

December 5, 2022

Patented Medicine Prices Review Board (PMPRB)  
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**RE: 2022 Proposed updates to the PMPRB Guidelines**

Dear PMPRB Board Members,

On behalf of AstraZeneca Canada Inc. (AstraZeneca), please find below our feedback on the proposed PMPRB 2022 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.

In terms of our footprint in Canada, AstraZeneca currently employs more than 1,200 Canadians who work to research, develop and commercialize innovative medicines. Our vaccines and medicines help prevent and treat diseases across a wide spectrum of medical conditions, including breast, lung, ovarian, prostate and liver cancers in oncology, renal disorders, diabetes, heart failure, asthma, COPD, lupus, influenza, COVID-19, respiratory syncytial virus (RSV) and various rare disorders. In 2021, AstraZeneca invested more than \$135.6 million in Canadian health sciences research in our core therapy areas, with an R&D to sales ratio of 16.3%.

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 the pandemic.<sup>1</sup> We are incredibly proud to have delivered over 3 billion doses across 185 countries worldwide, which is estimated to have saved over 6 million lives. Our commitment to innovation to combat the biggest health crisis of our time didn't stop there: our novel therapeutic, Evusheld<sup>(R)</sup>, was recently approved by Health Canada for the prevention and treatment of COVID-19, adding to Canada's capacity to deal with the ongoing pandemic.

As we started to emerge from the COVID-19 pandemic earlier this year, we saw the government's new direction on the PMPRB file as an opportunity to turn the page on what has been a very challenging and uncertain period for our industry and for broader health system stakeholders. We were also encouraged by the increasing clarity from the courts on the PMPRB's well-defined mandate in the healthcare system.

Unfortunately, this new policy direction and clarified PMPRB mandate is not reflected in the proposed 2022 Guidelines framework. The PMPRB continues to pursue an agenda that is not

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<sup>1</sup> <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>

reflective of the world we live in today, nor the health and economic crises we have endured in the past few years.

Instead of using the new context that has emerged from the pandemic to provide a clear, predictable, and forward-looking regulatory framework for our sector, the PMPRB has proposed a nebulous and unworkable new approach that lacks rationale and raises more questions than answers.

In this context, below we outline our main concerns with respect to the PMPRB's proposed 2022 Guidelines approach and describe exactly how and why the draft Guidelines are so problematic.

## **KEY ISSUES**

### **1. Lack of predictability and significant administrative burden**

The new Guidelines represent a significant paradigm shift in how the PMPRB operates. The PMPRB has dropped price guidelines in favour of vague investigation criteria that provide no regulatory certainty for patentees. This means that companies are forced to launch at risk.

Moreover, the PMPRB has given itself unprecedented, open-ended power in the context of investigations. The proposed framework does not give any confidence that PMPRB staff will conduct the price tests in a consistent manner. Additionally, there is no clarity as to what will happen once an investigation is triggered and there is no standard or transparent approach for conducting price reviews.

It is extremely difficult for companies to make commercial decisions when the PMPRB has effectively given itself a "carte blanche" to improvise the rules as it goes along. Instead of the "bright lines" that were originally the goal of the PMPRB, the new rules create a "floating ceiling price" that changes based on launches in other jurisdictions, exchange rates, and new indications.

The need to continually adjust the price of a medicine in Canada as international list prices fluctuate is extremely problematic and unpredictable from a price setting perspective. Managing contract agreements with public and private drug plans, distributors, pharmacies and patient support programs will become very difficult and administration-heavy with constant adjustments to the medicine prices. These arrangements are critical for seamless supply chains and services that patients and the healthcare system rely upon every day.

The PMPRB's new approach creates uncertainty and administrative burden that will not lead to any new net savings, operational efficiencies, or improvements in healthcare. Moreover, it could impact Canada's position in medicine launch sequencing, as pricing uncertainty in Canada could lead to knock-on effects in other markets due to international reference pricing.

### **2. Runs contrary to government priorities and recently clarified PMPRB mandate**

The PMPRB's approach is in direct conflict with a number of key federal and provincial initiatives and priorities, including life sciences growth strategies.

For instance, the proposed Guidelines run contrary to the federal government's Biomanufacturing and Life Sciences Strategy, which aims to make Canada a more attractive destination for life sciences innovation. The proposed new guidelines will ultimately put Canada's ability to achieve economic and healthcare "security" at risk. The new Guidelines will also undermine the forthcoming Drugs for Rare Diseases strategy, as many promising rare disease treatments and clinical research will simply not come to Canada in such an uncertain pricing environment.

It is also worth noting that recent court decisions have clarified that the PMPRB does not have a broad consumer protection mandate or an imperative to lower medicine prices. Rather, according to these decisions, the PMPRB's mandate is to prevent companies from abusing their patent monopolies. The PMPRB's investigation triggers that include reference to the "lower-of" regularly changing benchmarks are inconsistent with this mandate and appear to be a way of side-stepping the economic factors, which were struck down by the courts and removed from the final regulations that came into effect on July 1, 2022.

### **3. Does not consider value of innovation**

The PMPRB's current approach also devalues innovation, meaning companies will look elsewhere to make investments and launch new medicines. For example, the inappropriate use of domestic therapeutic class comparisons (dTCC) devalues innovation as it could, in some instances, compare highly innovative drugs with low-cost generics, putting unreasonable downward pressure on prices.

Moreover, the PMPRB's decision to remove the consideration of the level of therapeutic improvement a medicine may provide further devalues innovation and will be especially problematic for many vital therapeutic areas, including rare diseases and precision oncology. Devaluing innovation in this manner will certainly impact Canada's position in launch sequencing of medicines globally.

## **FINAL THOUGHTS**

We are at a point now where the world is fundamentally different from the pandemic and from when the PMPRB was first created. Having access to early research and supply chains for vaccines and pharmaceuticals is a strategic imperative. 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 to chronic diseases to climate change.

AstraZeneca has proudly commercialized dozens of medicines in Canada in areas of high unmet need. We hope to continue to save and improve lives in Canada and to invest in our world-class research ecosystem.

However, the PMPRB's new proposed Guidelines are completely disconnected from the Canadian and global imperative to build a successful and resilient life sciences and pharmaceutical system. The Guidelines fail to value innovation and create unprecedented barriers to the introduction of medical advances in this country. We hope that the PMPRB will revisit its proposed approach for the benefit of all Canadians and our country's future health and economic wellbeing.

**Given how dramatic a change these Guidelines represent and especially the uncertainty they create, we strongly recommend discarding the PMPRB's proposed approach. The PMPRB should go back to the drawing board, starting with working tables that are co-led by experts from the industry and other health system stakeholders to develop Guidelines that support innovation and access to medicines for Canadians.**

Sincerely,



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