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September 11, 2024

Thomas J. Digby
Chairperson, Patented Medicine Prices Review Board (PMPRB)
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1
Via the PMPRB consultation submissions portal

Subject: Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines

Dear Mr. Digby,

On behalf of Astellas Pharma Canada, I am providing our feedback on the consultation related to the PMPRB's Discussion Guide.

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, and urology, and to help address unmet needs for women's health and within ophthalmology.

Our input is aligned with and supports the feedback provided by our industry association Innovative Medicines Canada (IMC).

This submission provides several recommendations and considerations in response to issues raised in the PMPRB's Discussion Guide. We hope our input helps shape clear and predictable pricing guidelines that create a stable commercial environment to facilitate business planning by rights holders. Additionally, we believe that the PMPRB's statutory mandate — to ensure patented medicine prices are not excessive without setting prices— should be carried out in a balanced manner that supports prompt medicine access for Canadian patients and the growth and development of Canada's health research ecosystem.

1. Highest International Price (HIP) as the standard aligned with the PMPRB's mandate

Recent court decisions confirming the PMPRB's legislated role in price regulation have been clear: the PMPRB is responsible for protecting against patent abuse and excessive pricing, not general price regulation, consumer protection or any other imperative related to affordability or reasonable pricing.

This is why we recommend HIP as the appropriate pricing level for initial pricing assessments based on the PMPRB11 reference countries. The medium international price (MIP) or the midpoint level between MIP and HIP would be inconsistent with the PMPRB's court-defined mandate. As drug prices are regulated in the PMPRB11 countries, none of them can be considered excessive.

Opting for the HIP would also help enhance administrative efficiency, which is one of the PMPRB's stated goals in its Discussion Guide. In particular, the guide specifies that in 2023, 32% of patented medicines had list prices above HIP, 53% were above the midpoint threshold and 78% were higher than the MIP. Therefore, utilizing the HIP would reduce the number of patented medicines requiring an in-depth review.

We also recommend that initial price assessments only be undertaken when pricing data from at least five countries in the PMPRB11 basket is available. Relying on price data from only two countries, as proposed by the PMPRB, could delay new products being launched in Canada since manufacturers might opt to introduce their products at a later time when pricing is available in more countries. The Canadian drug review system should avoid creating more barriers to the introduction of new medicines, especially given Canada's poor performance in making medicines available compared to other similar countries. Canada ranks nearly last of all OECD countries when it comes to accessing new treatments.

2. Ensure more predictability with no re-benching of prices

Patented medicines should not be continuously re-benched as this would be inconsistent with the PMPRB's legal mandate. Reducing prices over time would effectively amount to price controls, which would go against the PMPRB's legal mandate.

Continuous price reassessments would also create significant uncertainty for pharmaceutical companies. Successfully commercializing medicines, and attracting investments in Canada depend on long-term stability and predictable regulations for setting drug prices.

Finally, re-benching prices would also negatively impact other key players in the pharmaceutical ecosystem by imposing an important administrative burden. Specifically, public plans, insurers, pharmacies and distributors would be required to make continuous contract and operational changes to reflect the new pricing.

3. Grandfather existing medicines to ensure a more stable market

Medicines already launched in Canada (i.e. existing medicines) should be grandfathered and not subject to the PMPRB's new Guidelines. The pricing of these medicines was tied to compliance

with previous guidelines and the assumptions and business conditions that existed at the time they were launched. Changing the rules retroactively would undermine the reasonable expectations and intellectual property of rights holders.

As with re-benching, changing the rules for existing medicines would also create unnecessary instability for the entire pharmaceutical sector. Public plans, insurers, pharmacies and distributors would all need to adjust drug prices at the same time, which would be challenging from an operational perspective and could result in adversely affecting the procurement and distribution processes of patented medicines in this country.

4. Limit the eligibility for making complaints

Attractiveness of Canada for investments and launch of new treatments hinges on market predictability, with pricing as a critical component. To maintain stability, complaints should be limited and assessed based on explicit criteria specified in the new Guidelines, such as international price comparisons (IPC) and allowable increases tied to the Consumer Price Index (CPI). A key aspect of this approach would be to confine complaints to those submitted by federal, provincial, or territorial health ministers.

As well, we recommend enhancing the transparency of the complaint process by allowing rights holders to receive more comprehensive information about the complaint. This could potentially avoid the need for resource-intensive in-depth reviews, as rights holders might be able to respond and address some concerns right from the outset.

5. Establish technical working groups as part of meaningful consultations with the industry

The best way the PMPRB can ensure it works constructively to develop practical, clear and efficient new Guidelines would be to establish technical working groups with the industry. This consultation approach used to be standard practice for previous changes proposed to the PMPRB Guidelines prior this current reform.

Working groups would go a long way towards preventing both misunderstandings and unintended consequences. Specifically, they would provide a constructive forum to discuss the best parameters and processes for international and domestic class comparisons proposed by the PMPRB for in-depth reviews. These issues are complex and require sustained dialogue to ensure solutions are found and well understood by rights holders.

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Thank you in advance for considering the recommendations outlined in this submission. 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.

In this context, Astellas Pharma Canada would be pleased to take part in working groups and provide examples to develop practical case studies to help understand the impact of the proposed changes.

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.