August 21, 2023

AstraZeneca Canada Inc.
1004 Middlegate Road, Suite 5000
Mississauga, Ontario, L4Y 1M4, Canada
T: +905-277-7111
F: +905-270-3248
www.astrazeneca.ca

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

RE: Notice and Comment - Amendment to the Interim Guidance re: New Medicines

Dear PMPRB Board Members,

On behalf of AstraZeneca Canada Inc. (AstraZeneca), thank you for the opportunity to provide our feedback on the PMPRB's proposed interim pricing guidance in advance of the development of final guidelines.

This submission aligns with those from our associations, Innovative Medicines Canada and BIOTECanada, and highlights the issues that matter most to AstraZeneca, drawing on our experience in Canada and around the world.

AstraZeneca is a leading innovation-driven biopharmaceutical business with a focus on the discovery, development and commercialization of therapeutics 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.

We employ more than 1,300 employees across Canada, including 800 employees at our Mississauga, Ontario head office and R&D hubs. The company is one of Canada's leading R&D contributors, investing $148 million in Canadian R&D in 2022. In February 2023, AstraZeneca hosted Prime Minister Justin Trudeau, Minister Jean-Yves Duclos, Premier Doug Ford and other Canadian dignitaries to announce a major expansion of our research footprint in Canada – including the creation of 500 scientific and high technology roles to support the expansion of our existing AstraZeneca R&D Hub and the creation of a new Alexion Development Hub for Rare Diseases. The AstraZeneca R&D Hub in Mississauga is presently leading more than 130 global clinical studies in areas such as breast, lung and prostate cancer, COVID-19, and chronic kidney disease. The Alexion Development Hub will focus on rare disease research in haematology, nephrology, neurology, metabolic disorders and ophthalmology.

AstraZeneca supports the efforts of governments around the world to protect public health and the environment. Globally, we comply with regulations and ethical and sustainability standards across our manufacturing chain to mitigate risks to people and the environment. We are an industry leader in accelerating sustainable healthcare innovation while lowering the environmental burden of healthcare.

In this context, AstraZeneca is pleased to provide the following considerations, which we hope can inform the PMPRB's approach in the interim period and beyond.

1. PMPRB's interim and final guidelines approach should use HIP to be consistent with excessive pricing mandate

The 2023 update to the interim guidance suggests that new medicines falling below the median of the PMPRB11 will be prioritized to receive "early guidance and greater predictability." While we recognize and understand the PMPRB's efforts to address a growing backlog and reduce uncertainty for certain files, the use of median-based considerations to implement the PMPRB11 basket of countries is inconsistent with the PMPRB's excessive pricing mandate, as outlined in the *Patent Act* and clarified by recent court decisions.[1]

As highlighted in previous industry submissions, the median international price (MIP) test will negatively impact Canada's position in the global launch sequence, and therefore patient access, due to the knock-on effects to pricing in other markets, as a result of international reference pricing. To ensure alignment with the PMPRB's statutory mandate and avoid unintended consequences on medicine access, the highest international price (HIP) would be the most appropriate pricing test for the PMPRB.

2. CPI adjustments are permitted under the Patent Act and must be explicitly referenced in the guidance document

The PMPRB's proposed update to the interim guidance lacks clarity on consumer price index (CPI) adjustments, which are permitted under the *Patent Act*. The 2022 interim guidance included references to the 2022 CPI increases as well as to the 2022 non-excessive average price (NEAP) because the expectation was that the interim period would last only until the end of 2022. Notably, in its 2022 Interim Guidance FAQ document, the PMPRB stated that it will "revisit the issue" when asked whether the 2022 NEAP will continue to apply if the guidelines are not in place by the end of 2022.[2] Based on the above, the permissibility of CPI adjustments taken in 2023 and beyond needs to be explicitly referenced in the proposed 2023 guidance document.

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

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 into force. Those medicines were commercialized in Canada on the basis of the regulations and additional price mitigation policies as they existed at the time. Grandfathering these medicines will also help support business continuity and mitigate potential challenges down the supply chain.

4. PMPRB's approach must align with broader federal priorities to improve medicine access and build Canada's life sciences ecosystem

The PMPRB has an important role to play in supporting a vibrant life sciences sector and ensuring Canadians can benefit from new health innovations. In this context, the PMPRB must not develop its policies in isolation. Its approach to price regulation must align with broader government imperatives to build Canada's life sciences sector in the wake of COVID-19 and in response to ongoing health system capacity challenges. Our sector is partnering with the Federal government to help deliver key priorities such as the *Biomanufacturing and Life Sciences Strategy*[3] -which promises world class regulation for our sector- and the *National Strategy for Drugs for Rare Diseases,*[4] among others. For this reason, the PMPRB must work collaboratively with the pharmaceutical industry and other health system partners to arrive at clear and predictable rules that align with the PMPRB's mandate of regulating for price excessiveness, recognizing that there are other mechanisms in Canada's drug review system to manage affordability. By adopting such an approach, the PMPRB can facilitate timely patient access to medications while fostering the growth of a robust and competitive life sciences sector in Canada.

5. Industry should be involved in the development of the final guidelines

AstraZeneca commends the PMPRB's intention to "advance a fulsome consultation process on the new guidelines," which signals a more collaborative approach with our sector. In this context, AstraZeneca strongly recommends establishing working groups – consisting of both PMPRB and industry representatives – to address any potential issues that may emerge using case studies and a regulatory sandbox approach.

The use of regulatory sandboxes is a priority for the Treasury Board and a recommended best practice for all federal government departments and agencies because it allows "regulators to test a regulatory approach in a controlled space, collect evidence on how the approach works in practice, and then use that evidence to make any permanent regulatory changes or decisions – all while continuing to uphold protections for health, safety, and the environment."[5] Using such an approach will help the PMPRB test new approaches in a controlled environment prior to the adoption of final pricing guidelines, ensuring that potential challenges and unintended consequences are thoroughly assessed and mitigated. It will also help ensure the development of clear pricing guidelines that support innovation and access to medicines for Canadians.

Final thoughts

AstraZeneca, along with our industry partners, continues to work hand in hand with governments to solve complex and critical Canadian health, economic and societal challenges, from pandemic impacts to chronic diseases to climate change. We hope that the PMPRB will work collaboratively with our sector to develop an approach to pricing that benefits all Canadians and our country's future health and economic wellbeing.

Please don't hesitate to reach out to us if you require further information regarding our input.

Sincerely,

Heather McDonald
Heather McDonald (Aug 21, 2023 13:38 EDT)

Heather McDonald
Vice President, Market Access and Pricing
AstraZeneca Canada

[1] https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/521063/index.do
[2] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-price-review-approach/decision-price-review-approach.html
[3] https://ised-isde.canada.ca/site/biomanufacturing/en/canadas-biomanufacturing-and-life-sciences-strategy
[4] https://www.canada.ca/en/health-canada/news/2023/03/investments-to-support-access-to-drugs-for-rare-diseases.html
[5] https://letstalkfederalregulations.ca/sandboxes?tool=story_telling_tool