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

Subject: 2022 Proposed updates to the PMPRB 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. For 30 years, patients and their caregivers have been at the center of everything we do, and our mission is driven by understanding who they are as unique individuals, not just their disease. Every day, we are inspired to think differently and follow the science in order to create better outcomes for them and their families.

We have contributed to and support the submissions of our industry associations, including BIOTECanada and the Canadian Forum for Rare Disease Innovators (RAREi), as well as to 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 outline our considerations with respect to the PMPRB's latest Guidelines approach:

ISSUES AND CONSIDERATIONS

1. An unpredictable and uncertain approach

The PMPRB's latest Guidelines do not provide industry with clear and well-defined instructions for managing drug prices in Canada. For example, it is unclear what would happen if a new medicine were launched in Canada but not in any of the other PMPRB11 countries. According to the new rules, this would trigger an investigation and imply a penalty for launching in Canada first. Without pricing certainty companies will be forced to abide by 'reasonable' pricing guidelines or launch new medicines at risk. This makes it very difficult for patentees to make a clear business case for commercializing new medicines and investing in clinical trials in Canada. This uncertainty will impact Canada's position in global medicine launch sequencing, and delay or deprive Canadians from accessing many potentially lifesaving and life-improving innovations.

This latest approach removes the well-understood price tests that have been in effect for many years, and introduces new investigation criteria without a defined path for resolution. The proposal does not provide guidance to patentees beyond investigation criteria. The investigation criteria may indicate an excessive price, but there is no framework to define what may or may not be excessive. Patentees will interpret the investigation criteria as excessive price thresholds because there are no instructions to defend pricing above these thresholds.

The proposed Guidelines make the median of the new basket a *de facto* price ceiling price for new medicines. This is not set in a way that would allow market certainty and forecasting – the ceiling is effectively 'floating' as it can fluctuate based on a number of factors, including drug launches in other jurisdictions, the exchange rate, etc. This means medicine prices will need continuous adjustment, which is impractical and creates significant administrative burden for patentees.

2. Devalues and discourages innovation

The previous Guidelines included a mechanism to reward innovation through the therapeutic improvement reviews conducted by the Human Drug Advisory Panel (HDAP). There is no such mechanism under the newly proposed system. One of the most problematic aspects of PMPRB's proposed approach is the mechanism by which to compare new medicines to other medicines in the same therapeutic class. This could lead to a situation in which a highly innovative treatment is compared to a generic medicine, which would put significant downward pressure on its potential list price in Canada. This is especially damaging for medicines for rare diseases because such treatments often have fewer direct comparators. The proposed Guidelines create a disincentive to invest in innovative medicines to treat important unmet needs for patients.

Benchmarking innovative new medicines against low-cost existing treatments is contrary to the purpose of patent protection and disincentivizes innovation. The purpose of patents is to reward innovation by granting patent holders a temporary monopoly and the opportunity to charge a premium price during their patent window to recoup the costs of their research investments. There is no explanation provided as to why anything above the median of the PMPRB11 is considered excessive as a function of abuse of patent monopoly. This devaluing of innovation will further dissuade many patentees from launching their treatments in Canada.

In response to the COVID-19 pandemic, governments across Canada have implemented life sciences growth strategies as a way to prepare for future health emergencies. At the federal level, last year the Government of Canada created the Biomanufacturing and Life Sciences Strategy, which includes a commitment to "world class regulation" for our sector. The PMPRB's uncertain approach is inconsistent with this objective and will further limit the success of other key initiatives, including the national Drugs for Rare Diseases strategy, by impeding new medicine launches and research in Canada. While there are over 11,000 known rare diseases, over 90% do not have an approved treatment option

and the approach taken by PMPRB may create a further impediment for those committed to researching and discovering treatment options for those living with rare diseases.

3. PMPRB exceeding its mandate

Recent legal decisions, including the *Alexion Pharmaceuticals v. Canada (Attorney General),* 2021 FCA 157 (the "*Alexion* FCA" Decision), have confirmed that the PMPRB's mandate does not include general price control or consumer protection. The court narrowly defined the PMPRB's mandate as "preventing abusive pricing, i.e., excessive pricing". The PMPRB's proposed investigation criteria for new medicines include 'lower of' conditions that relate more to 'reasonableness' and 'affordability' than protecting against excessive pricing.

The proposed Guidelines circumvent the direction provided by the courts by replacing transparent price thresholds with ambiguous investigation criteria and discretionary rulings. While the Guidelines note that investigations may not necessarily lead to remedial action, in the absence of clear rules manufacturers will treat the investigation criteria as *de facto* excessive pricing thresholds. The new PMPRB Guidelines approach will therefore lead to significant price reductions and force some companies to avoid or deprioritize Canada for new medicine launches to protect pricing in other markets. It will also certainly encourage future litigation.

4. No impact assessment or rationale

The PMPRB has provided no rationale for why it has decided on its current approach, nor has it provided information as to how this approach will impact medicines and the health system. This is vital information that needs to be included as part of any new proposal.

5. Short timeline for implementation

The PMPRB's intention to implement its new Guidelines by January 1, 2023 does not allow enough time to reasonably review, respond, and implement stakeholder feedback before finalizing its Guidelines. The PMPRB should revisit its approach and work collaboratively with all stakeholders to develop Guidelines that help support innovation or it could have negative consequences on Canada's life sciences sector and patients who depend on new medicines to live longer and better lives.

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,

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