Explanation of Changes from November 2019 Draft Guidelines: https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/2020/PMPRB-Backgrounder2020-en.pdf

through the recent release of the Biomanufacturing and Life Sciences Strategy.[2] Importantly, the PMPRB's proposals run at odds with the strategy's fifth pillar, which is to enable innovation by ensuring world class regulation, and its aim to "grow a strong and competitive domestic life sciences sector, and ensure Canada's readiness for future pandemics or other health emergencies."

Conclusion

In light of the above considerations, Astellas strongly recommends that the PMPRB:

- Ensure Grandfathered medicines and their line extensions are in fact grandfathered in terms of the impacts of any changes to support business continuity for the entire supply chain
- Revert back to the 12-month transition period from the entry into force date of the regulations to reflect the spirit and intent of the federal government's decision to delay the regulations

Thank you again for the opportunity to provide input on the proposed guideline changes.

Sincerely,

Frank Stramaglia
General Manager
Astellas Pharma Canada, Inc.

[2] https://www.canada.ca/en/innovation-science-economic-development/news/2021/07/the-government-of-canada-announces-biomanufacturing-and-life-sciences-strategy.html