Alexion Pharma Canada Corp.
1004 Middlegate Road, Suite 5000
Mississauga, Ontario, L4Y 1M4
T : +1 866.393.1188
www.alexion.com

August 21, 2023

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

Subject: Proposed 2023 amendment to the PMPRB interim guidance

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.

In this context, below we offer several recommendations with respect to the PMPRB's proposed 2023 interim guidance approach:

RECOMMENDATIONS

1. Address ambiguity related to CPI adjustments

The *Patent Act* permits price increases corresponding to changes in the consumer price index (CPI). However, the PMPRB's proposed interim guidance lacks clarity regarding CPI adjustments taken after July 1, 2022. This uncertainty affects our ability to make compliant price decisions and will have a compounding effect on future list price decisions. In this context, the PMPRB should explicitly state that any price increases taken in 2023 and beyond that are consistent with the way PMPRB has traditionally assessed CPI changes will be deemed compliant and will not automatically subject a product to "under review" status or trigger an investigation. Moreover, PMPRB should

strive to update its CPI-Based Price-Adjustment Factors for Patented Drug Products on an ongoing basis to ensure that pricing remains in line with the CPI and maintains transparency and fairness in the regulation of patented medicines.

2. Anchor interim and final guidelines approach to an excessive price standard

The proposed 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 during the interim period and beyond.

3. Clarify the terms 'reviewed' and 'under review'

The concepts of 'reviewed' and 'under review' require further clarification. Importantly, retroactive reviews of prices that were established based on previous PMPRB guidance will create unnecessary uncertainty for patentees and affect business planning. PMPRB can help address some of this uncertainty by explicitly ruling out reassessments for "reviewed" products, provided that any price increases have been limited to inflation and are consistent with the CPI adjustment factors published by the board.

Moving forward, Alexion strongly believes that 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*.

It is worth noting that the PMPRB's long-standing emphasis on rare diseases as a high-risk area for excessive pricing needs to be addressed as it contradicts the approaches in other jurisdictions that offer targeted incentives for developing and commercializing medicines for small patient populations.

In order to arrive at clear pricing guidelines that align with broader government priorities and support, rather than hinder, medicine access, Alexion recommends establishing working tables comprised of PMPRB and industry representatives in the lead up to the development of final guidelines. This type of collaborative approach will help address issues before they arise and contribute to clear pricing rules that work for all.

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,

Cory Cowan
Cory Cowan (Aug 21, 2023 16:50 EDT)

Cory Cowan, PharmD
Director, Market Access & HTA
Alexion Pharma Canada
Cory-cowan@alexion.com
Mobile 1.416.434.3158