July 18, 2022

Mrs Mélanie Bourassa-Forcier
Interim Chair, Patented Medicine Prices Review Board
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RE: Notice and Comment – PMPRB Price Review Approach During the Interim Period following publication of Amendments to the Patented Medicines Regulation

Dear Mélanie Bourassa-Forcier,

On behalf of AstraZeneca Canada Inc. (AstraZeneca), thank you for the opportunity to provide input on the PMPRB's June 30, 2022 Notice and Comment: PMPRB Price Review Approach During the Interim Period following publication of Amendments of the Patented Medicines Regulation.

AstraZeneca has actively participated in all relevant consultations regarding the reform of the PMPRB including through our industry associations, Innovative Medicines Canada and BIOTECanada. The present submission is complementary to those made by our industry associations.

AstraZeneca is a leading innovation-driven biopharmaceutical business with a focus on the discovery, development and commercialization of prescription medicines used by millions of patients worldwide. We are focused on leading in the therapy areas where we believe we can make the most meaningful difference to patients: Oncology; Rare Diseases; Cardiovascular, Renal & Metabolic Diseases (CVRM); Respiratory & Immunology; and Vaccine & Immune Therapies. AstraZeneca has been playing a significant role in the fight against COVID-19, developing a vaccine, followed by Evusheld – the first long-acting antibody combination with demonstrated benefit in both prevention and treatment of COVID-19.

AstraZeneca currently employs over 1,100 people in Canada, including roughly 700 employees at our head office in Mississauga. We have an additional 430 employees at our Global Clinical Hub in Mississauga, and Clinical Site Management and Monitoring team across Canada. In 2021, AstraZeneca invested more than $135.6 million in Canadian health sciences research and development in Canada, an R&D to sales ratio of 14.8%.

AstraZeneca has entered an exciting new period of research, innovation and scientific advances. We have ground-breaking new treatments across all our therapeutic areas that we are hoping to bring to Canadians as soon as possible.

AstraZeneca appreciates the proposal of an interim "status quo" approach stated in the Notice and Comment during this time of uncertainty, which will allow various stakeholders to consult on the new Guidelines that are expected to be finalized this year. However, it is important to note that the PMPRB Price Review Approach for the interim period (the "Interim Approach") does not truly reflect a "status quo" as it proposes a list price freeze for the existing patented medicines. In addition, the Interim Approach requires further clarity on how PMPRB will review the prices of new medicines and recently launched existing medicines.

In this context, we would like to make the following recommendations for the PMPRB's consideration:

Interim Approach:

1. Guarantee no accumulation nor payment of excessive revenues for sales during the interim period

The Interim Approach provides no guidance on how the prices of new medicines will be reviewed. In recognition of this, PMPRB has proposed that they will not conduct a price review of any new patented medicines or open any investigations during the interim period. However, there should be a guarantee from PMPRB that patentees will not accumulate or be asked to pay "excessive revenue" for any sales during the interim period if they choose to launch before the new Guidelines are in place and there is clarity about how maximum non-excessive prices will be calculated.. Without such a commitment, there will be significant uncertainty and a detrimental impact on Canadian launch timelines and patient access as patentees may be asked to hold or delay launch and re-assess the environment by global parent corporations.

Interim Approach and New Guidelines:

1. Incorporate the Consumer Price Index (CPI) change in the Interim Approach and the future New Guidelines

Future New Guidelines, as well as the Interim Approach if the interim period lasts for more than six months (i.e. Interim period lasts into 2023), must reflect PMPRB's legislative mandate and relevant case law. "Changes in the Consumer Price Index" are explicitly referenced in the Patent Act so the PMPRB must include such changes in a fair price re-benching tool, especially considering the recent high inflation experienced globally.

2. Adopt a "complaint" based approach for vaccine price reviews in the Interim Approach and the future New Guidelines

Given the procurement ("tendering") process in Canada, the risk of excessive pricing for vaccines is low. PMPRB should review the vaccine prices only when the following criteria are met: 1) a complaint is received and; 2) the list price is deemed non-compliant by PMPRB. In addition, reporting should be minimized to Form 1 upon the first sale and Form 2 should be provided only upon request from the PMPRB.

New Guidelines:

1. Completely grandfather existing medicines launched before July 1, 2022

The Regulations Amending the Patented Medicines Regulations came into force on July 1, 2022, yet there is still no clarity around how the PMPRB will review the prices of the new medicines. For the future Guidelines, PMPRB should deem the list price of a patented medicine launched before July 1, 2022 (i.e. all existing patented medicines, including those launched in the first half of 2022) compliant if its latest average transaction price (ATP) was compliant with the non-excessive average price (NEAP) established by the previous regulation (i.e. PMPRB 7) and the compendium of policies and procedures as it stood before the Interim Guidelines came in to force. Taking such an approach will provide certainty for these medicines.

2. Adhere to PMPRB's statutory "Excessive Pricing" mandate

Any price test within the future PMPRB Guidelines and the Interim Approach must adhere to the excessive pricing mandate. The Federal Court of Appeal stated that the PMPRB's role is solely to determine whether a medicine has been priced excessively at a level that constitutes an abuse of patent (2021 FCA 157)[1] . It is our view that many of the previously proposed price tests (i.e., "lower-of". "lowest among", "median of") would not be justifiable under this mandate.

3. Ensure a minimum of twelve-month transition period post the final publication of the new Guidelines

A minimum twelve-month (two full reporting periods) transition period would be required following the final publication of the new Guidelines to allow patentees, provincial drug plans and pharmaceutical supply chain stakeholders to properly implement the new prices. The interim period must not be counted toward the transition period as there is no clarity on the new Guidelines that would allow Patentees to prepare for them. This twelve-month transition period is aligned with what PMPRB has previously proposed.[2]

Closing Thoughts

Thank you for considering our input on the PMPRB's Interim Approach. PMPRB changes over the last few years have made it increasingly challenging to make a compelling business case to our global headquarters for Canada to be a priority launch country for some of our new ground-breaking medical innovations, given the high level of uncertainty and unpredictability the current regime poses. We look forward to working with you to ensure the PMPRB's new Guidelines are consistent with PMPRB's core principles (sustainability, predictability, consistency, functionality, and fairness) and do not impede patient access to new innovations in Canada.

If you have any questions, please do not hesitate to contact me.

Yours Sincerely,

Mo Amin MD, PhD
Vice President, Value, Access & Policy AstraZeneca
Canada

[1] https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/500849/index.do

[2] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-definition-gap/decision-definition-gap-medicines.html