February 15, 2021

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

On behalf of Astellas Pharma Canada, Inc. (Astellas Canada), I am writing to provide feedback on the PMPRB Notice and Comment regarding the change to the definition of Gap medicines and the timeline for compliance, issued January 13, 2021.

Astellas Canada 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 of importance to Astellas.

In previous submissions to PMPRB, Astellas Canada has expressed concern regarding the potential negative impacts of the proposed Guidelines on the timely access to innovative therapies and research investments in Canada. The comments below are intended as recommended amendments if the Guidelines are implemented as drafted. While Astellas Canada is committed to constructive engagement with the PMPRB on the Guidelines, Astellas Canada's engagement is not intended and should not be interpreted as supporting the amendments to the Regulations or the Guidelines.

Comments on the Proposed Consequential Amendments to the January 1, 2021 Guidelines:

1. **Definition of Gap Medicines:**

Although Astellas is concerned about the ongoing uncertainty and disruption caused by the repeated delays in the implementation of the new framework and the new framework itself, we agree that if the Guidelines are implemented in July 2021, the definition of gap drugs should be extended to include those drugs that are first sold in the first half of this year.

2. Compliance Timelines for Grandfathered and Gap Medicines:

Under the current draft Guidelines, compliance with the Maximum List Price (MLP) for Grandfathered and Gap medicines is proposed to be assessed after two filing periods, on January 1, 2022. Notwithstanding the additional 6-month delay in implementation of the Regulations, **the PMPRB is now proposing that January 1, 2022 will remain the operative date for assessing compliance, thereby reducing the implementation period by six months**.

The proposal to enforce a potential price reduction in the same period as the new rules are implemented is not practical. As explained in the webinars held by Board Staff in December 2020 (prior to the most recent delay in implementation), companies will only be provided with the first estimate of the Maximum List Price (MLP), for existing drugs, 45 days after the filing deadline. This means that if the Guidelines are implemented on July 1, 2021, the initial MLP will only be available mid-September.

In the initial draft of the Guidelines, implementation would have come into force in July 2020. The deadline for coming into compliance was set at 18 months after implementation. This provided both Board staff and patentees the opportunity to adjust to any technical issues with the new filing software that is expected to be implemented in parallel with the new Guidelines, understand, and address any complexities in implementing the rules as written. It is not clear why the Board would alter the original plan of allowing 18 months to implement compliance by now introducing additional risk and complexity by trying to accelerate the deadline for compliance to December 2021.

Accelerating the compliance deadline to December 2021, when the Guidelines will only be implemented July 1st, increases the risk of confusion and unnecessary confrontation as the finer points of the new online filing tool, the new guidelines and the new calculations are worked out. Astellas Canada requests that the PMPRB take a long-term view and take the necessary time to ensure the implementation is as efficient as possible. Consistent with the Board's original vision of the transition described above, the appropriate deadline for compliance should be December 31, 2022, 18 months after implementation of the new regulatory framework.

Thank you in advance for considering our submission.

Sincerely,

Frank Stramaglia
General Manager
Astellas Pharma Canada, Inc.