December 20, 2023

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: Scoping Paper for the Consultations on the Board's Guidelines (November 2023)

Dear Mr. Digby,

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, rare diseases, and to help address unmet needs for women's health.

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 broad recommendations and considerations in response to the PMPRB's Scoping Paper, which we hope can contribute to the development of clear pricing guidelines that support medicine access and Canada's health research ecosystem.

1. Work within PMPRB's mandate

Recent court decisions confirming 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 or reasonable pricing. Any approach to regulate prices below the highest international price (HIP) of the PMPRB11 would be inconsistent with

this mandate. Moving forward, PMPRB should adopt an approach that falls within its legal mandate.

2. Focus on creating a clear and predictable pricing framework

A clear regulatory framework, underpinned by transparent rules and predictable price tests, is essential to creating an environment that supports medicine access and continued industry investment in Canada. Without such a framework, companies may face significant challenges in bringing new medicines to the market, potentially limiting the range of treatment options available to Canadians. In this context, we encourage the PMPRB to focus on developing a clear, transparent, and predictable pricing framework that is both easy to understand and implement.

3. **Allow grandfathering and avoid re-benching**

Medicines already launched in Canada (i.e. Existing Medicines) must 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 prevailed at the time of their launch. Changing the rules retroactively would undermine patentees' rights and expectations, as well as create unnecessary instability for the entire pharmaceutical sector.

Similarly, medicines should not be reassessed or re-benched over time as this creates uncertainty for pharmaceutical companies, which require predictably to commercialize their medicines and invest in Canada. It would also impose an administrative burden on other key stakeholders involved in the pharmaceutical ecosystem – including public plans, insurers, pharmacies and distributors – that would need to make continuous contract and operational changes to reflect the new pricing.

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. The PMPRB's Guidelines approach must align with and not run against these critical efforts.

Thank you in advance for considering our submission. Moving forward we strongly recommend working with our sector on the development of the final Guidelines, including through working groups and case studies. Please do not hesitate to reach out to our team if you require any further clarification regarding our position.

Sincerely,

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Frank Stramaglia
General Manager
Astellas Pharma Canada, Inc.