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Patented Medicine Prices Review Board (PMPRB)
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario, K1P 1C1
Canada

Subject: Alexion submission to PMPRB scoping paper consultation on new guidelines

Dear PMPRB Board Members,

On behalf of Alexion Pharma Canada Corp. (Alexion) thank you for the opportunity to provide feedback on the above noted consultation.

Alexion is a company dedicated to research and development of life-transforming therapies for patients with devastating rare and ultra-rare diseases, including in the areas of hematology, metabolic and neurological disorders. Alexion is also a leading contributor of R&D in Canada. Most recently, in February 2023, together with our parent company AstraZeneca, we announced a $500 million investment in Mississauga, Ontario to expand the AstraZeneca R&D Hub and create the new Alexion Development Hub for Rare Diseases.

Alexion has contributed to and supports the submissions of our industry associations, including BIOTECanada and the Canadian Forum for Rare Disease Innovators (RAREi), as well as Innovative Medicines Canada (through our colleagues at AstraZeneca Canada). We hope the following additional comments help highlight some of the issues and recommendations that are important to Alexion.

Please note that some of the specific questions in the PMPRB scoping paper would be difficult to answer without a comprehensive understanding of the Guidelines as a whole, including how some of the potential provisions will interact with one another. In other words, more information is needed to help inform more substantive input.

In this context, below we offer our high-level input on some of the key themes and questions identified in the PMPRB's scoping paper.

Theme 1: Efficient Monitoring of Prices Without Price Setting

- **Anchor final Guidelines approach to an excessive price standard:** Reliance on median-based considerations to implement the new PMPRB 11 basket of countries is inconsistent with an excessive price standard and contradicts recent court decisions clarifying the PMPRB's mandate. The Government of Canada has already

constrained ceiling prices by removing higher-priced countries from this basket, so any prices that fall within the revised PMPRB11 schedule should be considered compliant. References to the MIP, or any tests other than the HIP, create uncertainty regarding compliant prices and should be avoided in the PMPRB's final guidelines. There may also be justification for allowing ex-factory (list) prices to be considered non-excessive above the HIP of the PMPRB11 in certain circumstances.

- **Continue to apply PMPRB principles (fair, transparent, open, predictable):** To support the introduction of innovative medicines into Canada, the final Guidelines should uphold the PMPRB's long-standing principles of fairness, transparency, openness, and predictability. This means avoiding overly complicated processes and procedures, providing clear and consistent rules and methodologies for price determination and reporting, and avoiding the introduction of retroactive changes that could create uncertainty and instability in the market. In terms of whether any element of the 2010 Guidelines should be retained depends on how it would interact with the entirety of any newly proposed Guidelines. Moreover, we would also like to add that a tiered price review process may reduce predictability and fairness, which would be incongruent with the principles identified above.

- **Recognize innovation**: We support the inclusion of elements within the Guidelines to recognize innovation, but the Level of Therapeutic Improvement as it was applied in the 2010 Guidelines is only one possible mechanism. For instance, innovation can be integrated as a guiding principle that informs all aspects of the PMPRB's work. This could include adopting an innovation lens through which all policies are viewed. As well, the PMPRB Guidelines could be evaluated against how they align with and support federal and provincial life sciences and rare disease strategies.

Theme 2: Transition to PMPRB11 – New Versus Existing Medicines

- **Allow grandfathering of medicines already launched in Canada:** Medicines launched in Canada before the finalization of the PMPRB's new Guidelines should be grandfathered according to the Guidelines in place at the time those medicines were introduced. This would ensure that patentees are not subject to retroactive changes in the price review process that could undermine multi-year business planning and investment decisions. Grandfathering would also avoid creating unnecessary administrative burden and complexity for both patentees and the PMPRB, as well as potential legal challenges and disputes.

Theme 3: Price Reviews During Product Life Cycle

- **Avoid ceiling price reassessments / rebenching:** The possibility for continuous adjustments to the maximum allowable price of a medicine would create uncertainty and volatility for patentees, as they could face unexpected price disruptions after launching their products in Canada. Importantly, this will also have compounding

spillover effects on pricing in other markets that reference Canadian prices. To help minimize these disruptions, and avoid potential unintended consequences on medicine access, once the maximum price for a new medicine is set at its launch, it should not be subject to ongoing revision.

- **Allow price adjustments to account for inflation:** Price adjustments based on the consumer price index (CPI) serve as a crucial mechanism to allow companies to adapt their pricing strategies according to economic conditions and the cost of doing business in Canada. Changes to the CPI are also included in section 85 of the *Patent Act* as a factor to consider when determining whether a medicine sold in Canada is priced excessively, therefore CPI adjustments should be permitted. It is worth noting that list prices are not the same as net prices, which are applied confidentially in Canada, and are not captured by the PMPRB. This makes drawing conclusions based on international list prices misleading.

Theme 4: Price Reviews During Product Life Cycle

- **Create a clear and transparent investigation process**: The Guidelines should continue to support the PMPRB's principles of predictability, openness, fairness, and transparency by clearly describing the situations that may lead to an investigation, the investigation process, options to remedy, and consequences of an investigation, as well as all associated timelines, in detail.

Theme 5: Relation to pan-Canadian Health Partners and Broader Government Initiatives

- **Support broader government objectives by working within established mandate**: The PMPRB's mandate is to determine excessive pricing as a function of abuse of market exclusivity, a responsibility that operates independently from other healthcare stakeholders such as the Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et services sociaux (INESSS), and the pan-Canadian Pharmaceutical Alliance (pCPA). Given this distinct mandate and the fact that it is not a required process of evaluation in advance of commercialization, there is no immediate advantage to coordinating decisions and timelines with these other players. Importantly, cost-effectiveness considerations fall under the purview of these other stakeholders and should not be duplicated by the PMPRB. Ultimately, the PMPRB's final guidelines approach must align with, and not work against, broader government priorities to build a thriving health and life sciences ecosystem and improve access to therapeutics in Canada through initiatives such as the Biomanufacturing and Life Sciences Strategy and the National Strategy for Drugs for Rare Diseases.

Thank you in advance for considering our submission. We look forward to working through this feedback with the PMPRB, and in collaboration with other stakeholders, to develop guidelines that provide certainty, predictability and a pricing environment that enables research and access to medicines in Canada.

Sincerely,

Electronically signed by: Cory Cowan
Reason: I approve this document
Date: Dec 20, 2023 10:07 EST

Cory Cowan,
Director, Market Access and HTA,
Alexion Pharma Canada