Submitted via the consultation portal

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Patented Medicine Prices Review Board
Standard Life Centre, Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Subject: Astellas submission to PMPRB GMEP consultation

On behalf of Astellas Pharma Canada, Inc. (Astellas), thank you for the opportunity to provide input on the abovementioned consultation. Our input is meant to align and support the submission of our industry association, Innovative Medicines Canada.

Astellas is a pharmaceutical company dedicated to changing tomorrow by improving the health of people in Canada and around the world through innovative medicines. Our diversified product portfolio includes therapies used in oncology, transplantation, urology, and rare diseases.

We would like to start by expressing our concern regarding the Patented Medicine Prices Review Board's (PMPRB) intention to monitor the impacts of its own guidelines. From the outset of the reform process, the PMPRB has insisted that its reforms will not impact access to medicines or investments in research and development (R&D), yet it has been unwilling to share its data and calculations to support these assumptions. The PMPRB has also not been sufficiently transparent in how it presents information, often with no references and only looking at certain aspects while ignoring others.

The PMPRB's February 2021 communications plan on the reforms, which was recently made public, is emblematic of this problem.[1] The plan includes a range of tactics and key messages directed at Members of Parliament, the public and others, in order to discredit and undermine stakeholders who are worried about the consequences of the pricing reforms. These are concerning actions taken by a government regulator, whose mandate is to regulate drug prices in Canada in a fair, neutral, impartial and objective manner.

This communications plan, along with the PMPRB's entrenched position on its approach, raises concerns about selective information being used to downplay the actual and potential impacts of the reforms on access to medicines, clinical trials, and investments in research.

[1] https://www.dropbox.com/s/eusxuabcq26uqt9/PMPRB%20ATIP%20Disclosure.pdf?dl=0

For this reason, we believe that an external review of the reforms and their impacts is necessary.

In the hope that this and other input on this consultation may help inform an external evaluator, we are pleased to provide the following more specific comments on the some of the areas proposed in the PMPRB Guideline Monitoring and Evaluation Plan (GMEP):

- **Baseline date**: The GMEP consultation document notes that "Baseline results (benchmarks) will be generated based on the years immediately preceding the coming-into-force of the amended Regulations." The PMPRB's decision to remain vague on the baseline dates is problematic. We recommend that the starting point for the benchmark be made December 2017, which is when the regulatory changes were posted for comment in the Canada Gazette Part I. This is the date from which patentees started to change their outlook on the Canadian market, and from which the impacts on access began to take hold.
- **Prices**: The discussion document makes several unreferenced assertions about medicine prices that are contradictory. Moreover, there appear to be contradictions based on previous PMPRB communications. For instance, p. 3 of the GMEP document says that Category 1 medicines will account for over 75% of new patented medicine spending by 2030. However, this figure is much higher than what the PMPRB presented in the November 2020 webinar on the new guidelines, when it was stated that Category 1 medicines would only account for 34% of medicines within 10 years. Discrepancies such as this one should be acknowledged and addressed.
- **Pharmaceutical ecosystem**: We commend the PMPRB for its intention to consider R&D investments made by industry beyond the SR&ED definition, as well as pharmaceutical research that is publicly funded. The use of the current outdated definition of R&D has led to an artificially low sales-to-R&D ratio, which has been used to justify the need for the PMPRB reforms. Moving forward, using this expanded definition will provide a much more holistic and accurate illustration of the pharmaceutical industry's actual sales-to-R&D ratio. However, for the purposes of monitoring the impacts of the reforms, it will be important to apply the same definition of industry R&D pre and post PMPRB implementation to get a true "apples to apples" comparison. Otherwise, it may seem as though industry R&D has doubled in the post-implementation phase, when in fact it would just be the expanded R&D definition that covers more investments.
- **Processes:** The current GMEP plan appears to be overly broad. It would be more useful to focus on a smaller, more manageable number of key metrics that really matter, including access to medicines, research investments (R&D), jobs within the sector and the administrative burden on patentees. There is no need to collect and report information on dozens of metrics across four quadrants that in effect constitute an environmental scan of nearly every aspect of the Canadian regulatory, review and funding process for pharmaceuticals.

In closing, we would like to reiterate the need for a third-party auditing firm or agency to carry out this assessment.

We would also like to use this opportunity to ask for a delay to the July 1, 2021 implementation date of the regulations. Implementing the reforms during the pandemic will divert our sector's attention and resources away from the crisis and would be inadvisable. We believe that a delay for the duration of the pandemic will help facilitate the 'all hands on deck' approach that we need during this difficult period, in addition to providing more time to review the reforms and explore alternative approaches, an ask that was echoed by the Ontario government in a recent letter submitted to the federal government on May 31, 2021.[2] A delay would also allow more time to obtain legal clarity on the reforms, which continue to be challenged in the courts, mostly recently by the province of Quebec.[3]

Thank you for the opportunity to provide input. If you have any questions about our submission, please do not hesitate to reach out.

Sincerely,

Frank Stramaglia
General Manager
Astellas Pharma Canada, Inc.

[2] https://hilltimesresearch.ca/ontario-and-quebec-push-back-on-pmprb-rule-changes/
[3] https://hilltimesresearch.ca/ontario-and-quebec-push-back-on-pmprb-rule-changes/