August 31, 2021

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

RE: Notice and Comment - On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions

Dear Dr. Levine,

On behalf of AstraZeneca Canada Inc. (AstraZeneca), thank you for the opportunity to provide input on the PMPRB's proposed amendments to its Guidelines.

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.

In terms of our footprint in Canada, AstraZeneca employs more than 950 Canadians who work to research, develop and commercialize innovative medicines across our main therapeutic areas of cardiovascular, renal and metabolic diseases; oncology; and respiratory, inflammation and autoimmunity illnesses. In 2020, AstraZeneca invested more than $112 million in Canadian health sciences research in our core therapy areas, an R&D to sales ratio of 12.8%.

AstraZeneca has also been deeply involved in the fight against COVID-19. Our COVID-19 vaccine was made widely accessible to Canadians and countries around the world at no profit during this pandemic.[1] Along with our partners, AstraZeneca has now supplied one billion doses of our COVID-19 vaccine to more than 170 countries globally. We are the third biggest supplier of COVID-19 vaccine doses in the world, and the majority have gone to low- and lower-middle-income countries. Nearly 100 million doses of our vaccine have been delivered through the COVAX Facility, accounting for more than two-thirds of shipments to COVAX. Since the first international launches in early 2021, the vaccine has helped prevent hundreds of thousands of hospitalizations and helped save countless lives.

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

[1] https://www.astrazeneca.com/media-centre/articles/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-potential-covid-19-vaccine.html

However, the PMPRB changes 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 these new ground-breaking medical innovations, given the uncertainties and unpredictable price reductions mandated by the new rules.

Now, with the unexpected release of new price tests for grandfathered medicines as proposed on July 16, 2021, the PMPRB has added an additional and unexpected layer of uncertainty to what was already a very challenging commercial environment.

In this context, we would like to express the following concerns regarding the PMPRB's proposed changes to its Guidelines:

1. No rationale is provided to justify changing the HIP to MIP for grandfathered medicines:

The PMPRB's consultation document notes that the proposed changes are *"an appropriate response to the most recent six-month extension in the coming-into-force date of the Regulations, to January 1, 2022"* and in the accompanying *Frequently Asked Questions (FAQ)* document, that the changes *"would allow the PMPRB to move forward in implementing the October 23, 2020 Guidelines."*[2] However, no substantive explanation is provided as to why these changes are being made. How are these changes an appropriate response and what is its connection to the delay?

2. No impact analysis or case studies are provided:

This is a major and unexpected change to the PMPRB Guidelines framework, yet no analyses, case studies or forecasts have been done to review the impacts on individual therapeutic levels and supply chains.

The FAQ claims the price decreases would be 10% on average, however, a Poster Presentation from the CADTH Symposium 2020, showed a weighted average price reduction of 28% for list prices for a move to the median of the PMPRB11. We anticipate the move to the median of the PMPRB7 would produce a similar price reduction – much higher than the 10% claimed by the PMPRB.[3]

In this context, it is important to note that the PMPRB's unilateral and unexplained changes to its guidelines could disrupt already-strained supply chains and undermine regulatory and business certainty for many treatments.

[2] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-references-comparator-countries/frequently-asked-questions.html

[3] https://virtualsymposium.cadth.ca/2020/07/27/impact-of-patented-medicine-prices-review-board-new-reference-countries-on-drug-prices-in-canada-a-comparison-of-current-and-anticipated-list-prices-for-top-drugs-in-the-country/

3. The proposed changes are arbitrary and outside of the PMPRB's statutory mandate:

Recently, the Federal Court of Appeal, stated that the PMPRB's role is solely to determine whether a medicine or vaccine has been priced excessively at a level that constitutes an abuse of patent (2021 FCA 157). It is not logical to determine that a public list price is excessive on the sole basis that it is higher than the median of comparator countries.

4. The reduced compliance timelines run contrary to the spirit and intent of the government's decision to delay the implementation of the PMPRB regulation changes:

The PMPRB's proposed amendments use technical language to effectively reduce the timelines for enforcement of regulated price reductions for Grandfathered medicines from twelve months to six months. Not only is there no rationale provided for the proposed timeline reduction, but this also goes directly against the spirit and intent of the federal government's decision to delay the coming into force date of the regulations by six months – namely to free up resources for companies to remain focused on responding to the COVID-19 pandemic.

The entire healthcare system, including the pharmaceutical sector, has been under enormous strain in the current global health crisis.[4] Over the past year, AstraZeneca staff members have been working day and night to align our pricing and business strategies according to the new pricing regime, while simultaneously supporting Canadian and global vaccine roll-out efforts. Now, in the middle of summer, we are confronted with an entirely new set of proposed changes that will detract significant time, attention and resources away from our efforts to respond to the pandemic and support health system recovery.

It is also worth noting that the Board is effectively re-adopting a proposal that it rejected earlier this year. Specifically, the Board proposed, adopted and then reversed its position on compliance timelines.

5. There have been insufficient consultations, which does not meet the standards required under the *Patent Act*:

The proposed amendments are substantive changes that require adequate consultation, analysis and consideration. However, the proposed changes and perfunctory consultation were announced abruptly in the middle of summer (while many stakeholders are on holiday).

Despite a two-week extension, insufficient time has been given to submit input, no rationale or impact assessments have been provided regarding the change from HIP to MIP, and no information sessions or webinars have been announced to explain the proposed changes.

[4] IQVIA PharmaFocus Update, April 2016, Slide 15.

Further, the PMPRB is proposing to introduce these new changes despite a majority of stakeholders (including provincial governments, researchers, patients and the regulated sector) raising concerns regarding their impact on medicines and research.

6. The changes run counter to broader federal government priorities:

The proposed changes have not been considered in the context of broader government priorities that include pandemic preparedness, the Biopharmaceutical Manufacturing and Life Sciences Strategy, and an emerging National Strategy for Drugs for Rare Diseases.

In terms of the recently announced Biopharmaceutical Manufacturing and Life Sciences Strategy, the 5th pillar seeks to enable innovation by ensuring world class regulation. Specifically, the 5th pillar seeks to make regulations and market access "more agile and responsive to innovation." How can the government work to ensure world-class regulation if the PMPRB is intent on moving forward with new changes that will impact medicine supply chains and hurt biopharmaceutical research investments?

In Budget 2021, the federal government committed more than $2.2 billion to grow Canada's biomanufacturing and life sciences capacity over the next seven years. These investments will not achieve significant value if the PMPRB continues on its current path.

For these reasons, AstraZeneca strongly recommends against the adoption of the changes to the guidelines.

Thank you for considering our submission. 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