September 11th, 2024

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

RE: AstraZeneca submission to "Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines" (September 2024)

Dear PMPRB Board Members,

AstraZeneca Canada Inc. (AstraZeneca) appreciates the opportunity to provide input on the PMPRB's Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines ("the Discussion Guide") published on June 26, 2024.

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

We would like to start by commending the PMPRB for its efforts to undertake a more "informed, focused, and productive consultation process in developing new Guidelines." We appreciate the PMPRB's renewed commitment to transparency and engagement throughout this process and look forward to continued collaboration to achieve a sustainable pricing system.

We would like to emphasize that the PMPRB's future policy approach must stem from its statutory mandate, as clarified by recent legal decisions, including Alexion Pharmaceuticals v. Canada (Attorney General), 2021 FCA 157. Notably, that decision confirmed that "The excessive pricing provisions in the *Patent Act* are directed at controlling patent abuse, not reasonable pricing, price regulation or consumer protection at large."[1]

In this context, AstraZeneca would like to provide the following general recommendations and considerations with respect to some of the topics, which we hope can inform the PMPRB's approach.

Topic 1: Price level within the PMPRB11 to be used in the initial and post-initial price review:

- **HIP (Highest International Price) is most consistent with the PMPRB's excessive pricing mandate**: To ensure alignment with the PMPRB's statutory mandate and avoid unintended consequences to medicine access in Canada, the HIP of the PMPRB11 is the most appropriate measure for non-excessiveness. That said, the PMPRB's new pricing rules

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

should also support pricing above the HIP in certain circumstances to recognize breakthrough innovations.

- **Focus on providing clear and predictable rules**: The primary purpose of the guidelines is to provide a clear and transparent pricing framework to support voluntary compliance by patentees with the *Patent Act*. In this context, while the previous (2010) guidelines were not perfect and are no longer relevant, they were at least well understood by patentees and provided the requisite level of predictability needed to support pricing decisions. We encourage the PMPRB to strive for the same level of certainty and predictability in its future guidelines approach.

- **Adhere to an excessive pricing mandate**: The proposed annual price reviews and in-depth reviews suggests that the PMPRB is seeking to decrease medicine prices over time. This was noted in the previous scoping paper (Box 3: Pricing trends in Canada vs. PMPRB11) that over the years list prices in some other countries tend to decline whereas list prices in Canada tend to rise. Once again, we would like to emphasize that the PMPRB's mandate, as clarified recently by the courts, is to monitor for patent abuse and prevent excessive prices, rather than to decrease prices over time.

- **Avoid continuous price ceiling changes**: The research and commercialization of new medicines require significant and long-term business planning. A stable and predictable pricing environment is therefore vital for any country aiming to bring medicines to patients. In this context, once the ceiling price of a new medicine has been established at launch, it should not be subject to continuous reassessment. Importantly, the PMPRB is part of a broader ecosystem of actors, others of whom have a role in addressing affordability (e.g., the pCPA). For this reason, we strongly recommend against continuous ceiling price changes by the PMPRB. This approach will help reduce administrative burden, support business continuity and planning, and limit spillover effects in other countries that reference Canadian prices. Furthermore, it will reinforce the PMPRB's stated goal of creating a "system that allows for the most efficient monitoring of cases of potential excessive pricing," and ensure that Canada remains an attractive market for new medicine launches.

Topic 2: Timing to decide if medicine meets IPC identification Criteria

- **Exemption of existing medicines:** There is currently no policy rationale to support the retroactive application of the new PMPRB11 rules to medicines marketed and deemed compliant under the previous PMPRB7 framework. These medicines were commercialized in Canada based on multi-year business planning decisions and on the basis of the regulations and additional price mitigation policies that existed at the time. For this reason, if a product was compliant before the final PMPRB guidelines have been adopted, it should continue to be compliant if it stays within consumer price index increases moving forward.

This will help support business continuity and mitigate potential challenges down the supply chain.

Topic 3: CPI Increase Criteria

- **Allow for price adjustments based on inflation:** The cost of doing business in Canada evolves over time. The PMPRB's future guidelines must allow pricing changes that reflect global and Canadian inflationary forces, irrespective of prices in other markets. Section 85(1) of the Patent Act also sets out consumer price index (CPI) changes as a factor for determining whether a price is excessive. The PMPRB's future guidelines should therefore establish clear and predictable rules for price adjustments that fall within the scope of the CPI. PMPRB must continue to update its CPI-Based Price-Adjustment Factors for Patented Drug Products on an ongoing basis.

Topic 4: The individuals/groups permitted to submit a complaint

- **Establish a clear and transparent process for investigations**: The procedural process for investigations and hearings should be clearly articulated and easily understandable to ensure a fair and accessible framework for patentees, while enhancing the effectiveness of the PMPRB's oversight framework. Eligibility for complaints should be narrow, consistent with s. 86(2) of the *Patent Act* and be limited to Option 1 (Federal Minister of Health or any of his/her Provincial or Territorial counterparts.

- **Adopt a complaint-based approach for vaccine price reviews**: The risk of excessive pricing for vaccine is low given the procurement ("tendering") process in Canada. AstraZeneca believes the PMPRB should simplify and only review the vaccine prices when: 1) a complaint is received and; 2) the list is price is deemed excessive by PMPRB. The reporting should also be minimized to Form 1 upon the first sale and Form 2 should be provided only upon request from the PMPRB. This would ensure the PMPRB can focus its resources on the therapeutics that have the most potential to be priced excessively.

- **Introduce a buffer for price tests to account for exchange rate fluctuation**: The PMPRB uses prices in other countries to determine whether a medicine launched in Canada is excessively priced. However, the exchange rates between different currencies can fluctuate over time and affect price comparisons. Therefore, the PMPRB should allow a margin of error for price tests to account for the variability of exchange rates. This would reduce the risk of triggering an investigation based on minor or temporary fluctuations in relative currency values.

Topic 5, 6 & 7: In depth reviews & the Future Role of HDAP

- **Insufficient information to provide input on proposed options**: The proposed options under these sections create a lot of uncertainty and a lack of predictability for rights holders when making pricing and launch decisions.

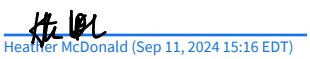
- **Role of HDAP in future unclear**: The role of HDAP is unclear given that a level of therapeutic improvement is no longer assessed. As such, it is premature to comment on timing and the nature of any scientific review that would be part of in-depth reviews. More information is required to understand how scientific review and comparator selection may or may not relate to determining if the price of a medicine is excessive. In addition, the ability to have dialogue and a fair process is key for HDAP review to play a meaningful and effective role.

Final thoughts

AstraZeneca, along with our industry partners, continues to work hand in hand with governments and other health system leaders to solve complex and critical Canadian health, economic and societal challenges, from the pandemic to chronic diseases to climate change. We hope that the PMPRB will work collaboratively with our sector, e.g., through working groups, 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 (Sep 11, 2024 15:16 EDT)

11-Sep-2024

Heather McDonald
Vice President, Market Access and Pricing
AstraZeneca Canada

ABOUT ASTRAZENECA

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 1,600 employees across Canada, including approximately 1000 employees at our Mississauga, Ontario head office and R&D hubs. The company is one of Canada's leading R&D contributors, investing over $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 the environment and public health. 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.

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Final Audit Report 2024-09-11

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