December 5, 2022

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

Subject: Consultation on the proposed changes to the PMPRB's Guidelines to give effect to recent amendments to *the Patented Medicines Regulations*

On behalf of Astellas Pharma Canada, I am writing to provide our feedback on the above-noted consultation.

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.

Our input aligns with and supports the submissions of our industry association, Innovative Medicines Canada (IMC), as well as the Canadian Forum for Rare Disease Innovators (RAREi).

Below we offer several recommendations and considerations, which we hope can contribute to a better Guidelines approach moving forward.

1. Address uncertainty

The PMPRB's new approach represents a wholesale departure from how things were done in the past. Notably, the PMPRB has decided to abandon the pricing rules and thresholds that were defined in the previous Guidelines and has proposed a brand-new system based on vague investigation criteria that do not provide clear guidance for companies regarding what may constitute excessive pricing.

Moreover, the PMPRB has given itself significant discretion and powers to unilaterally adapt its approach on a case-by-case basis, including the ability to use "any methods or tests deemed appropriate… regardless of whether they are addressed in the Guidelines." This will lead to increased investigations, hearings, and litigation moving forward, and will continue to undermine Canada's attractiveness as a place to do business.

Without a clear regulatory framework based on transparent rules and price tests, companies will be challenged to bring new medicines and investments to Canada. We therefore strongly recommend moving away from the proposed approach and addressing this uncertainty in a future iteration of the Guidelines.

2. Recognize the value of innovation

The PMPRB's approach discourages new innovative medicines from coming to Canada. For instance, the PMPRB has decided to drop the 'level of therapeutic improvement' criteria from the previous guidelines, which applied a range of predictable price tests to establish a ceiling, under which we could engage with various payers to ensure patient access in Canada. The new therapeutic class comparisons for investigation criteria go a step in the

opposite direction: they could, in some cases, compare highly innovative medicines with generics, and drive price reductions below the lowest international price for the patented medicine. This diminishes the value of patents as rewards for innovation and disincentivizes the introduction of patented medicines into Canada.

PMPRB should reassess its approach and reintroduce incentives for bringing new innovations to Canada in the Guidelines.

3. Work within mandate

Recent court decisions clarifying the PMPRB's proper 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.

However, the approach taken in the latest PMPRB Guidelines, i.e., to regulate prices at the median of the PMPRB11 or lower, is inconsistent with this mandate. Moreover, the PMPRB has provided no rationale or explanation for this approach. Moving forward, PMPRB needs to adopt an approach that falls within its mandate.

4. Align approach with national priorities

Throughout the COVID-19 pandemic, federal and provincial/territorial governments across Canada have recognized the importance of fostering a strong domestic biopharmaceutical industry to prepare for future health challenges and ensure that health innovations are there for Canadians when they need them. These governments are also working to implement a national rare disease strategy of which access to treatments plays a pivotal role, as well as collaborating on the federal government's Biomanufacturing and Life Sciences Strategy.

However, the uncertainty and significant price reductions that underpin the PMPRB's latest Guidelines approach will undermine these efforts by reducing Canada's attractiveness for medicine launches and research investments. The PMPRB's approach needs to align with, not run against these critical efforts.

Thank you in advance for considering our submission. Moving forward we strongly recommend pausing the current Guidelines process and working with our sector to develop an alternative approach. Please don't hesitate to reach out to our team if you require any further clarification regarding our position. We look forward to working with the PMPRB to develop clear pricing guidelines that support better access to medicines and research.

Sincerely,

Frank Stramaglia
General Manager
Astellas Pharma Canada, Inc.


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