Submitted via the consultation portal

July 18, 2022

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

Dear PMPRB staff,

Subject: Notice and Comment - PMPRB Price Review Approach During the Interim Period following publication of Amendments to the Patented Medicines Regulations

On behalf of Astellas Pharma Canada, Inc. (Astellas), I am writing to provide our feedback on the PMPRB's draft approach for the Interim Guidelines. [i]

Astellas has contributed to and supports the submissions of our industry associations, Innovative Medicines Canada (IMC) and the Canadian Forum for Rare Disease Innovators (RAREi). We hope that the following additional comments help to highlight some of the issues and recommendations that are important to Astellas.

While we are for the most part satisfied that some of the problematic aspects of the reforms have been revised, we still believe the new regime, including the interim period, could prove to be challenging for our portfolio and pipeline of therapies, many of which help or many of which have the potential to allow patients with limited life expectancies to live longer and better-quality lives.

In this context, we ask that the PMPRB consider the following comments, which we hope will help inform the PMPRB's approach moving forward:

- **Work within mandate**: Recent legal decisions have clearly laid out that the PMPRB's mandate is to monitor for excessive pricing linked to patent abuse, not consumer protection. The PMPRB's approach in the interim and final guidelines must be guided by these decisions.

- **Align priorities with national rare disease strategy**: As part of our recovery and resilience efforts from the COVID-19 pandemic, governments across Canada have adopted strategies to help grow the life sciences sector and support better access to medical innovation. The PMPRB's approach should reflect and align with this important imperative. Moreover, the federal government has made a significant multi-year commitment to invest in improving patient access to rare disease medicines through a new strategy that is scheduled to come into effect in the current fiscal year. PMPRB guidelines should enable and support these broader government efforts.

- **Apply a true status quo approach by grandfathering on-market medicines**: We are supportive of the PMPRB's intention to maintain a status quo approach for already launched medicines in the absence of the final guidelines. The status quo approach should carry through in final guidelines. Companies need predictability to guide commercial decisions and long-term planning. Requiring companies to go back and revisit pricing strategies that were developed years prior is inadvisable and could lead to significant business disruptions and knock-on effects up and down the supply chain, which could cause medicine shortages and other unintended consequences.

- **Address uncertainty related to interim period:** The PMPRB's proposed approach for medicines launched during the interim period has several points of uncertainty. For instance, there is little guidance on what constitutes a non-excessive price in the absence of the final guidelines. This means that companies must launch at risk, which could lead to a chilling effect for new medicine launches during this period. To mitigate this uncertainty and build on the above point, it would be prudent for the PMPRB to assure patentees that it will not seek payment of 'excessive revenues' for medicines launched during this period. On a related point, the PMPRB's proposed *de facto* prohibition on price increases during the interim period fails to reflect the current inflationary environment (patentees are already effectively prevented from taking price increases in the public health system). "Changes in the Consumer Price Index" is an explicit factor in the *Patent Act* that should be reflected in future Guidelines, especially in the current inflationary period and when other countries in larger markets look to benchmark and reference against Canadian public list prices.

- **Provide a twelve-month transition period following publication of final guidelines**: Given that patentees lack visibility on what the final Guidelines will look like, it will be necessary to maintain the twelve-month (two reporting period) transition period committed to previously by the PMPRB following the publication of the final Guidelines. This will provide companies with the time needed to adjust their commercial operations and contracts.

Thank you in advance for considering our submission. We look forward to further dialogue with the PMPRB to develop guidelines that provide certainty, predictability and a pricing environment that enables research and access to medicines in Canada.

Sincerely,

Frank Stramaglia
General Manager
Astellas Pharma Canada, Inc.

[i] **Astellas Pharma Canada, Inc.** understands that the PMPRB intends to apply Guidelines within the framework of amendments to the *Patented Medicines Regulations* (**Regulations**), which came into force on July 1, 2022. While Astellas is committed to constructive engagement with the PMPRB, Astellas' engagement should not be interpreted as supporting the validity of the amended Regulations, which remain, as of the date of this submission, under review by the Federal Court of Appeal in Court File No. A-215-20. Astellas reserves the right to oppose any aspect of the amended Regulations, Guidelines, or other decision that exceeds the jurisdiction of the Board.