March 19, 2025

Anie Perrault
Acting Chairperson, Patented Medicine Prices Review Board (PMPRB)
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario, K1P 1C1
Via the PMPRB consultation portal

Subject: Draft PMPRB Guidelines (December 2024 version)

Dear Ms. Perrault,

On behalf of Astellas Pharma Canada, Inc. (Astellas), thank you for the opportunity to provide feedback on the above-noted draft PMPRB guidelines (Draft Guidelines).

Astellas Pharma Canada, Inc. is a Canadian affiliate of Tokyo-based Astellas Pharma Inc., a global life sciences company conducting business in more than 70 countries around the world. We were the first Japanese pharmaceutical company to open an affiliate in Canada in 1989 (Fujisawa Canada), and following the merger with Yamanouchi in 2005, we established the name Astellas around the world.

We are a cutting-edge, value-driven life science innovator working at the forefront of healthcare change to turn innovative science into VALUE for patients. What sets us apart is our Focus Area approach to prioritize unmet needs, our collaborative culture, and the passion of our talented people. We are extremely proud of our legacy in oncology, overactive bladder, and provision of transformative therapies in disease areas including oncology and women's health.

Astellas' commitment to patients includes a promising pipeline in immuno-oncology, genetic regulation, mitochondrial and targeted protein degradation approaches to deliver potentially life-changing treatments.

Our input aligns with and supports the input provided by our industry association, Innovative Medicines Canada (IMC). The comments below highlight key issues that are most relevant to Astellas.

We hope our input contributes to developing clear and predictable pricing guidelines that create a stable commercial environment for pharmaceuticals in Canada. Given the current economic and trade climate, we strongly encourage the PMPRB to implement our proposed recommendations, as they will help minimize market disruption and establish a more balanced pricing framework – one that supports innovation while ensuring access to essential medicines for Canadians.

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RECOMMENDATIONS

1. Retain Highest International Price (HIP) for initial reviews

Astellas welcomes the PMPRB's proposal to use the Highest International Price (HIP) for initial reviews. This aligns with the PMPRB's mandate to ensure patented medicine prices in Canada are not excessive. Anchoring price reviews to the HIP within the PMPRB11 reference countries acknowledges that Canadian prices within this range do not warrant additional scrutiny. This approach helps maintain Canada's competitiveness in attracting new medicines while providing a stable framework for pricing decisions. The recent removal of the U.S. and Switzerland – historically higher-priced countries – from the PMPRB11, along with the inclusion of lower-priced markets, has already lowered medicine prices in Canada. Given these changes, setting a price threshold below the HIP for international price comparisons would exceed the PMPRB's mandate and could discourage timely medicine launches.

2. Limit annual price reviews to inflation (CPI) adjustments only

The Draft Guidelines propose annual price reassessments based on updated international comparisons. However, this approach introduces uncertainty, as global prices can fluctuate significantly due to factors outside a manufacturer's control, including exchange rate volatility. Continual re-benchmarking against shifting international price landscapes creates instability and an unnecessary administrative burden, forcing rights holders to constantly adjust their pricing strategies. This added uncertainty could discourage companies from introducing new products in Canada, as they may struggle to predict long-term revenue potential or justify the financial risks associated with launching innovative treatments in an unpredictable pricing environment. Instead, once a medicine's ceiling price is established at launch, it should be reassessed only in relation to Consumer Price Index (CPI) adjustments, rather than ongoing international price comparisons. This pragmatic approach ensures price stability while accounting for inflation.

3. Grandfather existing medicines

The Draft Guidelines propose applying the new rules to medicines launched before July 1, 2022, when the regulatory amendments were adopted. These medicines were already assessed under the previous pricing regime. This retrospective approach is problematic, as rights holders make long-term investment decisions based on the regulatory framework in place at the time of a product's launch. To ensure fairness, medicines first sold before July 1, 2022, should be grandfathered so that they would not be subject to an in-depth review, provided they remain within allowable inflation-based price adjustments.

In the Draft Guidelines, the PMPRB opted for a minimum transition of one year for existing medicines. While Astellas believes full grandfathering is the appropriate approach for these medicines, if the Board decides against it, a three-year transition would be the most appropriate option among those under consideration. Public plans, insurers, pharmacies, and distributors

will need more time to adjust drug prices and prevent disruptions in the procurement and distribution processes of patented medicines in this country.

4. Implement a transition period for medicines launched between July 2022 and final Guidelines

Medicines introduced between July 1, 2022, and the implementation of final Guidelines were launched without clarity on the new regulatory environment. These medicines should be granted a transition period, allowing rights holders time to adjust to the new compliance requirements. A minimum one-year transition period after the final Guidelines take effect would provide necessary stability and fairness, ensuring manufacturers are not penalized for regulatory uncertainty outside of their control.

5. Minimize the level of uncertainty created by In-Depth Reviews

Astellas recognizes several key challenges with the PMPRB's proposed process for In-Depth Reviews and offers the following recommendations to improve predictability, fairness, and efficiency in these reviews:

- **Enhance clarity and consistency**: The Draft Guidelines grant PMPRB Staff broad discretion in assessing Section 85(1) factors, creating uncertainty for rights holders and making pricing outcomes difficult to predict. A more transparent and structured approach is needed to ensure consistency in reviews. Therapeutic class comparisons should focus on relevant brand-name comparators, and patented medicines should be allowed the higher of the "top of the TCC" or the Highest International Price (HIP). Prices within the comparator range should not be presumed excessive, and clear criteria should be established to determine when an In-Depth Review is warranted. Standardizing the process will reduce unnecessary regulatory burden, improve predictability, and ensure the PMPRB remains focused on addressing truly excessive pricing concerns.

- **Ensure procedural fairness**: Transparency and fairness are crucial in the review process. Under the Draft Guidelines, rights holders are not granted full access to the PMPRB's pricing analysis when an In-Depth Review is initiated. This lack of transparency limits a manufacturer's ability to understand and respond to pricing concerns effectively. To ensure fairness, the PMPRB should provide rights holders with all relevant review documents and analyses.

- **Avoid unfounded complaints triggering In-Depth Reviews**: The Draft Guidelines propose automatic In-Depth Reviews triggered by complaints, even if a medicine has already passed initial and annual reviews. First, the eligibility of complaints should be restricted to federal and provincial/territorial health ministers, consistent with the approach taken in s. 86(2) of the *Patent Act*. If not, an open-ended complaint process could result in excessive regulatory intervention, particularly when complaints are unfounded or strategically motivated.

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Second, to avoid unnecessary reviews, the Draft Guidelines should ensure that complaints meet specific documentation standards and demonstrate clear evidence of excessive pricing. Moreover, the PMPRB should apply a statute of limitations for excessive revenue calculations. If a medicine has been sold at an approved price for several years without any issues, it should not automatically trigger a review – along with the calculation and collection of long-past revenues – unless there is a compelling justification.

Thank you once again for the opportunity to provide input. Collaborating with rights holders to develop a clear regulatory pricing framework with transparent rules and predictable price tests will be essential to enhance compliance with the system while also supporting medicine access and research investments in Canada.

Please do not hesitate to reach out to me or our team for any clarifications regarding our recommendations.

Sincerely,

Sandra Heller
General Manager
Astellas Pharma Canada, Inc